1. TITLE PAGE

Vaccine Name and Compound Number:	BNT162 RNA-Based COVID-19 Vaccines, Compound Number: PF-07302048
Report Title:	Final Analysis Interim Report: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals
Protocol Number:	Protocol C4591001
Sponsor:	BioNTech
Sponsor Agent:	Pfizer Inc
Phase of Development:	Phase 1/2/3
First Subject First Visit:	29 April 2020
Primary Completion Date:	Not applicable
Data Cutoff Dates:	24 August 2020 (Phase 1 safety and immunogenicity data through 1 month after Dose 2) 02 September 2020 (Phase 2 safety data 7 days after Dose 2 only) 04 November 2020 (Phase 2/3 first interim analysis for efficacy) 14 November 2020 (Phase 2/3 final analysis for efficacy, safety data 1 month after Dose 2 for 37,586 participants with a median of at least 2 months of follow-up, and available safety data for all 43,252 participants)

Serology Completion Date(s):	17 September 2020 (Phase 1, Visit 7 [post-Dose 2 blood draw] assay completed) 12 October 2020 (Phase 2, Visit 3 [post-Dose 2 blood draw] assay completed)
Name and Affiliation of Coordinating/Leading Investigator:	Stephen Thomas, MD SUNY Upstate Medical University 725 Irving Ave, Ste. 311 Syracuse, NY 13210 The names of the principal investigators, site addresses, and number of participants enrolled at each site are provided in the appendix titled List and Description of Investigators and Service Providers, Appendix 16.1.4.
Sponsor's Signatories:	John L. Perez, MD, MBA, MA Vice President, Vaccines Clinical Research and Development, Pfizer Inc Kenneth Koury, PhD Clinical Biostatistics Head, Vaccines Clinical Research and Development, Pfizer Inc Ugur Sahin, MD Chief Executive Officer, BioNTech
Internal Reports Referenced:	Not applicable
Date of Current Version:	03 December 2020
Date(s) of Previous Report(s):	Not applicable

GCP STATEMENT

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

2. SYNOPSIS

3. TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

16. APPENDICES

16.1. Study Information

16.1.1. Final Protocol and Protocol Amendments

16.1.2. Sample Case Report Form(s) (CRF)/Data Collection Tool(s) (DCT)

16.1.3. Independent Ethics Committees (IECs) or Institutional Review Boards (IRBs) and Sample Standard Subject Information Sheet and Informed Consent Document (ICD)

16.1.4. List and Description of Investigators and Service Providers

16.1.5. Signatures of Principal or Coordinating/Leading Investigator(s) or Sponsor's Responsible Medical Officer, Depending on the Regulatory Authority's Requirement

16.1.5.1. Sponsor and Sponsor Agent

16.1.5.2. CSR Investigator Declaration

16.1.6. Listing of Subjects Receiving Investigational Product From Specific Batches, Where More Than One Batch Was Used

16.1.7. Randomization Scheme and Codes (Subject Identification and Vaccine Assigned)

16.1.8. Audit Certificates

16.1.9. Documentation of Statistical Methods

16.1.10. Documentation of Interlaboratory Standardization Methods (and Quality Assurance Procedures if Used) (Refer to Module 5.3.1.4 for immunoassay and RT-PCR methods)

16.1.11. Publications Based on the Study

16.1.12. Important Publications Referenced in the Report (Available on Request)

16.1.13. Independent Oversight Committees

16.2. Subject Data Listings

16.2.1. Discontinued Subjects

16.2.2. Protocol Deviations

16.2.3. Subjects Excluded From the Analysis

16.2.4. Demographic Data

16.2.5. Subject Compliance Data

16.2.6. Assay Data

16.2.7. Adverse Events by Subject

16.2.8. Individual Laboratory Measurements by Subject

16.3. Case Report Form(s) (CRF) or Data Collection Tool(s) (DCT)

16.3.1. CRFs (or DCTs) For Deaths, Other Serious Adverse Events, and Subject Withdrawals due to Adverse Events

16.3.2. Other CRFs (or DCTs)

16.4. Individual Subject Data Listings

4. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
AE	adverse event
AESI	adverse event of special interest
BDR	blinded data review
BLQ	below the level of quantitation
BMI	body mass index
CDC	Centers for Disease Control and Prevention (United States)
COVID-19	coronavirus disease 2019
CRF	case report form
CRO	contract research organization
CSR	clinical study report
CV	curriculum vitae
DCT	data collection tool
DMC	data monitoring committee
e-diary	electronic diary
EU	European Union
FIH	first-in-human
FSFV	first subject first visit
GCP	Good Clinical Practice
GMC	geometric mean concentration
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
HBc Ab	hepatitis B core antibody
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCS	human convalescent serum
HCV	hepatitis C virus
HCV Ab	hepatitis C virus antibody
HIV	human immunodeficiency virus
IA	interim analysis
ICD	informed consent document
ICH	International Council for Harmonisation
ICU	intensive care unit
IEC	independent ethics committee
IgG	immunoglobulin G
IgM	immunoglobulin M
IND	Investigational New Drug
IRB	institutional review board
IRC	internal review committee
IRR	illness rate ratio
IRT	interactive response technology
LLOQ	lower limit of quantitation
LNP	lipid nanoparticle
MedDRA	Medical Dictionary for Regulatory Activities

Abbreviation	Definition
MERS	Middle East respiratory syndrome
modRNA	nucleoside-modified messenger ribonucleic acid
NAAT	nucleic acid amplification test
N-binding	SARS-CoV-2 nucleoprotein binding
NT50	neutralizing titer 50
NT90	neutralizing titer 90
NVA	nonvaccine antigen
P2 S	SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein
PD	protocol deviation
Prevax	prevaccination
PT	preferred term
QA	quality assurance
QTL	quality tolerance limit
RBD	receptor-binding domain
RCDC	reverse cumulative distribution curve
RDC	remote data capture
RNA	ribonucleic acid
SAE	serious adverse event
SAP	statistical analysis plan
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SIRVA	shoulder injury related to vaccine administration
SMQ	standardized MedDRA queries
SOC	system organ class
Tdap	diphtheria vaccine toxoid; pertussis vaccine acellular 3 component; tetanus vaccine toxoid
TME	targeted medical event
US	United States
Vax	vaccination
VE	vaccine efficacy
WBC	white blood cell count
WHO	World Health Organization

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. Informed consent was collected as detailed in the protocol. Refer to Appendix 16.1.1, Protocol Section 10.1.2 for further information regarding informed consent.

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The study was conducted by investigators contracted by and under the direction of Pfizer. The investigators were responsible for adhering to the study procedures described in the protocol, for keeping records of the study intervention, and for ensuring accurate completion of the CRFs and DCTs supplied by Pfizer.

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

No sites were terminated from the study to date.

7. INTRODUCTION

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, a novel coronavirus was discovered as the underlying cause. Later in January, the genetic sequence of the novel coronavirus became available to the WHO and public (MN908947.3), and the virus was categorized as a *Betacoronavirus*. By sequence analysis, the phylogenetic tree revealed a closer relationship to SARS coronavirus isolates than to other coronaviruses that infect humans, including the MERS coronavirus.[1,2]

Infections by the virus, named SARS-CoV-2, and the resulting disease, COVID-19, have spread globally.

On 11 March 2020, the WHO declared the COVID-19 outbreak to be a pandemic.[3] The United States currently has the most reported cases globally. At the time of this report, the

number of confirmed cases exceeds 32 million globally and continues to rise.[4] There are currently no licensed vaccines to prevent SARS-CoV-2 infections or COVID-19.[5]

An RNA-based prophylactic COVID-19 vaccine is one of the most flexible and fastest approaches available to potentially protect against the emerging virus.[6,7]

BioNTech has developed RNA vaccine platforms, including modRNA, with enhanced intracellular stability and translation efficiency, blunted innate immune sensor activating capacity and corresponding increased antigen expression in the host cell. BioNTech has also licensed an LNP delivery system, with which the RNA is formulated. Each modRNA candidate encodes either a P2 mutant S glycoprotein (P2 S) or the trimerized RBD of the S glycoprotein. Each candidate is given a V number that indicates the specific version of the optimized antigen coding sequence. Further details can be found in the investigator's brochure.[8] The candidates tested in this study were:

- **BNT162b1** (RBP020.3) modRNA encoding RBD (V5)
- **BNT162b2** (RBP020.2) modRNA encoding P2 S (V9).

BioNTech has been conducting a FIH, dose level–finding, Phase 1/2 study (BNT162-01) in Germany to gather safety and immunogenicity data to evaluate multiple vaccine candidates, This study is conducted under an approved German Clinical Trial Agreement and not under the US IND.

In order to facilitate the interpretation of the immunogenicity data generated by the Phase 1 study, a human convalescent serum (HCS) panel was obtained from Sanguine Biosciences (Sherman Oaks, CA), the MT Group (Van Nuys, CA), and Pfizer Occupational Health and Wellness (Pearl River, NY). The 38 sera in the HCS were collected from SARS-CoV-2 infected or /COVID-19 positive individuals 18 to 83 years of age at least 14 days after PCR-confirmed diagnosis, and at a time when subjects were asymptomatic. The serum donors predominantly had symptomatic infections (35/38), and one had been hospitalized.[9]

Following evaluation of Phase 1 safety and immunogenicity data for BNT162b1 and BNT162b2 administered at different dose levels to adults in 2 age groups (18 to 55 years of age and 65 to 85 years of age), Phase 2/3 evaluation commenced for this study on 27 July 2020 using BNT162b2 at the 30 µg dose level in adult individuals.

This study is ongoing, and participants are continuing to be enrolled and evaluated in Phase 3 at the time of this CSR. Efficacy data are presented at the data cutoff dates for the interim and final analysis of efficacy. Demographic, disposition and safety data are presented as 2 cohorts. The first cohort includes 37,706 (N~38,000) participants who have a median follow-up time of 2 months after the second dose. Safety data are also presented separately for a subset of this cohort of 19,067 (N~19,000) participants who have 2 months or more of safety follow-up. The second cohort comprises all participants enrolled in the study as of a data cutoff date (N~44,000). The latter cohort is intended to provide a comprehensive evaluation of safety as of the cutoff date, but the follow-up time will not be uniform across all participants. This interim CSR summarizes:

- Phase 1 results of safety and immunogenicity for BNT162b1 and BNT162b2 in the candidate- and dose level-finding part of the study for each dose level, age group, and vaccine group (data cutoff date 24 August 2020) and long-term safety follow-up (approximately 4 months after Dose 2 [as of cutoff date 14 November 2020]) for BNT162b2 30-µg.

- Phase 2 primary safety analyses (7 days after Dose 2) for the first 360 participants (180 randomized to active vaccine BNT162b2 and 180 to placebo, and stratified approximately equally between 18 to 55 years and >55 to 85 years) dosed at the commencement of the Phase 2/3 part of the study (data cutoff date 02 September 2020) and long-term safety follow-up (includes at least 2 months of follow-up after Dose 2 [as of the cutoff date of 14 November 2020]).

- Phase 2 exploratory immunogenicity analyses for the first 360 participants 1 month after Dose 2 (data cutoff date 12 October 2020)

- Phase 2/3 primary safety analysis (1 month after Dose 2) for 37,706 participants who had a median of at least 2 months of follow-up after Dose 2 (data cutoff date 14 November 2020). Safety data are also presented separately for a subset of this cohort of 19,067 participants who have at least 2 months of safety follow-up after Dose 2.

    - During the conduct of this study, 1 participant was identified to be randomized across 2 sites in this trial as 2 distinct participant identification numbers. This participant was excluded entirely from all efficacy and safety analyses, including disposition and demographic tabulations. Separate listings were generated for this participant (Section 10.2.3).

    - The actual dosing information from 3 participants included in this cohort was not available at the data cutoff date for this CSR (Appendix 16.2.3.2.5); data from the 3 participants were not included tables/figures but were included in the listings.

- Phase 2/3 safety analysis for all 43,448 participants, including the 37,706 participant cohort (data cutoff date 14 November 2020, data summarized as is).

    - There were 4 participants (5 participant identification numbers) with special data issues: 1 multi-enrolled participant (2 participant identification numbers) and 3 participants whose actual treatment was not confirmed in IRT at the time of data cutoff (Appendix 16.2.3.2.6). All 5 participants are described above for the primary safety analysis.

- Phase 2/3 first successful interim analysis (data cutoff date 04 November 2020) for the primary efficacy analysis of prophylactic BNT162b2 against confirmed COVID-19 among participants without evidence of infection before vaccination 18 to 85 years of age, and final efficacy analysis after the accrual of at least 164 cases of confirmed COVID-19 (data cutoff date 14 November 2020) among participants without evidence of infection before vaccination 12 to 91 years of age.

At the time of this report, individuals 16 to 91 years of age were analyzed for the first 37,706 participants. Individuals 12 to 15 years of age were later permitted to enroll in the study, and these results will be reported at a later time.

8. STUDY OBJECTIVES AND ENDPOINTS

8.1. Phase 1

Note: The primary safety estimand of SAEs from Dose 1 to 6 months after the last dose is not presented in this interim CSR but will be summarized when results are available.

Table 1. Phase 1 Objectives, Estimands, and Endpoints

Objectives	Estimands	Endpoints
Primary:	**Primary:**	**Primary:**
To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the last dose • SAEs from Dose 1 to 6 months after the last dose In addition, the percentage of participants with: • Abnormal hematology and chemistry laboratory values 1 and 7 days after Dose 1; and 7 days after Dose 2 • Grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1; and before Dose 2 and 7 days after Dose 2	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs Hematology and chemistry laboratory parameters detailed in Appendix 16.1.1, Protocol Section 10.2
Secondary:	**Secondary:**	**Secondary:**
To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses	In participants complying with the key protocol criteria (evaluable participants) at the following time points after receipt of study intervention: 7 and 21 days after Dose 1; 7 and 14 days and 1, 6, 12, and 24 months after Dose 2 • GMTs at each time point • GMFR from before vaccination to each subsequent time point after vaccination • Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination	SARS-CoV-2 neutralizing titers
	• GMCs at each time point • GMFR from prior to first dose of study intervention to each subsequent time point • Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination	S1-binding IgG levels and RBD-binding IgG levels
	• GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers to the geometric mean of binding IgG levels at each time point	• SARS-CoV-2 neutralizing titers • S1-binding IgG levels • RBD-binding IgG levels

Source: Appendix 16.1.1, Protocol Section 3.1.

8.2. Phase 2/3

Note: The objectives, estimands, and endpoints presented in Table 2 are from Appendix 16.1.1, Protocol Amendment 9. The primary safety estimand of SAEs from Dose 1 to 6 months after the second dose in all participants in Phase 2/3, and most immunogenicity endpoints are not presented in this interim CSR but will be summarized at a later time. Only the exploratory immunogenicity estimand of GMTs/GMCs and GMFRs at 1 month after Dose 2 for Phase 2 participants are presented.

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

Objectives[a]	Estimands	Endpoints
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
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
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

To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:
	• Local reactions for up to 7 days following each dose
	• Systemic events for up to 7 days following each dose
	• AEs from Dose 1 to 1 month after the second dose
	• SAEs from Dose 1 to 6 months after the second dose
		• AEs
		• SAEs
		• In a subset of at least 6000 participants:
		  ○ Local reactions (pain at the injection site, redness, and swelling)
		  ○ Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)

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

Objectives[a]	Estimands	Endpoints
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
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
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
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
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
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
To describe the efficacy of prophylactic BNT162b2 against	In participants complying with the key protocol criteria (evaluable	COVID-19 incidence per 1000 person-years of follow-up based on central

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

Objectives[a]	Estimands	Endpoints
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	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]	laboratory or locally confirmed NAAT
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
Exploratory		
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, GMFR, and percentage of participants with titers greater than defined threshold(s), at baseline and 1, 6, 12, and 24 months after completion of vaccination	• S1-binding IgG levels and/or RBD-binding IgG levels • SARS-CoV-2 neutralizing titers
To evaluate the immune response (non-S) to SARS-CoV-2 in participants with and without confirmed COVID-19 during the study		• N-binding antibody
To describe the serological responses to the BNT vaccine candidate in cases of: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection without confirmed COVID-19		• S1-binding IgG levels and/or RBD-binding IgG levels • SARS-CoV-2 neutralizing titers
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
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]		• All safety endpoints described above • SARS-CoV-2 neutralizing titers

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 Section 9.4.3 for a description of the manufacturing process.
Source: Appendix 16.1.1, Protocol Section 3.2.

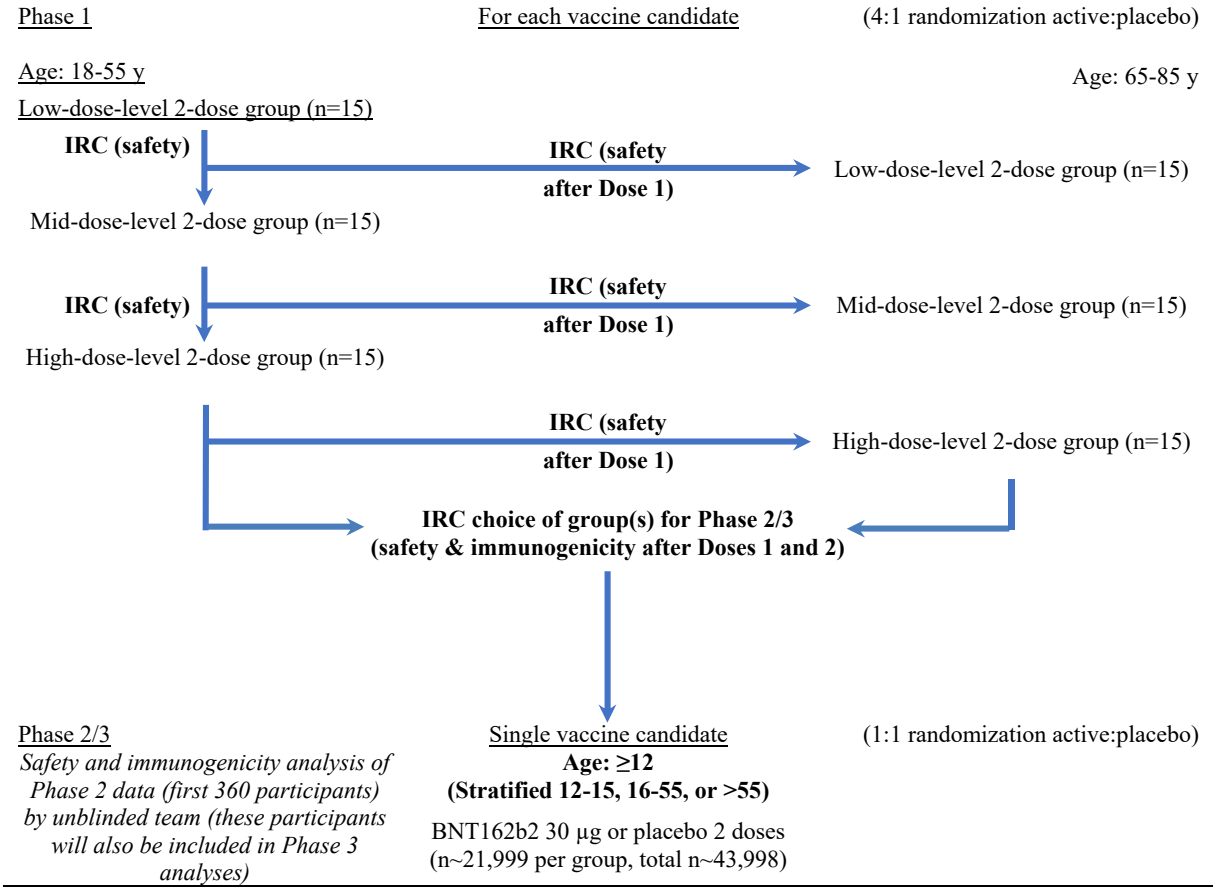
9. INVESTIGATIONAL PLAN

9.1. Overall Study Design and Plan

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

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

Figure 1. Study Schema



Source: Appendix 16.1.1, Protocol Section 1.2

The study evaluated the safety, tolerability, and immunogenicity of 2 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;
- 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.

9.1.1. Phase 1

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

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

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

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

Following review of all available safety and immunogenicity data through 14 days after Dose 2 for BNT162b1 and BNT162b2, both vaccine constructs were considered strong candidates to proceed to Phase 2/3. See Section 9.4.5 for details on selection of final candidate and dose for Phase 2/3.

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

9.1.2. Phase 2/3

Safety and immunogenicity data generated during the Phase 1 portion of this study and the BioNTech study conducted in Germany (BNT162-01) supported BNT162b2 at a dose of 30 µg as the vaccine candidate to proceed into Phase 2/3 (see Section 9.4.5).

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 to 55 years and >55 to 85 years] with approximately 50% in each age stratum) to assess safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from these Phase 2 360 participants. Enrollment continued during Phase 2 and these participants are included in the efficacy evaluation in the Phase 3 part of the study.

Participants in the ongoing Phase 3 part of the study are ≥12 years of age (stratified as 12 to 15, 16 to 55, or >55 years of age). The 12- to 15- year stratum will comprise 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 active vaccine or placebo.

The Phase 2/3 part of the study is event-driven. Under the assumption of a true VE rate of ≥60%, a target of 164 primary-endpoint cases of confirmed COVID-19 occurring at least 7 days following the second dose of the primary series of the candidate vaccine will be sufficient to provide 90% power to conclude true VE >30% with high probability. The total number of participants enrolled in Phase 2/3 may vary depending on the incidence of COVID-19 at the time of the enrollment, the true underlying VE, and a potential early stop for efficacy or futility.

Assuming a COVID-19 attack rate of 1.3% per year in the placebo group, accrual of 164 first primary endpoint cases within 6 months, an estimated 20% non-evaluable rate, and 1:1 randomization, the BNT162b2 vaccine candidate selected for Phase 2/3 is expected to comprise approximately 21,999 vaccine recipients per group, for a total sample size of 43,998. This is the number of participants initially targeted for Phase 2/3 and may be adjusted based on advice from DMC analyses of case accumulation and the percentage of participants who are seropositive at baseline. Dependent upon the evolution of the pandemic, it is possible that the COVID-19 attack rate may be higher, in which case accrual would be expected to be more rapid, enabling the study's primary endpoint to be evaluated sooner.

In Phase 3, 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 will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin.

The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with BNT162b2 manufactured with "Process 1" and each lot of BNT162b2 manufactured with "Process 2", which was developed to support an increased scale of manufacture, will be described.

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

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

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

The purpose of the study is to describe the safety, tolerability, and immunogenicity of 2 BNT162 RNA-based COVID-19 vaccine candidates against COVID-19, and the efficacy of one (selected) candidate, in healthy individuals.

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

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

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

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

Phase 2/3 was designed to evaluate the efficacy of the vaccine candidate selected for development, and to provide additional safety and immunogenicity data in a larger population, including adolescents (adolescents were later permitted to enroll as part of Phase 3; data are not available at the time of this report).

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 apply:

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

   Refer to Appendix 16.1.1, Protocol 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).

Informed Consent:

5. 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:

6. 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.

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

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

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

10. 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.

11. **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

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

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

14. **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).

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

16. Women who are pregnant or breastfeeding.

Prior/Concomitant Therapy:

17. Previous vaccination with any coronavirus vaccine.

18. 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.

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

20. 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:

21. Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation.

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

Diagnostic Assessments:

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

24. **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.)

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

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

Other Exclusions:

27. 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.

9.3.3. Criteria for Temporarily Delaying Vaccine Administration

The following conditions were temporary or self-limiting and a participant may have been vaccinated once the condition(s) resolved and no other exclusion criteria were met.

- Current febrile illness (body temperature ≥100.4°F [≥38°C]) or other acute illness within 48 hours before study intervention administration. This included current symptoms that could represent a potential COVID-19 illness:
    - New or increased cough;
    - New or increased shortness of breath;
    - Chills;
    - New or increased muscle pain;
    - New loss of taste/smell;
    - Sore throat;
    - Diarrhea;

- Vomiting.

Refer to Appendix 16.1.1, Protocol Section 5.5 for details of additional criteria for temporarily delaying vaccine administration.

9.3.4. Withdrawal of Participants From the Study

Refer to Appendix 16.1.1, Protocol Section 7.2 for details for when and how participants may have withdrawn from the study.

9.4. Investigational Product

9.4.1. Vaccines Administered

The study evaluated a 2-dose (separated by 21 days) schedule of 2 investigational RNA vaccine candidates for active immunization against COVID-19 or saline placebo:

- BNT162b1 (BNT162 RNA-LNP vaccine containing modRNA that encodes the RBD): 10 µg, 20 µg, 30 µg, 100 µg
- BNT162b2 (BNT162 RNA-LNP vaccine containing modRNA that encodes P2 S): 10 µg, 20 µg, 30 µg
- Normal saline (0.9% sodium chloride solution for injection)

The vaccine candidate selected for Phase 2/3 evaluation was BNT162b2 at a dose of 30 µg.

Refer to Appendix 16.1.1, Protocol Sections 6.1 and 6.1.1 for details of the study intervention(s) and study intervention administration.

9.4.2. Identity of Investigational Product(s)

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

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

Table 3. Investigational Product Lot Numbers – Final Analysis Interim

Investigational Product	Phase	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
BNT162b1 (10 µg, 20 µg, 30 µg, and 100 µg)	1	BioNTech	BCV10320-A	E220395-0001L
BNT162b2 (10 µg, 20 µg, and 30 µg)	1	BioNTech	BCV40420-A	E220395-0004L
Normal saline (0.9% sodium chloride	1	Pfizer	DK1589	20-001592

Table 3. Investigational Product Lot Numbers – Final Analysis Interim

solution for injection)				
BNT162b2 (30 µg)	2/3	BioNTech	BCV40420-A	E220395-0006L003/P220395-0012L
			BCV40420-A	E220395-0035L002/P220395-0048L
			BCV40420-A	E220395-0035L003/P220395-0048L
			BCV40420-A	EU2065896/E220395-0004L
			BCV40420-A	PA2070104/P220395-0008L
			BCV40620-A	PA2071394/P220395-0029L
			BCV40620-A	PA2072393/P220395-0019L
			BCV40620-B	PA2071395/P220395-0016L
			BCV40620-B	PA2072396/P220395-0016L
			BCV40620-C	PA2071396/P220395-0047L
			BCV40620-C	PA2072439/P220395-0047L
			BCV40620-D	PA2072442/P220395-0042L
			BCV40620-D	PA2072765/P220395-0042L
			BCV40720-A	PA2074172/P220395-0053L
			BCV40720-A	PA2074998/P220395-0060L
			BCV40720-B	PA2074173/P220395-0051L
			BCV40720-C	PA2074071/P220395-0052L
			ED3938	PA2074300/P220395-0021L
			ED3938	EU2074330/E220395-0036L
			ED3938	PA2074300/P220395-0022L
			ED3938	PA2074300/P220395-0023L
			EE3813	PA2074838/P220395-0024L
			EE3813	PA2074838/P220395-0020L
			EE8493Z	PA2077905/P220395-0026L

Table 3. Investigational Product Lot Numbers – Final Analysis Interim

Normal saline (0.9% sodium chloride solution for injection)	2/3	Pfizer	DK1589;20 - 001592	PA2064251/P220395-0005L
			DK1589;20 - 001776	PA2065311/P220395-0007L
			DK2074;20 - 002029	PA2067775/P220395-0030L
			DK2074;20 - 002108	PA2067774/P220395-0013L
			DK2074;20 - 002221	PA2069407/P220395-0031L
			DK2074;20 - 002221	PA2069407/P220395-0032L
			DK2074;20 - 002221	PA2069407/P220395-0033L
			DK2074;20 - 002221	PA2069407/P220395-0034L
			DK2074;20 - 002221	PA2069407/P220395-0044L
			DK2074;20 - 002221	PA2069407/P220395-0045L
			DK2074;20 - 002221	PA2069407/P220395-0046L
			DK2074;20 - 002221	PA2069407/P220395-0054L
			DK2074;20 - 002221	PA2069407/P220395-0055L
			DK2074;20 - 002221	PA2069407/P220395-0056L
			DK2074;20 - 002221	PA2069407/P220395-0062L
			DK2074;20 - 002221	PA2069407/P220395-0065L
			DK2074;20 - 002221	PA2069407OTH/E220395-0049L

Note: C4591001 End of Study Information and Quality Control (QC) Record for Study Drug Appendix (Section D) dated 19Nov2020 was used to create this table.
a. Lot number assigned to the investigational product by Pfizer Global Clinical Supply.
Protocol C4591001 Investigational Product Lot Numbers Table – Final Analysis Interim, Final, Version 1.0, 19Nov2020.

9.4.3. Manufacturing Process

The scale of the BNT162b2 manufacturing has been increased to support future supply. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with material generated using the existing manufacturing process (Process 1) and with material from lots generated using the manufacturing process supporting increased supply (Process 2) is planned to be evaluated.

Refer to Appendix 16.1.1, Protocol Section 6.1.1 for further details on manufacturing process and evaluation of material generated by the 2 processes.

9.4.4. 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.

9.4.5. Selection of Dose Levels/Regimen

9.4.5.1. 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.

9.4.5.2. Phase 2/3

Both BNT162b1 and BNT162b2 20 µg and 30 µg dose levels demonstrated robust SARS-CoV-2 neutralizing titer responses during the Phase 1 portion of the study. Both vaccine constructs were considered to be strong candidates for further clinical development; however, the totality of data favored selection of BNT162b2 at 30 µg based on the following findings:

- Earlier clearance of SAR CoV-2 RNA from the nose of BNT162b2 immunized and challenged rhesus monkeys.
- A more favorable reactogenicity profile for BNT162b2 compared with BNT162b1 in both younger and older adults.

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

9.4.6. Blinding

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

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

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

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

- An unblinded statistical team supporting interactions with, and interim analyses for, the DMC (see Appendix 16.1.1, Protocol Section 9.6) and the initial version of this interim CSR (12 November 2020). This is comprised of a statistician, programmer(s), a clinical scientist, and a medical monitor who reviewed cases of severe COVID-19 as they were received, and reviewed AEs at least weekly for additional potential cases of severe COVID-19 (see Section 9.5.2.3).

- After the formal data release of the final efficacy analysis of at least 164 cases, which is considered the primary completion of the study efficacy objectives, additional limited statisticians and programmers were unblinded at the participant level to prepare unblinded analyses and other regulatory activities. A group of statisticians and programmers will remain blinded and continue supporting the blinded conduct of the study.

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

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

9.4.7. Prior and Concomitant Vaccines, Medications, and Procedures

Prohibited During the Study

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

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

Permitted During the Study

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

9.4.8. 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 for potential cases of COVID-19.

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

- SARS-CoV-2 neutralizing titers
- Antigen binding antibodies specific to SARS-CoV-2
  - RBD-binding IgG levels (most relevant to BNT162b1, which encodes the RBD)
  - S1-binding IgG levels (most relevant to BNT162b2 which encodes P2 S)
  - N-binding antibody (Phase 2/3 only)

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

9.5.2. Safety Evaluations

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

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

Clinical safety laboratory evaluations were only conducted for Phase 1 participants and described in Appendix 16.1.1, Protocol Section 8.2.1. The laboratory tests performed are described in Appendix 16.1.1, Protocol Appendix 2.

9.5.2.2. Electronic Diary

All participants in Phase 1 and a subset of at least the first 6000 participants randomized in Phase 2/3 recorded local reactions, systemic events, and antipyretic/pain medication usage for 7 days, following administration of study intervention using an e-diary. Any participants in Phase 3 who are HIV-positive or 12 to 15 years of age may also have been included in this

subset (will be reported at a later time). In addition, participants 16 through 17 years of age enrolled under Protocol Amendment 9 (finalized 29 October 2020) and onwards will be included in the reactogenicity subset. Use of an e-diary allowed recording of these assessments within a fixed time window and provided an accurate representation of the participant's experience at that time. For participants who were not in the reactogenicity subset, local reactions and systemic events consistent with reactogenicity were detected and reported as AEs (Section 9.5.2.5).

For local reactogenicity, during the reactogenicity e-diary reporting period, participants were asked to assess redness, swelling, and pain at the injection site and to record the symptoms in the reactogenicity e-diary. If a local reaction persists beyond the end of the reactogenicity e-diary period following vaccination, the participant was requested to report that information. The investigator entered this additional information in the CRF. Redness and swelling were measured and recorded in measuring device units (range: 1 to 21) and then categorized during analysis as absent, mild, moderate, or severe based on the grading scale. Pain at the injection site was assessed by the participant as absent, mild, moderate, or severe according the grading scale.

For systemic reactogenicity, during the reactogenicity e-diary reporting period, participants were asked to assess vomiting, diarrhea, headache, fatigue, chills, new or worsened muscle pain, and new or worsened joint pain and to record the symptoms in the reactogenicity e-diary. The symptoms were assessed by the participant as absent, mild, moderate, or severe according to the grading scale.

The investigator or designee obtained stop dates from the participant for any ongoing local reactions, systemic events, or use of antipyretic medication on the last day that the reactogenicity e-diary was completed.

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.

9.5.2.3. Phase 1 Stopping Rules

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

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

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

Participants in all phases of the study were surveilled for potential COVID-19 illness from Visit 1 onwards. If a participant experienced any potential symptoms for COVID-19 illness,

a COVID-19 illness and subsequent convalescent visit (in-person or telehealth) occurred. As part of these visits, samples (nasal [midturbinate] swab and blood) were taken for antigen and antibody assessment as well as recording of COVID-19–related clinical and laboratory information (including local diagnosis).

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

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

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

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

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

9.5.2.5. Adverse Events and Serious Adverse Events

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

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

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

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

9.5.2.6. Events of Special Interest

While AESIs were not prespecified in the protocol, Pfizer utilizes a safety review as part of the signal detection processes that highlights specified targeted medical events (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 pre-specified in the protocol, TMEs are maintained in a separate list as part of the Safety Surveillance Review Plan for the vaccine program. By definition, TMEs are considered to be AESIs specific for a product or program's protocol(s). They are based on review of known pharmacology, toxicology findings, possible class effects, published literature, and potential signals arising from safety data assessments.

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

Other events of clinical interest identified by the sponsor were also reviewed and summarized (Section 12.3.4.4).

9.6. Data Quality Assurance

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

Given the unprecedented medical need due to the magnitude and speed of the COVID-19 pandemic, Pfizer implemented an innovative solution to obtain written investigator attestations that participant-level CRF data were accurate and complete, to enable regulatory submissions as quickly as possible while adhering to GCP. Pfizer finalized the database for this CSR by releasing CRF data in batches on a weekly basis from 23 October 2020 through the data cutoff date of 17 November 2020. A participant's CRF data included in a given batch was signed by the investigator on the date of batch completion. All participants included in analyses in this CSR had at least 1 investigator attestation of their CRF data on or after 23 October 2020. In cases where a site made updates to a participant's CRF data after the investigator had provided an attestation, attempts were made to re-obtain the investigator attestation when CRF updates were associated with adverse events/serious adverse events or COVID-19 illness visits.

For completeness, this CSR includes all safety data for all participants available at the time of the data cutoff date for the efficacy analysis. For safety data obtained after the initial 37,706 participants had a median follow-up of 2 months after the second dose, it is possible that an updated investigator attestation was not obtained prior to the database finalization for the CSR.

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.

Pfizer recently became aware of a data entry issue at 2 sites [1219,1235] that resulted in 15 participants being asked to provide responses in the vaccination e-diary to collect reactogenicity data when they had not consented to provide reactogenicity information and were not trained on the use of the e-diary for this purpose. Pfizer is currently working with the sites to obtain consent to use these data. The data for these participants are consistent with the overall reactogenicity profile and are included in the reactogenicity analyses in this CSR in order to provide complete information to regulatory authorities.

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.

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.

A QTL was set to monitor the proportion of potential COVID-19 illness visits for which a swab was provided for NAAT detection of SARS-CoV-2 at the central laboratory since this is a critical component of the case definition of COVID-19. The threshold was set at 90% for all illness visits from the start of Phase 2/3, regardless of whether the case could contribute to the primary endpoint or not, since more than 10% of potentially missing data was considered undesirable for the primary endpoint. On 04 November 2020, the QTL dropped to 89%, just below the predefined threshold.

The protocol design is such that, if a participant experiences any of the specified trigger symptoms that could indicate COVID-19 (irrespective of perceived etiology or clinical significance), a potential COVID-19 illness visit should occur, including obtaining a swab for the central laboratory. Despite expecting such a visit to occur irrespective of perceived etiology or clinical significance, there have been circumstances where investigators have exercised their clinical judgment and initially recorded potential symptoms as AEs. We observed this trend (the QTL dropped from 95% on 30 September 2020 to 92% on 08 October 2020) and conducted investigator retraining at a scheduled meeting on 09 October 2020. Training for all site staff was posted to the training portal on 03 November 2020. During data cleaning, these data have been transferred to potential COVID-19 illness CRFs although in many such cases a swab was not obtained. However, the fact that the investigators considered these unlikely to represent COVID-19, suggests that there is a low risk of having missed true COVID-19 cases as a result.

Whilst the QTL for all visits dropped to 89%, considering potential COVID-19 illnesses that occurred at least 7 days post-dose 2 and could therefore contribute to the primary efficacy analysis, the corresponding QTL was 91.3%.

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.

9.7. Statistical Methods Planned in the Protocol

9.7.1. Statistical and Analytical Plans

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

9.7.1.1. Analysis Sets

Refer to Appendix 16.1.9, SAP Section 4 for details of the analysis sets.

The analysis populations are defined in Table 4.

Table 4. Analysis Populations

Population	Description
Enrolled	All participants who had a signed ICD.
Randomized	All participants who were assigned a randomization number in the IWR system.
Dose 1 evaluable immunogenicity	For Phase 1 only, all eligible randomized participants who received the vaccine to which they were randomly assigned at the first dose, had at least 1 valid and determinate immunogenicity result from the blood collection within an appropriate window after Dose 1 (same as visit window, ie, within 19-23 days after Dose 1) and had no other important protocol deviations as determined by the clinician.
Dose 2 evaluable immunogenicity	All eligible randomized participants who received 2 doses of the vaccine to which they were randomly assigned, with Dose 2 received within the predefined window (19-42 days after Dose 1), had at least 1 valid and determinate immunogenicity result from the blood collection within an appropriate window after Dose 2 (6-8 days after Dose 2 for Phase 1 and 28-42 days after Dose 2 for Phase 2/3), and had no other important protocol deviations as determined by the clinician.
Dose 1 all-available immunogenicity	For Phase 1 only: all randomized participants who received at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2.
Dose 2 all-available immunogenicity	All randomized participants who received at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2.

Table 4. Analysis Populations

Population	Description
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.
Evaluable efficacy (14 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 14 days after Dose 2.
Dose 1 all-available efficacy	All randomized participants who received at least 1 vaccination.
Dose 2 all-available efficacy	All randomized participants who completed 2 vaccination doses.
Safety	All randomized participants who received at least 1 dose of the study intervention.

9.7.2. Determination of Sample Size

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

9.7.3. Efficacy Analysis

The efficacy assessment in Phase 2/3 portion of the study was event-driven. Initially, 4 interim analyses were planned to be performed by an unblinded statistical team supporting the DMC after accrual of at least 32, 62, 92, and 120 confirmed COVID-19 cases, with the final analysis performed after accrual of at least 164 cases. For operational reasons, the first planned IA (after at least 32 cases) was not performed. Protocol Amendment 9 eliminated the planned interim analysis with at least 32 cases and provided for 3 interim analyses to be performed after accrual of at least 62, 92, and 120 cases. At each of the IAs, vaccine efficacy with respect to the first primary efficacy endpoint was to be assessed. At the final analysis (at least 164 cases) vaccine efficacy with respect to all efficacy endpoints was to be assessed.

Assessment of VE of BNT162b2 for the first primary efficacy endpoint was performed for confirmed COVID-19 cases observed at least 7 days after the receipt of Dose 2 onwards among participants 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). The Bayesian 95% credible interval and the posterior probability for the true vaccine efficacy greater than 30% conditioning on the available data, i.e. P[VE >30%|data], were calculated using a beta-binomial model and a pre-specified minimally informative beta distribution as prior. The calculation of posterior probability and 95% credible interval were adjusted for surveillance time. All efficacy endpoints were to be analyzed using the same Bayesian approach unless stated otherwise.

If the posterior probability of VE>30% is greater than 99.5% at any pre-planned interim analysis, or greater than 98.6% at the final analysis, the vaccine efficacy of BNT162b2 would be declared.

If the predicted posterior probability of demonstrating vaccine efficacy at the final analysis is less than 5.0% at any of the first 2 planned interim analyses, the study would stop for lack of benefit (futility).

For the subgroup analyses of the efficacy endpoints, and for the analyses of efficacy for COVID-19 cases determined according to the CDC-defined symptoms, VE and the 2-sided 95% confidence interval (CI) for VE was derived based on the Clopper and Pearson method adjusted for surveillance time.

The efficacy analysis for Phase 2/3 is described in Appendix 16.1.1, Protocol Section 9.4.2, Appendix 16.1.9, SAP Section 6.1.2. and Appendix 16.1.9, SAP Section 6.2.2.

9.7.4. Immunogenicity Analysis

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

GMFRs are limited to participants with nonmissing values prior to the first dose and at the postvaccination time point. The GMFR was calculated by exponentiating the mean of the difference of logarithmically transformed assay results (later time point – earlier time point). Two-sided CIs were obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.

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

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

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

For participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection, the GMR of SARS-CoV-2 neutralizing titers in participants 12 to 15 years of age to those in participants 16 to 25 years of age and 2-sided

95% CIs will be provided at 1 month after Dose 2 for noninferiority assessment. The GMR and its 2-sided 95% CI will be derived by calculating differences in means and CIs on the natural log scale of the titers based on the Student's t-distribution and then exponentiating the results. The difference in means on the natural log scale will be 12 to 15 years minus 16 to 25 years. Noninferiority will be declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.

The immunogenicity analysis is 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 6.3.1 and SAP Section 6.3.2 for Phase 2/3.

9.7.5. Safety Analysis

The primary safety objective was evaluated by descriptive summary statistics for local reactions, systemic events, AEs/SAEs, and abnormal hematology and chemistry laboratory parameters (Phase 1 only), for each vaccine group. A 3-tier approach was used to summarize AEs in Phase 2/3. Under this approach, AEs were classified into 1 of 3 tiers:

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

The safety analysis is described in Appendix 16.1.1, Protocol Section 9.4.3, and Appendix 16.1.9, SAP Section 6.1.

9.7.6. Other Analyses

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

The safety and immunogenicity results for individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2" will be summarized descriptively.

All severe COVID-19 cases occurring after Dose 1 were summarized descriptively.

Other analyses are described in Appendix 16.1.1, Protocol Section 9.4.4, and Appendix 16.1.9, SAP Section 6.3.2.

9.7.7. Analysis Timing

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

During Phase 2/3, IAs were planned to be performed by an unblinded statistical team after accrual of at least 62, 92, and 120 cases. For operational reasons, the first interim analysis was conducted after accrual of greater than 62 cases.

Statistical analyses were or will be carried out as the following data become available:

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

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

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

- IAs for efficacy after accrual of at least 62, 92, and 120 cases and futility after accrual of at least 62 and 92 cases.

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

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

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

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

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. The SAP was amended twice and changes to the original planned analysis are described in Appendix 16.1.9, SAP Section 1.

Additional changes in study conduct or planned analysis not noted in the protocol or SAP were as follows:

- For Phase 1, Visit 3 (7 days after Dose 1) blood samples for immunogenicity assessment were not tested in the younger age group (20-µg dose group), older age group (65 to 85 years of age) for BNT162b1 and in both age groups (18 to 55 years of age and 65 to 85 years of age) for BNT162b2. Results from the younger age group (10-µg and 30-µg dose groups) 7 days after BNT162b1 Dose 1 indicated that there is no meaningful serological response at 7 days following the first vaccination. Therefore, results for this time point are only analyzed and presented in the younger age group (18 to 55 years of age) for 10 µg and 30 µg BNT162b1.

- Based on IRC decision, Dose 2 was suspended for participants randomized to BNT162b1 100 µg or placebo. Participants later received Dose 2 at the 10-µg dose level or placebo, and results after Dose 2 are not available at the time of this report. The group of participants 65 to 85 years did not receive any doses of BNT162b1 at the 100-µg dose level. No participants in either age group received any dose of BNT162b2 at the 100-µg dose level.

- In Phase 2/3, for all participants with safety data at the time of the data cutoff date, ad hoc summary tables of AEs within 7 days after each dose were generated in order to evaluate whether AEs reported may have been attributed to reactogenicity events in participants who did not have an e-diary to report reactogenicity.

- During Phase 2/3, interim analyses were planned to be performed after accrual of at least 62, 92, and 120 cases. For operational reasons, the first interim analysis was conducted after accrual of greater than 62 cases. The subsequent planned interim analyses were not performed due to rapid accrual of the final number of cases.

- Post hoc summary tables for efficacy were generated to:

  - Evaluate the imbalance of important PDs in the BNT162b2 group compared with the placebo group observed in the evaluable efficacy (7 days) population;

  - Assess additional subgroups by age and risk status.

10. STUDY PARTICIPANTS

10.1. Disposition of Participants

10.1.1. Phase 1

Disposition of all Phase 1 participants is presented in Figure 2 and Supplemental Table 14.1.

BNT162b1

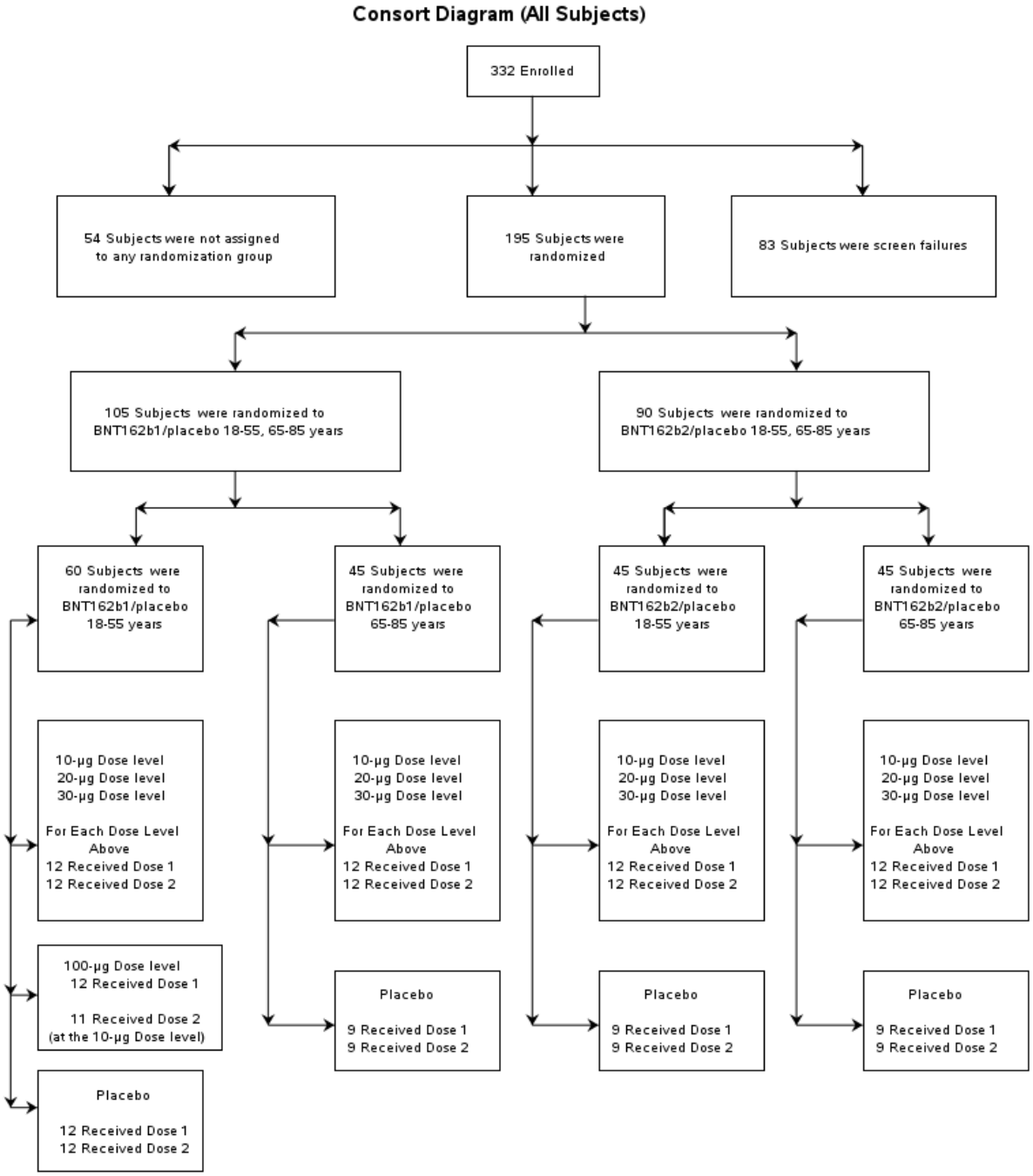
In the younger age group, all participants randomized to the 10-µg, 20-µg, and 30-µg dose groups received both doses of BNT162b1 or placebo (Supplemental Table 14.2). All participants randomized to the 100-µg dose group received Dose 1 of BNT162b1 or placebo (Supplemental Table 14.3). The IRC determined not to administer the second dose of 100 µg due to reactogenicity (see Section 12.1.1 and Section 12.1.2). At the time of the data cutoff date (24 August 2020), 11 of 12 participants in this group received Dose 2 of BNT162b1 at 10 µg (Figure 2), but results for Dose 2 are not yet available at the time of this report. After the data cutoff date (24 August 2020), the remaining participant received Dose 2 of BNT162b1 at 10 µg.

All participants in the older age group randomized to each dose group received both doses of BNT162b1 or placebo (Supplemental Table 14.4).

BNT162b2

All participants randomized to each dose group in the younger and older age groups received both doses of BNT162b2 or placebo (Supplemental Tables 14.5 and 14.6, respectively).

Figure 2. Disposition of All Phase 1 Participants



PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 01SEP2020 (18:39)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/consort_p1

10.1.2. Phase 2

10.1.2.1. Disposition up to 7 Days After Dose 2

The first 360 participants enrolled as part of Phase 2 were randomized 1:1 (180 participants each) to the BNT162b2 and placebo groups. Among participants randomized to the BNT162b2 group, 88 participants were in the younger age group (18 to 55 years of age) and 92 participants were in the older age group (56 to 85 years of age) (Table 5).

Except for 1 participant in the BNT162b2 younger age group who was withdrawn after Dose 1 but before Dose 2 and 1 participant in the placebo group (who had not yet received Dose 2 at the time of data cutoff date [02 September 2020]), all other participants received both doses of study intervention. One participant noted above in the BNT162b2 younger age group was withdrawn from the study (after Dose 1 but before Dose 2) because of an SAE of gastric adenocarcinoma 23 days after receiving Dose 1 (Section 12.2.4.2).

Disposition of all randomized participants in the younger age group and in the older age group are presented in Supplemental Tables 14.183 and 14.184, respectively.

Table 5. Disposition of All Randomized Subjects – Phase 2

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	Total (N[a]=360) n[b] (%)
Randomized	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)	360 (100.0)
Not vaccinated	0	0	0	0	0
Vaccinated					
Dose 1	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)	360 (100.0)
Dose 2	87 (98.9)	92 (100.0)	179 (99.4)	179 (99.4)	358 (99.4)
Withdrawn after Dose 1 and before Dose 2	1 (1.1)	0	1 (0.6)	0	1 (0.3)
Withdrawn after Dose 2	0	0	0	0	0
Reason for withdrawal					
Adverse event	1 (1.1)	0	1 (0.6)	0	1 (0.3)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:11) Source Data: adds Table Generation: 10SEP2020 (13:50) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2 unblinded/C4591001 IA P2/adds s002 p2 rand

10.1.2.2. Disposition From 7 Days After Dose 2 to the Data Cutoff Date of 14 November 2020

From 7 days after Dose 2 to the data cutoff date of 14 November 2020, 1 additional participant in the BNT162b2 older age group was withdrawn from the study because of an SAE of cardiac arrest 60 days after receiving Dose 2, which resulted in death (Supplemental Table 14.226 and Section 12.2.4.2). The death was assessed by the investigator as not related to the study intervention.

10.1.3. Phase 2/3

10.1.3.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Safety Population

The disposition of the first 37,796 participants (including the 360 participants in Phase 2) randomized was similar in the BNT162b2 and placebo groups (Table 6). Most participants randomized (≥98.1%) received Dose 1 and Dose 2. There were 121 (0.6%) participants in the BNT162b2 group and 111 (0.6%) participants in the placebo group discontinued from the vaccination period who are continuing in the study to be followed for safety. The most frequently reported reasons for discontinuation from the vaccination period included: no longer meets eligibility criteria, withdrawal by subject, and AE. Few participants in the BNT162b2 and placebo groups were withdrawn from the study (1.0% and 1.4%, respectively), and most were withdrawals by the participant, or they were lost to follow-up. Eight participants in the BNT162b2 group and 5 participants in the placebo group were withdrawn due to an AE.

One participant was randomized but did not sign an ICD and is not included in any analysis population (Appendix 16.2.3.2.4). HIV-positive participants (120 participants) are included in this summary but were not included in the analyses of the overall study objectives. Because of a dosing error, 2 participants received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving 1 dose of BNT162b2 (30 µg) and 1 dose of placebo.

Due to a data-related issue for this ongoing study that is being corrected, 2 participants were reported as 'discontinued from the vaccination period but continue in the study' with the reason as lost to follow-up, although the participants discontinued from the study.

The total of 37,796 participants excluded 4 participants (5 participant identification numbers) with special data issues: 2 participant identification numbers from 1 multi-enrolled participant and 3 participants whose actual treatment was not confirmed in IRT at the time of data cutoff.

- During the conduct of this study, 1 participant was identified to be randomized across 2 sites in this trial as 2 different participant identification numbers. Because the significant misconduct of this participant compromised the integrity of the study data, results from this participant were excluded entirely from all efficacy and safety analyses, including disposition and demographic tabulations. Separate listings were generated for this participant (Section 10.2.3).

- Three participants who were randomized and vaccinated, but actual treatment was not confirmed in IRT at the time of data cutoff (Appendix 16.2.3.2.5). Participants were vaccinated as per CRF, but due to lack of matching actual vaccination data, these were not assigned to any actual dosing group. These participants were excluded from all tables/figures but were included in the listings.

Table 6. Disposition of All Randomized Subjects – ~38000 Subjects for Phase 2/3 Analysis

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18904) n[b] (%)	Placebo (N[a]=18892) n[b] (%)	Total (N[a]=37796) n[b] (%)
Randomized	18904 (100.0)	18892 (100.0)	37796 (100.0)
Not vaccinated	46 (0.2)	43 (0.2)	89 (0.2)
Vaccinated			
Dose 1	18858 (99.8)	18849 (99.8)	37707 (99.8)
Dose 2	18555 (98.2)	18533 (98.1)	37088 (98.1)
Completed 1-month post–Dose 2 visit (vaccination period)	16902 (89.4)	16804 (88.9)	33706 (89.2)
Discontinued from vaccination period but continue in the study	121 (0.6)	111 (0.6)	232 (0.6)
Discontinued after Dose 1 and before Dose 2	121 (0.6)	107 (0.6)	228 (0.6)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.0)	4 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	48 (0.3)	81 (0.4)	129 (0.3)
Withdrawal by subject	45 (0.2)	9 (0.0)	54 (0.1)
Adverse event	20 (0.1)	12 (0.1)	32 (0.1)
Pregnancy	4 (0.0)	4 (0.0)	8 (0.0)
Physician decision	2 (0.0)	1 (0.0)	3 (0.0)
Lost to follow-up	0	2 (0.0)	2 (0.0)
Medication error without associated adverse event	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	1 (0.0)	3 (0.0)
Withdrawn from the study	180 (1.0)	259 (1.4)	439 (1.2)
Withdrawn after Dose 1 and before Dose 2	132 (0.7)	164 (0.9)	296 (0.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	44 (0.2)	84 (0.4)	128 (0.3)
Withdrawn after 1-month post–Dose 2 visit	4 (0.0)	11 (0.1)	15 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	84 (0.4)	157 (0.8)	241 (0.6)
Lost to follow-up	80 (0.4)	86 (0.5)	166 (0.4)
Adverse event	8 (0.0)	5 (0.0)	13 (0.0)

Table 6. Disposition of All Randomized Subjects – ~38000 Subjects for Phase 2/3 Analysis

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18904) n[b] (%)	Placebo (N[a]=18892) n[b] (%)	Total (N[a]=37796) n[b] (%)
Death	2 (0.0)	3 (0.0)	5 (0.0)
Physician decision	1 (0.0)	2 (0.0)	3 (0.0)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)
Other	3 (0.0)	3 (0.0)	6 (0.0)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 17NOV2020 (16:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 p3 rand

There were no clinically meaningful differences in disposition of the first 37,796 randomized participants by age group, baseline SARS-CoV-2 status, ethnicity, race, or sex. These data are presented in the following tables:

Age Group: 16 to 55 Years	Supplemental Table 14.242
Age Group: >55 Years	Supplemental Table 14.243
Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.244
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.245
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: 16-55 Years	Supplemental Table 14.246
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: >55 Years	Supplemental Table 14.247
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: 16-55 Years	Supplemental Table 14.248
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: >55 Years	Supplemental Table 14.249
Ethnicity: Hispanic/Latino	Supplemental Table 14.250
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.251

Ethnicity: Not Reported	Supplemental Table 14.252
Race: White	Supplemental Table 14.253
Race: Black or African American	Supplemental Table 14.254
Race: All Others	Supplemental Table 14.255
Sex: Male	Supplemental Table 14.256
Sex: Female	Supplemental Table 14.257

10.1.3.2. All Participants – Safety Population

From Dose 1 to the data cutoff date (14 November 2020), disposition of all 43,548 participants randomized (which excludes 3 participants whose actual treatment was not confirmed in IRT at the time of the data cutoff and 2 additional participant identification numbers from 1 multi-enrolled participant) was generally similar in the BNT162b2 and placebo groups (Supplemental Table 14.258). Almost all participants randomized received Dose 1 (99.8%) and approximately 94.2% of participants received Dose 2 at the cutoff date for the analyses in this CSR. At the time of the data cutoff, 137 (0.6%) participants in the BNT162b2 group and 129 (0.6%) participants in the placebo group were discontinued from the vaccination period but were continuing in the study for safety follow-up. The most frequently reported reasons for discontinuation from the vaccination period included: no longer meets eligibility criteria, withdrawal by participant, and AE.

Of the 181 (0.8%) and 263 (1.2%) participants who were withdrawn from the study in the BNT162b2 and placebo groups, respectively, most were withdrawn after Dose 1 and before Dose 2 (133 [0.6%] in the BNT162b2 group and 168 [0.8%] in the placebo group) (Supplemental Table 14.258). Most of these were withdrawals by the participant, or they were lost to follow-up. Eight participants in the BNT162b2 group and 6 participants in the placebo group were withdrawn because of an AE (Supplemental Table 14.258). Nine participants withdrew from the study due to pregnancies (Section 12.3.4.5). There were 6 deaths: 2 in the BNT162b2 group and 4 in the placebo group (Section 12.3.4.1). None of the deaths were assessed by the investigator as related to study intervention.

Due to a data-related issue for this ongoing study that is being corrected, a total of 3 participants were reported as 'discontinued from the vaccination period but continue in the study' with the reason as lost to follow-up (inclusive of the 2 participants who were part of the ~38,000 participants), although the participants discontinued from the study.

The Phase 2/3 total of 43,548 randomized participants excluded 4 participants (5 participant identification numbers) with special data issues: 1 multi-enrolled participant (2 participant identification numbers) and 3 participants whose actual treatment was not confirmed in IRT at the time of data cutoff (Appendix 16.2.3.2.6). All 4 participants (5 participant identification numbers) were part of the ~38,000 population (Section 10.1.3.1).

Disposition of all participants is presented by age group in Supplemental Tables 14.259 and 14.260.

10.2. Protocol Deviations

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

Appendix 16.2.2.1, 16.2.2.1.1, 16.2.2.2, and 16.2.2.3 lists important PDs that may have significantly impacted the completeness, accuracy, and/or reliability of the study data or that may have significantly affected a participant's rights, safety, or well-being.

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

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

10.2.1. Phase 1

Five participants were randomized and received study intervention, but all 5 participants met exclusion criterion #19 (any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality) but were enrolled (Appendix 16.2.2.1); 4 of these participants were from the same site These participants were included in the safety population and Dose 1 and Dose 2 all-available immunogenicity populations, but they were excluded from the Dose 1 and Dose 2 evaluable immunogenicity populations.

Three participants (1 younger participant in the 10-µg BNT162b2, 1 older participant in the 30-µg BNT162b2 group, and 1 younger participant in the placebo group) had Grade 1 or Grade 2 total bilirubin at screening but were enrolled (Appendix 16.2.8.2.1); the site was retrained on exclusion criteria #19. One older participant in the 10-µg BNT162b1 group had Grade 1 hemoglobin at screening that was not repeated, and the site was retrained. One younger participant in the placebo group had Grade 1 hemoglobin (Appendix 16.2.8.1.1) and Grade 1 blood urea nitrogen (Appendix 16.2.8.2.1) at screening but did not have a second sample analyzed per the protocol.

10.2.2. Phase 2

Appendix 16.2.2.2 lists important PDs for Phase 2 up to the data cutoff date of 14 November 2020.

10.2.3. Phase 2/3

Appendix 16.2.2.3 lists important PDs for Phase 2 and Phase 3 up to the data cutoff date of 14 November 2020.

One participant (2 distinct participant identification numbers) was enrolled at multiple sites, and therefore was withdrawn from the study. The participant was excluded from all efficacy

and safety data. Important PDs for this participant are listed in Appendix 16.2.2.4, and AEs for this participant are listed in Appendix 16.2.7.4.6.

For this study, any dose of study intervention greater than 30 µg within a 24-hour time period was considered an overdose (Appendix 16.1.1, Protocol Section 8.4). An error in dilution during the study resulted in 52 participants receiving a higher than intended dose of BNT162b2; instead of receiving 30 µg of BNT162b2, 58 µg of BNT162b2 was administered (Appendix 16.2.2.3). The participants did not report an increase in reactogenicity or AEs.

10.3. Vaccine Administration and Timing

10.3.1. Phase 1

BNT162b1

All participants in the younger age group received BNT162b1 (10 µg, 20 µg, or 30 µg) or placebo as randomized (Supplemental Table 14.7). All participants randomized to the 100-µg dose group only received Dose 1 of BNT162b1 at the 100-µg dose level or placebo as randomized (Supplemental Table 14.8), following the IRC decision to not continue dosing in the 100-µg group based on reactogenicity (see Section 12.1.1 and Section 12.2.2).

All participants in the older age group received BNT162b1 (10 µg, 20 µg, or 30 µg) or placebo as randomized (Supplemental Table 14.9). No participants in the older age group received BNT162b1 100 µg.

Participants in the younger and older age groups received Dose 2 within the protocol-specified time frame (Supplemental Tables 14.10 and 14.11, respectively).

BNT162b2

All participants in the younger (Supplemental Table 14.12) and older age groups (Supplemental Table 14.13) received BNT162b2 (10 µg, 20 µg, or 30 µg) or placebo as randomized. All participants in the younger and older age groups received Dose 2 within the protocol-specified time frame (Supplemental Tables 14.14 and 14.15, respectively).

10.3.2. Phase 2

Except for 1 participant in the BNT162b2 younger group and 1 participant in the placebo group (who had not yet received Dose 2 at the time of the data cutoff date [02 September 2020]), all other participants received both doses of vaccine. No participants received the incorrect study intervention (Supplemental Table 14.185). The majority of participants received Dose 2 between 19 to 23 days after Dose 1 in the BNT162b2 (97.2%) and placebo (96.7%) groups (Supplemental Table 14.186).

10.3.3. Phase 2/3

For the N~38,000 participants, almost all participants were administered study intervention as randomized; 99.7% received Dose 1 and 98.1% received Dose 2 of BNT162b2 in the BNT162b2 group, and 99.8% received Dose 1 and 98.1% received Dose 2 of placebo in the placebo group (Table 7). For Dose 1, 3 participants randomized to the placebo group

received BNT162b2, and 2 participants randomized to the BNT162b2 group received placebo. For Dose 2, 4 participants randomized to the placebo group received BNT162b2, and 5 participants randomized to the BNT162b2 group received placebo. The majority of participants received Dose 2 between 19 to 23 days after Dose 1 in the BNT162b2 (93.1%) and placebo (92.9%) groups (Table 8).

Table 7. Vaccine as Administered by Vaccine Group – ~38000 Subjects for Phase 2/3 Analysis – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=18904)	Placebo (N[a]=18892)
Vaccine (as Administered)	n[b] (%)	n[b] (%)
Vaccinated	18858 (99.8)	18849 (99.8)
Not vaccinated	46 (0.2)	43 (0.2)
Dose 1		
BNT162b2 (30 µg)	18855 (99.7)	3 (0.0)
Placebo	2 (0.0)	18846 (99.8)
Dose 2		
BNT162b2 (30 µg)	18549 (98.1)	4 (0.0)
Placebo	5 (0.0)	18529 (98.1)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (09:11) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 IA P3 2MPD2/advx s002 adm p3 rand

Table 8. Vaccine Administration Timing – ~38000 Subjects for Phase 2/3 Analysis – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=18904)	Placebo (N[a]=18892)
	n[b] (%)	n[b] (%)
Randomized	18904 (100.0)	18892 (100.0)

Table 8. Vaccine Administration Timing – ~38000 Subjects for Phase 2/3 Analysis – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=18904) n[b] (%)	Placebo (N[a]=18892) n[b] (%)
Not vaccinated	46 (0.2)	43 (0.2)
Dose 1	18857 (99.8)	18849 (99.8)
Dose 2[c]	18554 (98.1)	18533 (98.1)
<19 Days	159 (0.8)	163 (0.9)
19 to 23 Days[d]	17605 (93.1)	17555 (92.9)
>23 Days	791 (4.2)	815 (4.3)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Days calculated since Dose 1.
d. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (09:40) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/advx_s002_time_p3_rand

10.4. Data Sets Analyzed

10.4.1. Phase 1

BNT162b1

All participants randomized to receive BNT162b1 or placebo in the younger age group (Supplemental Tables 14.16 and 14.17) and older age group (Supplemental Table 14.18) were included in the safety population.

In the younger age group, all participants randomized to receive BNT162b1 (10 µg, 20 µg, or 30 µg) or placebo were included in all-available immunogenicity populations (Supplemental Table 14.19). In the 100-µg dose group, results for Dose 2 (10 µg) are not available at the time of this report, so these participants were included only in the Dose 1 available and evaluable immunogenicity populations (Supplemental Table 14.20).

In the older age group, 1 (8.3%) participant in the 10-µg dose group was excluded from the Dose 1 and Dose 2 evaluable immunogenicity populations because of a protocol deviation. (Supplemental Table 14.21). This participant met exclusion criterion #19 (any screening hematology and/or blood chemistry laboratory value that meets the definition of ≥ Grade 1 abnormality) but was included in the Dose 1 and Dose 2 all-available immunogenicity populations.

BNT162b2

All participants randomized to receive BNT162b2 or placebo in both the younger and older age groups were included in the safety population (Supplemental Tables 14.22 and 14.23, respectively).

In the younger age group, 1 (8.3%) participant in the 10-µg dose group and 2 (22.2%) participants in the placebo group were excluded from the Dose 1 and Dose 2 evaluable immunogenicity populations because of a protocol deviation (Section 10.2.1 and Supplemental Table 14.24). These participants met exclusion criterion #19 (any screening hematology and/or blood chemistry laboratory value that meets the definition of ≥ Grade 1 abnormality). One (8.3%) participant in the 30-µg dose group was excluded from the Dose 2 evaluable immunogenicity population because the blood sample collection did not occur within 6 to 8 days after Dose 2.

In the older age group, 1 (8.3%) participant in the 20-µg dose group did not have blood collected within 6 to 8 days after Dose 2 and was excluded from the Dose 2 evaluable immunogenicity population (Supplemental Table 14.25). One (8.3%) participant in the 30-µg dose group was excluded from the Dose 1 and Dose 2 evaluable immunogenicity populations because of a protocol deviation. This participant met exclusion criterion #19 (any screening hematology and/or blood chemistry laboratory value that meets the definition of ≥ Grade 1 abnormality).

10.4.2. Phase 2

The proportions of participants in the safety population were the same in the BNT162b2 group and the placebo group (180 participants each). Within the BNT162b2 group, 88 participants were in the younger age group and 92 were in the older age group (Table 9).

Table 9. Safety Population – Phase 2

	Vaccine Group (as Administered)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years n[a]	56-85 Years n[a]	18-85 Years n[a]	18-85 Years n[a]	Total n[a] (%)
Randomized[b]					360
Vaccinated	88	92	180	180	360 (100.0)
Safety population	88	92	180	180	360 (100.0)

Table 9. Safety Population – Phase 2

	Vaccine Group (as Administered)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years n[a]	56-85 Years n[a]	18-85 Years n[a]	18-85 Years n[a]	Total n[a] (%)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 09SEP2020 (23:33) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adsl_s003_saf_pop_p2

A total of 7 participants (3 in the BNT162b2 group and 4 in the placebo group) were excluded from the Dose 2 all-available immunogenicity population because they did not have at least 1 valid and determinate immunogenicity result after Dose 2 (Supplemental Table 14.187). The Dose 2 evaluable immunogenicity population included 93.9% of participants who received BNT162b2 and 92.8% of participants who received placebo. Most participants were excluded from the Dose 2 evaluable immunogenicity population because there was no blood collection sample within 28 to 42 days after Dose 2. Serology data at 1 month after Dose 2 from 2 participants who had a post baseline positive SARS-CoV-2 test result were excluded in the analysis based on the Dose 2 evaluable immunogenicity populations, according to the study protocol and SAP.

10.4.3. Phase 2/3

10.4.3.1. Safety Populations

For the 37,706 participants, the duration of follow-up was ≥2 months after Dose 2 for 50.6% of participants. Duration of follow-up was ≥1 month after Dose 2 for 91.6% of participants (Table 10).

Table 10. Follow-Up Time After Dose 2 – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Placebo (N[a]=18846) n[b] (%)	Total (N[a]=37706) n[b] (%)
Subjects (%) with length of follow-up of:			
<2 Months	9329 (49.5)	9310 (49.4)	18639 (49.4)

Table 10. Follow-Up Time After Dose 2 – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=18860) n^b (%)	Placebo (N^a=18846) n^b (%)	Total (N^a=37706) n^b (%)
<2 Weeks	363 (1.9)	388 (2.1)	751 (2.0)
≥2 to <4 Weeks	1223 (6.5)	1200 (6.4)	2423 (6.4)
≥4 to <6 Weeks	3239 (17.2)	3235 (17.2)	6474 (17.2)
≥6 to <8 Weeks	4504 (23.9)	4487 (23.8)	8991 (23.8)
≥2 Months	9531 (50.5)	9536 (50.6)	19067 (50.6)
≥8 to <10 Weeks	6296 (33.4)	6329 (33.6)	12625 (33.5)
≥10 to <12 Weeks	2853 (15.1)	2809 (14.9)	5662 (15.0)
≥12 to <14 Weeks	382 (2.0)	398 (2.1)	780 (2.1)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (05:34) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s005_fup_time_d2_saf

10.4.3.1.1.1. Participants with Median 2 Months of Follow-Up After Dose 2

The safety population (N=37,706) included 18,860 participants in the BNT162b2 group and 18,846 participants in the placebo group (Table 11). In both treatment groups, 90 participants (0.2%) were randomized but excluded from the safety population (89 did not receive study intervention and 1 did not provide informed consent).

Overall, 0.3% of participants were HIV-positive and were evenly distributed between treatment groups. Note that HIV-positive participants were included in the safety population and are shown as part of the study demographics and disposition but did not have safety data available to contribute to the safety analyses at the time of the data cutoff.

Table 11. Safety Population – ~38000 Subjects for Phase 2/3 Analysis

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n^a	Placebo n^a	Total n^a (%)
Randomized[b]			37796

Table 11. Safety Population – ~38000 Subjects for Phase 2/3 Analysis

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Vaccinated	18861	18846	37707 (99.8)
Safety population	18860	18846	37706 (99.8)
HIV-positive	59	61	120 (0.3)
Excluded from safety population			90 (0.2)
Reason for exclusion			
Subject did not receive study vaccine			89 (0.2)
Did not provide informed consent			1 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (16:33) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s003 saf pop p3

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

Age Group	Supplemental Table 14.261
Baseline SARS-CoV-2 Status	Supplemental Table 14.262
Baseline SARS-CoV-2 Status and Age Group	Supplemental Table 14.263
Ethnicity	Supplemental Table 14.264
Race	Supplemental Table 14.265
Sex	Supplemental Table 14.266

10.4.3.1.1.2. All Participants

The safety population (N=43,448) included 21,720 participants in the BNT162b2 group and 21,728 participants in the placebo group (Supplemental Table 14.267). In both treatment groups, 100 (0.2%) were randomized but excluded from the safety population (99 did not receive study intervention and 1 did not provide informed consent).

The safety population for all participants is presented by age group in Supplemental Table 14.268.

Follow-up time for all participants is presented in Supplemental Table 14.269.

10.4.3.2. Efficacy Populations – Interim Analysis 1

The proportions of participants included in the efficacy populations were similar in both vaccine groups (Table 12). The first row of Table 12 includes all participants randomized (43,325) by 04 November 2020. For participants who were excluded from the evaluable efficacy population, the most common reason was because participants did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19 to 42 days after Dose 1). Among the 36,998 participants included in the evaluable efficacy population, 32,279 Phase 2/3 participants had no evidence of infection up to 7 days after Dose 2.

Table 12. Efficacy Populations – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	**Placebo n[a] (%)**	**Total n[a] (%)**
Randomized[b]	21653 (100.0)	21672 (100.0)	43325 (100.0)
Dose 1 all-available efficacy population	21617 (99.8)	21633 (99.8)	43250 (99.8)
Subjects without evidence of infection before Dose 1	17237 (79.6)	17221 (79.5)	34458 (79.5)
Subjects excluded from Dose 1 all-available efficacy population	36 (0.2)	39 (0.2)	75 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	35 (0.2)	39 (0.2)	74 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	18868 (87.1)	18877 (87.1)	37745 (87.1)
Subjects without evidence of infection prior to 7 days after Dose 2	16463 (76.0)	16426 (75.8)	32889 (75.9)
Subjects excluded from Dose 2 all-available efficacy population	2785 (12.9)	2795 (12.9)	5580 (12.9)
Reason for exclusion[c]			
Did not complete 2 vaccination doses	2784 (12.9)	2795 (12.9)	5579 (12.9)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy population (7 Days)	18380 (84.9)	18618 (85.9)	36998 (85.4)
Subjects without evidence of infection prior to 7 days after Dose 2	16061 (74.2)	16218 (74.8)	32279 (74.5)
Subjects excluded from evaluable efficacy population (7 Days)	3273 (15.1)	3054 (14.1)	6327 (14.6)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	15 (0.1)	16 (0.1)	31 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	3038 (14.0)	3035 (14.0)	6073 (14.0)
Had other important protocol deviations on or prior to 7 days after Dose 2	302 (1.4)	52 (0.2)	354 (0.8)

Table 12. Efficacy Populations – Interim Analysis 1

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

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 06NOV2020 (01:29) Source Data: adsl Table Generation: 06NOV2020 (16:35) (Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2_unblinded_ia/C4591001_IA_62/adsl_eff_pop

10.4.3.3. Efficacy Populations – Final Analysis

The proportions of participants included in the final analysis efficacy populations was similar in the BNT162b2 and placebo groups (Table 13). The first row of Table 13 includes all participants randomized (43,651) by 14 November 2020. Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1). There were 311 participants (1.4%) in the BNT162b2 group and 60 participants (0.3%) in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2.

An adhoc table was generated to evaluate the imbalance of important PDs in the BNT162b2 and the placebo groups in the evaluable efficacy (7 days) population and shown in Table 14. Most exclusions from the evaluable efficacy (7 days) population in the BNT162b2 group (84.6%) were due to dosing/administration errors or administration of study intervention that was deemed not suitable for use.

Table 13. Efficacy Populations

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	21823 (100.0)	21828 (100.0)	43651 (100.0)
Dose 1 all-available efficacy population	21768 (99.7)	21783 (99.8)	43551 (99.8)
Subjects without evidence of infection before Dose 1	20314 (93.1)	20296 (93.0)	40610 (93.0)
Subjects excluded from Dose 1 all-available efficacy population	55 (0.3)	45 (0.2)	100 (0.2)
Reason for exclusion[c]			

Table 13. Efficacy Populations

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Did not receive at least 1 vaccination	54 (0.2)	45 (0.2)	99 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	20566 (94.2)	20536 (94.1)	41102 (94.2)
Subjects without evidence of infection prior to 7 days after Dose 2	18701 (85.7)	18627 (85.3)	37328 (85.5)
Subjects without evidence of infection prior to 14 days after Dose 2	18678 (85.6)	18563 (85.0)	37241 (85.3)
Subjects excluded from Dose 2 all-available efficacy population	1257 (5.8)	1292 (5.9)	2549 (5.8)
Reason for exclusion[c]			
Did not receive 2 vaccinations	1256 (5.8)	1292 (5.9)	2548 (5.8)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy (7 days) population	20033 (91.8)	20244 (92.7)	40277 (92.3)
Subjects without evidence of infection prior to 7 days after Dose 2	18242 (83.6)	18379 (84.2)	36621 (83.9)
Evaluable efficacy (14 days) population	20033 (91.8)	20243 (92.7)	40276 (92.3)
Subjects without evidence of infection prior to 14 days after Dose 2	18219 (83.5)	18315 (83.9)	36534 (83.7)
Subjects excluded from evaluable efficacy (7 days) population	1790 (8.2)	1584 (7.3)	3374 (7.7)
Subjects excluded from evaluable efficacy (14 days) population	1790 (8.2)	1585 (7.3)	3375 (7.7)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	36 (0.2)	26 (0.1)	62 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	1550 (7.1)	1561 (7.2)	3111 (7.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	371 (0.8)
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	372 (0.9)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsl_eff_pop

Table 14. Subjects Excluded From Evaluable Efficacy Population Due to Important Protocol Deviations on or Prior to 7 Days After Dose 2

	Vaccine Group (as Randomized)

	BNT162b2 (30 µg) (N[a]=311)	Placebo (N[a]=60)
	n[b] (%)	n[b] (%)
Concomitant Medications	3 (1.0)	2 (3.3)
Subject received systemic corticosteroids (>=20mg/day of prednisone or equivalent) for >=14 days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.	3 (1.0)	2 (3.3)
Inclusion/Exclusion	25 (8.0)	18 (30.0)
Participant failed to meet inclusion criterion #03 (Healthy participants who are determined by medical history, physical examination and clinical judgement of the investigator to be eligible for inclusion in the study)	7 (2.3)	6 (10.0)
Participant failed to meet inclusion criterion #04 (Participants who, in the judgment of the investigator, are at risk for acquiring COVID-19)	1 (0.3)	0 (0.0)
Participant met exclusion criterion #02 (participant having known infection with HIV, HCV or HBV)	6 (1.9)	3 (5.0)
Participant met exclusion criterion #05 (previous clinical or microbiological diagnosis of COVID-19)	1 (0.3)	1 (1.7)
Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	2 (0.6)	4 (6.7)
Participant met exclusion criterion #13 (participant receiving treatment with immunosuppressive therapy as specified in protocol)	4 (1.3)	1 (1.7)
Participant met exclusion criterion #16 (Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation)	0 (0.0)	1 (1.7)
Participant met exclusion criterion #22 (investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members)	4 (1.3)	2 (3.3)
Informed Consent	1 (0.3)	0 (0.0)
Subject/LAR did not sign ICD & did not give verbal consent	1 (0.3)	0 (0.0)
Investigational Product	263 (84.6)	20 (33.3)
Administration error, incorrect container, but correct IP administered	0 (0.0)	1 (1.7)
Dosing/administration error, subject did not receive correct dose of vaccine	105 (33.8)	3 (5.0)
IP administered that was deemed not suitable for use by Almac	144 (46.3)	0 (0.0)
IP documentation error – IP preparation form errors	1 (0.3)	2 (3.3)
Incorrect IP assigned to subject due to IRT not being utilized	3 (1.0)	0 (0.0)
Incorrect vaccine allocation/assigned to subject	4 (1.3)	6 (10.0)
Other IP deviation	3 (1.0)	6 (10.0)
Subject was vaccinated despite being ineligible	1 (0.3)	1 (1.7)
Subject was vaccinated despite meeting temporary delay criterion #4 (receiving short-term (	2 (0.6)	2 (3.3)
Laboratory	2 (0.6)	1 (1.7)
Nasal swab can't be analyzed due to incorrect shipping procedure	2 (0.6)	1 (1.7)
Other	21 (6.8)	22 (36.7)
All data considered unreliable due to lack of PI oversight identified as significant quality event	21 (6.8)	22 (36.7)

Table 14. Subjects Excluded From Evaluable Efficacy Population Due to Important Protocol Deviations on or Prior to 7 Days After Dose 2

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=311)	Placebo (N[a]=60)
	n[b] (%)	n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects excluded from evaluable efficacy population due to important protocol deviations in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 19NOV2020 (06:57) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164_PD/addv_s001

10.5. Demographic and Other Baseline Characteristics

10.5.1. Phase 1

BNT162b1

Overall, for the safety population, most participants were White (37 [82.2%]; 14 [93.3%] for the 100-µg dose group) in both the younger age group (Supplemental Tables 14.26 and 14.27) and older age group (Supplemental Table 14.28). Median age was 35.0 years in the younger age group (35.0 years for the 100-µg dose group) and 69.0 years in the older age group. There was a higher representation of males in the younger age group (up to 30 µg) (28 [62.2%]). There was a higher representation of females in younger 100-µg dose group (9 [60.0%]) and in the older age group (32 [71.1%]).

Demographic characteristics for the BNT162b1 Dose 1 and Dose 2 all-available and evaluable immunogenicity populations were generally similar to those in the safety population and are presented in the following tables:

18-55 Years of Age – Dose 1 All-Available Immunogenicity Population	Supplemental Table 14.29
18-55 Years of Age – BNT162b1 (100 µg) Dose 1 All-Available Immunogenicity Population	Supplemental Table 14.30
65-85 Years of Age – Dose 1 All-Available Immunogenicity Population	Supplemental Table 14.31
18-55 Years of Age – Dose 1 Evaluable Immunogenicity Population	Supplemental Table 14.32
18-55 Years of Age – BNT162b1 (100 µg) Dose 1 Evaluable Immunogenicity Population	Supplemental Table 14.33
65-85 Years of Age – Dose 1 Evaluable Immunogenicity Population	Supplemental Table 14.34
18-55 Years of Age – Dose 2 All-Available Immunogenicity Population	Supplemental Table 14.35
65-85 Years of Age – Dose 2 All-Available Immunogenicity Population	Supplemental Table 14.36

18-55 Years of Age – Dose 2 Evaluable Immunogenicity Population	Supplemental Table 14.37
65-85 Years of Age – Dose 2 Evaluable Immunogenicity Population	Supplemental Table 14.38

The study population of the younger age group (Supplemental Tables 14.39 and 14.40) and older age group (Supplemental Table 14.41) were healthy with a medical history profile consistent with those of the healthy general population in each age group.

BNT162b2

Overall, most participants were White in the younger age group (39 [86.7%]), and all participants were White in the older age group (45 [100%]) (Supplemental Tables 14.42 and 14.43, respectively). Median age was 37.0 years in the younger age group and 68.0 years in the older age group. There was a higher representation of females in both the younger (26 [57.8%]) and older (28 [62.2%]) age groups.

Demographic characteristics for the BNT162b2 Dose 1 and Dose 2 all-available and evaluable immunogenicity populations were generally similar to those in the safety population and are presented in the following tables:

18-55 Years of Age – Dose 1 All-Available Immunogenicity Population	Supplemental Table 14.44
65-85 Years of Age – Dose 1 All-Available Immunogenicity Population	Supplemental Table 14.45
18-55 Years of Age – Dose 1 Evaluable Immunogenicity Population	Supplemental Table 14.46
65-85 Years of Age – Dose 1 Evaluable Immunogenicity Population	Supplemental Table 14.47
18-55 Years of Age – Dose 2 All-Available Immunogenicity Population	Supplemental Table 14.48
65-85 Years of Age – Dose 2 All-Available Immunogenicity Population	Supplemental Table 14.49
18-55 Years of Age – Dose 2 Evaluable Immunogenicity Population	Supplemental Table 14.50
65-85 Years of Age – Dose 2 Evaluable Immunogenicity Population	Supplemental Table 14.51

The study population of the younger and older age groups were healthy with a medical history profile consistent with those of the healthy general population in each age group (Supplemental Tables 14.52 and 14.53, respectively).

10.5.2. Phase 2

Demographic characteristics for Phase 2 were similar in the BNT162b2 group and the placebo group for the safety population (Table 15). The male/female split was approximately 50/50 for both vaccine groups and also for both age groups within the BNT162b2 group.

Overall, most participants were White (85.8%), followed by Black or African American (9.2%). The proportions of Hispanic/Latino participants were similar in the BNT162b2 and placebo groups (8.9% and 11.1%, respectively). Within the BNT162b2 group, the younger age group had 14.8% of Hispanic/Latino participants and the older age group had 3.3%.

The median age was 56.0 years across participants ages 18 to 85. Median age was 44.0 years for the BNT162b2 younger age group and 65.0 years for the BNT162b2 older age group.

Demographic characteristics of the younger age group and the older age group are presented in Supplemental Tables 14.188 and 14.189, respectively.

Table 15. Demographic Characteristics – Phase 2 – Safety Population

	Vaccine Group (as Administered)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	Total (N[a]=360) n[b] (%)
Sex					
Male	46 (52.3)	50 (54.3)	96 (53.3)	94 (52.2)	190 (52.8)
Female	42 (47.7)	42 (45.7)	84 (46.7)	86 (47.8)	170 (47.2)
Race					
White	72 (81.8)	85 (92.4)	157 (87.2)	152 (84.4)	309 (85.8)
Black or African American	9 (10.2)	3 (3.3)	12 (6.7)	21 (11.7)	33 (9.2)
American Indian or Alaska native	0	1 (1.1)	1 (0.6)	1 (0.6)	2 (0.6)
Asian	5 (5.7)	0	5 (2.8)	4 (2.2)	9 (2.5)
Multiracial	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)	3 (0.8)
Not reported	1 (1.1)	2 (2.2)	3 (1.7)	1 (0.6)	4 (1.1)
Ethnicity					
Hispanic/Latino	13 (14.8)	3 (3.3)	16 (8.9)	20 (11.1)	36 (10.0)
Non-Hispanic/non-Latino	74 (84.1)	88 (95.7)	162 (90.0)	158 (87.8)	320 (88.9)
Not reported	1 (1.1)	1 (1.1)	2 (1.1)	2 (1.1)	4 (1.1)
Age at vaccination (years)					
Mean (SD)	41.4 (10.30)	65.9 (6.53)	53.9 (14.99)	51.3 (15.91)	52.6 (15.49)
Median	44.0	65.0	56.0	55.5	56.0
Min, max	(18, 55)	(56, 85)	(18, 85)	(20, 83)	(18, 85)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 09SEP2020 (23:19) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adsl_s005_demo_p2_saf

The 360 participants in Phase 2 had a diverse medical history profile consistent with individuals of the same age group in the general population (Supplemental Table 14.190). In

the BNT162b2 group, conditions in the surgical and medical procedures (89 [49.4%]), immune system disorders (63 [35%]), and metabolism and nutrition disorders (61 [33.9%]) SOCs were most frequently reported.

Demographic characteristics for the 336 participants included in the Dose 2 evaluable immunogenicity population were similar to those in the safety population in Phase 2 (Supplemental Table 14.191).

Demographic characteristics for the Dose 2 all-available immunogenicity population were similar to those in the Dose 2 evaluable immunogenicity population (Supplemental Table 14.192).

10.5.3. Phase 2/3

10.5.3.1. Participants with Median 2 Months of Follow-Up After Dose 2– Safety Population – Phase 2/3

Demographic characteristics for the 37,706 Phase 2/3 participants (who had a median 2 months of follow-up after Dose 2) were similar in the BNT162b2 and placebo groups (Table 16). Overall, most participants were White (82.9%), with 9.3% Black participants and 4.3% Asian participants, and other racial groups were <3%. There were 28% Hispanic/Latino participants. Median age was 52 years and 50.6% of participants were male. The younger and older age groups were 57.8% and 42.2% of participants, respectively. Obese participants made up 35.1% of this safety population.

Table 16. Demographic Characteristics – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Placebo (N[a]=18846) n[b] (%)	Total (N[a]=37706) n[b] (%)
Sex			
Male	9639 (51.1)	9436 (50.1)	19075 (50.6)
Female	9221 (48.9)	9410 (49.9)	18631 (49.4)
Race			
White	15636 (82.9)	15630 (82.9)	31266 (82.9)
Black or African American	1729 (9.2)	1763 (9.4)	3492 (9.3)
American Indian or Alaska native	102 (0.5)	99 (0.5)	201 (0.5)
Asian	801 (4.2)	807 (4.3)	1608 (4.3)
Native Hawaiian or other Pacific Islander	50 (0.3)	26 (0.1)	76 (0.2)
Multiracial	449 (2.4)	406 (2.2)	855 (2.3)
Not reported	93 (0.5)	115 (0.6)	208 (0.6)

Table 16. Demographic Characteristics – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Placebo (N[a]=18846) n[b] (%)	Total (N[a]=37706) n[b] (%)
Ethnicity			
Hispanic/Latino	5266 (27.9)	5277 (28.0)	10543 (28.0)
Non-Hispanic/non-Latino	13482 (71.5)	13459 (71.4)	26941 (71.5)
Not reported	112 (0.6)	110 (0.6)	222 (0.6)
Country			
Argentina	2883 (15.3)	2881 (15.3)	5764 (15.3)
Brazil	1145 (6.1)	1139 (6.0)	2284 (6.1)
South Africa	372 (2.0)	372 (2.0)	744 (2.0)
USA	14460 (76.7)	14454 (76.7)	28914 (76.7)
Age group			
16-55 Years	10889 (57.7)	10896 (57.8)	21785 (57.8)
>55 Years	7971 (42.3)	7950 (42.2)	15921 (42.2)
Age at vaccination (years)			
Mean (SD)	50.5 (15.65)	50.3 (15.72)	50.4 (15.68)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	201 (1.1)	235 (1.2)	436 (1.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	5517 (29.3)	5460 (29.0)	10977 (29.1)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	6578 (34.9)	6481 (34.4)	13059 (34.6)
Obese (≥30.0 kg/m^2)	6556 (34.8)	6662 (35.3)	13218 (35.1)
Missing	8 (0.0)	8 (0.0)	16 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (16:20) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo p3 saf

Within each age group, most demographic characteristics were similar in the BNT162b2 group and the placebo group. There was a lower proportion of non-Hispanic/non-Latino participants in the younger BNT162b2 and placebo groups (65.4% and 65.6%, respectively) than in the older BNT162b2 and placebo groups (79.8% and 79.4%, respectively) (Supplemental Tables 14.270 and 14.271, respectively).

Within each baseline SARS-CoV-2 status group, demographic characteristics were similar in the BNT162b2 group and the placebo group (Supplemental Tables 14.272 and 14.273). Most participants were White regardless of baseline status; however, there was a higher proportion of White participants with a negative baseline status (83.8%) than a positive baseline status (57.2%). The median age was 43.0 years in participants with a positive baseline status and 52.0 years in participants with a negative baseline status. There were 42.2% and 34.7% of participants in the baseline positive and negative groups, respectively, that were obese.

The safety population included 283 participants who were 16 or 17 years of age. Demographics for this age group were similar between the BNT162b2 and placebo groups and to the safety population in general (Supplemental Table 14.286).

Demographic characteristics are presented by subgroup in the following tables:

Age Group: 16 to 55 Years	Supplemental Table 14.270
Age Group: >55 Years	Supplemental Table 14.271
Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.272
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.273
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: 16 to 55 Years	Supplemental Table 14.274
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: >55 Years	Supplemental Table 14.275
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: 16 to 55 Years	Supplemental Table 14.276
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: >55 Years	Supplemental Table 14.277
Ethnicity: Hispanic/Latino	Supplemental Table 14.278
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.279
Ethnicity: Not Reported	Supplemental Table 14.280
Race: White	Supplemental Table 14.281
Race: Black or African American	Supplemental Table 14.282
Race: All Others	Supplemental Table 14.283
Sex: Male	Supplemental Table 14.284
Sex: Female	Supplemental Table 14.285

Participants in Phase 2/3 had a diverse medical history profile consistent with that of individuals in the general population in the same age group (Supplemental Table 14.287). In the BNT162b2 group, conditions in the surgical and medical procedures (7281 [38.6%]), metabolism and nutrition disorders (5663 [30.0%]), and immune system disorders (5097 [27.0%]) SOCs were most frequently reported.

Across both treatment groups, 20.5% had any comorbidity (per the Charlson comorbidity index) (Supplemental Table 14.288). The most frequently reported comorbidities were diabetes (with and without chronic complications, 8.4%) and pulmonary disease (7.8%) and were reported at similar frequencies in each group. More participants had comorbidities in the older population (31.1%) than the younger population (12.8%), including diabetes (14.6% and 3.8%), malignancy (7.4% and 1.0%), and pulmonary disease (8.8% and 7%) (Supplemental Tables 14.289 and 14.290).

10.5.3.2. All Participants – Safety Population

Demographic characteristics for all 43,448 Phase 2/3 participants included in the safety population to date were similar in the BNT162b2 and placebo groups for the safety population (Supplemental Table 14.291). Overall, most participants were White (82.2%) and non-Hispanic/non-Latino (73.3%), median age was 51.0 years, and 49.1% were female. There were 9.7% Black or African American, 4.3% Asian, 2.4% Multiracial, 0.7% American Indian or Alaskan native, and 0.2% Native Hawaiian or other Pacific Islander participants included in the safety population. Race was not reported for 0.5% of the participants. There were 58.9% of participants in the younger age group. Obese participants made up 34.7% of this safety population.

Within each age group, most demographic characteristics were similar in the BNT162b2 group and the placebo group. There was a lower proportion on non-Hispanic/non-Latino participants in the younger BNT162b2 and placebo groups (68.1% and 68.3%, respectively) than in the older BNT162b2 and placebo groups (80.9% and 80.6%, respectively) (Supplemental Tables 14.292 and 14.293).

Participants in Phase 2/3 had a diverse medical history profile consistent with that of individuals in the general population in the same age group (Supplemental Table 14.294). In the BNT162b2 group, conditions in the surgical and medical procedures (8306 [38.2%]), metabolism and nutrition disorders (6497 [29.9%]), and immune system disorders (5863 [27.0%]) SOCs were most frequently reported.

Across both treatment groups, 20.7% of participants had any Charlson comorbidity at baseline (Supplemental Table 14.295). The most frequently reported comorbidities were diabetes (with and without chronic complication, 8.3%) and chronic pulmonary disease (7.9%) and were reported at similar frequencies in each group. More participants had comorbidities in the older population (31.4%) than in the younger population (13.2%), including diabetes (with and without chronic complication, 14.7% vs 3.8%), malignancy (7.3% vs 1.0%) and chronic pulmonary disease (8.9% vs 7.2%) (Supplemental Tables 14.296 and 14.297).

10.5.3.3. Evaluable Efficacy Population – Without Evidence of Infection up to 7 Days After Dose 2 – Interim Analysis 1

Demographic characteristics were similar in the BNT162b2 and placebo groups among participants without evidence of infection up to 7 days after Dose 2 in the evaluable efficacy population for the first interim analysis (Table 17).

Table 17. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16061) n[b] (%)	Placebo (N[a]=16218) n[b] (%)	Total (N[a]=32279) n[b] (%)
Sex			
Male	8197 (51.0)	8144 (50.2)	16341 (50.6)
Female	7864 (49.0)	8074 (49.8)	15938 (49.4)
Race			
White	13502 (84.1)	13692 (84.4)	27194 (84.2)
Black or African American	1298 (8.1)	1303 (8.0)	2601 (8.1)
American Indian or Alaska native	88 (0.5)	82 (0.5)	170 (0.5)
Asian	712 (4.4)	716 (4.4)	1428 (4.4)
Native Hawaiian or other Pacific Islander	40 (0.2)	26 (0.2)	66 (0.2)
Multiracial	341 (2.1)	297 (1.8)	638 (2.0)
Not reported	80 (0.5)	102 (0.6)	182 (0.6)
Ethnicity			
Hispanic/Latino	4415 (27.5)	4383 (27.0)	8798 (27.3)
Non-Hispanic/non-Latino	11553 (71.9)	11736 (72.4)	23289 (72.1)
Not reported	93 (0.6)	99 (0.6)	192 (0.6)
Country			
Argentina	2445 (15.2)	2415 (14.9)	4860 (15.1)
Brazil	889 (5.5)	889 (5.5)	1778 (5.5)
South Africa	215 (1.3)	218 (1.3)	433 (1.3)
USA	12512 (77.9)	12696 (78.3)	25208 (78.1)
Age group			
16-55 Years	9093 (56.6)	9172 (56.6)	18265 (56.6)
>55 Years	6968 (43.4)	7046 (43.4)	14014 (43.4)
Age at vaccination (years)			
Mean (SD)	50.9 (15.58)	50.7 (15.68)	50.8 (15.63)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 91)	(16, 91)

Table 17. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16061) n[b] (%)	Placebo (N[a]=16218) n[b] (%)	Total (N[a]=32279) n[b] (%)

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 06NOV2020 (01:29) Source Data: adsl Table Generation: 06NOV2020 (16:35) (Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2 unblinded ia/C4591001 IA 62/adsl demo 7d eval eff

Demographic characteristics for the Dose 2 all-available efficacy population are presented in Supplemental Table 14.298.

10.5.3.4. Evaluable Efficacy Population – Without Evidence of Infection up to 7 Days After Dose 2 – Final Analysis

Demographics of participants in the final analysis evaluable efficacy population for participants without evidence of infection prior to 7 days after Dose 2 were similar in BNT162b2 and placebo groups (Table 18). This analysis population had generally similar demographics compared to the safety population (refer to Section 10.5.3.1).

Table 18. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18242) n[b] (%)	Placebo (N[a]=18379) n[b] (%)	Total (N[a]=36621) n[b] (%)
Sex			
Male	9318 (51.1)	9225 (50.2)	18543 (50.6)
Female	8924 (48.9)	9154 (49.8)	18078 (49.4)
Race			
White	15110 (82.8)	15301 (83.3)	30411 (83.0)
Black or African American	1617 (8.9)	1617 (8.8)	3234 (8.8)
American Indian or Alaska native	118 (0.6)	106 (0.6)	224 (0.6)

Table 18. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18242) n[b] (%)	Placebo (N[a]=18379) n[b] (%)	Total (N[a]=36621) n[b] (%)
Asian	815 (4.5)	810 (4.4)	1625 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)	77 (0.2)
Multiracial	448 (2.5)	402 (2.2)	850 (2.3)
Not reported	86 (0.5)	114 (0.6)	200 (0.5)
Ethnicity			
Hispanic/Latino	4886 (26.8)	4857 (26.4)	9743 (26.6)
Non-Hispanic/non-Latino	13253 (72.7)	13412 (73.0)	26665 (72.8)
Not reported	103 (0.6)	110 (0.6)	213 (0.6)
Country			
Argentina	2561 (14.0)	2539 (13.8)	5100 (13.9)
Brazil	1232 (6.8)	1223 (6.7)	2455 (6.7)
Germany	121 (0.7)	126 (0.7)	247 (0.7)
South Africa	287 (1.6)	279 (1.5)	566 (1.5)
USA	14041 (77.0)	14212 (77.3)	28253 (77.1)
Age group			
12-15 Years	46 (0.3)	42 (0.2)	88 (0.2)
16-55 Years	10428 (57.2)	10507 (57.2)	20935 (57.2)
>55 Years	7768 (42.6)	7830 (42.6)	15598 (42.6)
≥65 Years	3980 (21.8)	4038 (22.0)	8018 (21.9)
Age at vaccination (years)			
Mean (SD)	50.6 (15.70)	50.4 (15.81)	50.5 (15.76)
Median	52.0	52.0	52.0
Min, max	(12, 89)	(12, 91)	(12, 91)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo 7d eval eff

Demographic characteristics for the final analysis Dose 2 all-available efficacy population and the evaluable population without evidence of infection prior to 14 days after Dose 2 were similar to the Dose 2 evaluable efficacy (7 days) population (Supplemental Tables 14.299 and 14.300).

Demographic characteristics are presented in the additional following tables:

Dose 1 All-Available Efficacy Population	Supplemental Table 14.301
Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 –Evaluable Efficacy (7 Days) Population	Supplemental Table 14.302
Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population	Supplemental Table 14.303
Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population	Supplemental Table 14.304

10.6. Participant Compliance

10.6.1. Immunogenicity Blood Samples

10.6.1.1. Phase 1

Most participants in any dose group had immunogenicity blood samples taken within the protocol specified time frames, and results are presented in the following tables:

18-55 Years of Age – BNT162b1	Supplemental Table 14.54
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.55
65-85 Years of Age – BNT162b1	Supplemental Table 14.56
18-55 Years of Age – BNT162b2	Supplemental Table 14.57
65-85 Years of Age – BNT162b2	Supplemental Table 14.58

Two participants who received BNT162b2 were excluded from the Dose 2 evaluable immunogenicity population because blood sample collection did not occur within 6 to 8 days after Dose 2 (Section 10.4.1). The participant in the younger age group (30-µg dose group) had blood drawn at <6 days (Supplemental Table 14.57). The participant in the older age group (20-µg dose group) had blood drawn at >8 days (Supplemental Table 14.58).

10.6.1.2. Phase 2

Most participants in the vaccine groups had immunogenicity blood samples taken within the protocol specified time frames from 28 to 35 days after Dose 2 (Supplemental Table 14.193).

10.6.1.3. Phase 2/3

Evaluation of the immune response is a secondary (12 to 15 years of age compared with 16 to 25 years of age) and an exploratory objective for the Phase 3 part of the study. Blood samples drawn for immunogenicity testing will be reported at a later time and are not included in this interim CSR.

10.6.2. E-Diary

10.6.2.1. Phase 1

Transmission of e-diary data after either dose of BNT162b1 or placebo was ≥77.8% for each day during the 7 days following any vaccination in the younger age group (Supplemental

Tables 14.59 and 14.60) and older age group (Supplemental Table 14.61), and transmission rates were similar across dose groups in both age groups.

Transmission of e-diary data after either dose of BNT162b2 or placebo was ≥75.0% for each day during the 7 days following any vaccination in the younger and older age groups (Supplemental Tables 14.62 and 14.63, respectively), and transmission rates were similar across dose groups in both age groups.

10.6.2.2. Phase 2

Overall, transmission of e-diary data was ≥91.7% for each day during the 7 days after Dose 1 of BNT162b2. After Dose 2 of BNT162b2, transmission of e-diary data was 80.6% on Day 1 and ranged from 88.9% to 91.7% for each day during Day 2 through Day 7 (Supplemental Table 14.194). Transmission rates were similar in the BNT162b2 group and the placebo group.

10.6.2.3. Phase 2/3

Overall, transmission of e-diary data was ≥90.1% (range: 90.1% to 94.0%) for each day during the 7 days after Dose 1 of BNT162b2. After Dose 2 of BNT162b2, transmission of e-diary data was 76.0% on Day 1 and ranged from 83.3% to 85.1% for each day during Day 2 through Day 7 (Supplemental Table 14.305). Transmission rates were similar in the BNT162b2 group and the placebo group.

10.7. Prior and Concomitant Vaccines, Medications, and Procedures

10.7.1. Phase 1

BNT162b1

There were no participants in the younger age group who received a concomitant vaccine from Dose 1 to 1 month after Dose 2 of BNT162b1. In the older age group, only 1 participant received a concomitant vaccine (Tdap) from Dose 1 to 1 month after Dose 2 of BNT162b1 (Supplemental Table 14.64).

BNT162b2

In both age groups, there were no participants who received any concomitant vaccines from Dose 1 to 1 month after Dose 2 of BNT162b2.

10.7.2. Phase 2

There were no participants in Phase 2 who received any concomitant vaccine after Dose 1.

10.7.3. Phase 2/3

10.7.3.1. Participants with Median 2 Months of Follow-Up After Dose 2– Safety Population – Phase 2/3

A small percentage of participants in either group (≤10.7%) received any concomitant vaccine after Dose 1, and most concomitant vaccines received were the influenza vaccine (Supplemental Table 14.306).

10.7.3.2. All Participants – Safety Population

A small percentage of participants in either group (≤9.3%) received any concomitant vaccine after Dose 1, and most concomitant vaccines received were the influenza vaccine (Supplemental Table 14.307).

11. EFFICACY AND IMMUNOGENICITY EVALUATION

11.1. Efficacy Results

11.1.1. Interim Analysis 1

Vaccine efficacy of BNT162b2 against COVID-19 among participants without evidence of past SARS-CoV-2 infection was demonstrated at the first interim analysis conducted after accrual of at least 62 cases following the protocol and SAP. The primary efficacy results presented in this section are from that interim analysis.

Only the vaccine efficacy of BNT162b2 for the first primary efficacy endpoint (COVID-19 incidence based on central laboratory or locally confirmed NAAT in participants without serological or virological evidence of past SARS-CoV-2 infection before and during vaccination regimen) is analyzed and presented at this interim analysis. The vaccine efficacy from the second primary efficacy endpoint and the secondary efficacy endpoints are analyzed and presented in the final analysis (refer to Section 11.1.2).

11.1.1.1. First Primary Efficacy Endpoint – Interim Analysis 1

For the first primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in this evaluation for VE. Cases were counted from 7 days after Dose 2.

Among participants included in the evaluable efficacy population, 32,279 participants (16,061 in BNT162b2 group and 16,218 in placebo group) did not have evidence of infection with SARS-CoV-2 before and during vaccination regimen (Table 17). There were 4 COVID-19 cases in the BNT162b2 group compared to 90 COVID-19 cases reported in the placebo group. These data give an estimated vaccine efficacy of 95.5% for BNT162b2. The posterior probability of >99.99% met the prespecified interim analysis success criterion of > 99.5% (Table 19). The 95% credible interval for the vaccine efficacy was 88.8% to 98.4%, indicating that given the current observed data there is a 95% probability that the true VE lies in this interval. Also, note that the posterior probability that true VE > 86.0% is 99.5% and VE > 88.8% is 97.5%.

Table 19. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	4	1.722 (15899)	90	1.732 (16010)	95.5	(88.8, 98.4)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
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. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details. This probability must be at least 99.5% at the interim analysis in order to conclude that the vaccine is efficacious.
PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:48) Source Data: adc19ef Table Generation: 09NOV2020 (16:43)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File:
./nda2 unblinded ia/C4591001 IA 62/adc19ef ve cov 7pd2 wo eval

The vaccine efficacy of BNT162b2 for the same primary efficacy endpoint based on the all-available efficacy population was 95.7%, with 4 and 93 cases in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.308).

No clinically meaningful differences in VE by subgroup were observed by age group, country, ethnicity, sex, or race in the in the Dose 2 evaluable efficacy population, with VE estimates that ranged from 91.2% to 100.0% (Table 20).

Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)			
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	4	1.722 (15899)	90	1.732 (16010)	95.5	(88.1, 98.8)
Age group (years)						
16 to 55	2	0.954 (8994)	67	0.959 (9040)	97.0	(88.7, 99.6)
>55	2	0.767 (6905)	23	0.773 (6970)	91.2	(64.6, 99.0)
Sex						
Male	2	0.874 (8115)	38	0.865 (8029)	94.8	(79.8, 99.4)
Female	2	0.848 (7784)	52	0.867 (7981)	96.1	(85.1, 99.5)
Race						
White	4	1.477 (13399)	85	1.491 (13530)	95.3	(87.4, 98.7)
Black or African American	0	0.124 (1263)	4	0.124 (1277)	100.0	(-51.8, 100.0)
All others[f]	0	0.121 (1237)	1	0.118 (1203)	100.0	(-3690.1, 100.0)
Ethnicity						
Hispanic/Latino	1	0.464 (4389)	34	0.459 (4342)	97.1	(82.7, 99.9)
Non-Hispanic/non-Latino	3	1.247 (11418)	56	1.262 (11570)	94.6	(83.3, 98.9)
Country						
Argentina	0	0.271 (2436)	28	0.266 (2402)	100.0	(86.2, 100.0)
Brazil	0	0.087 (878)	2	0.087 (879)	100.0	(-432.5, 100.0)
USA	4	1.360 (12384)	60	1.376 (12530)	93.3	(81.8, 98.2)

Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)			
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 at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
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 to the surveillance time.
f. American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, not reported race categories are presented as "All others".
PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:53) Source Data: adc19ef Table Generation: 09NOV2020 (16:43)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2_unblinded_ia/C4591001_IA_62/adc19ef_ve_cov_7pd2_wo_sg_eval

Vaccine efficacy results by subgroup based on the Dose 2 all-available efficacy population are presented in Supplemental Table 14.309.

11.1.1.2. COVID-19 Narratives - Interim Analysis 1

Narratives of COVID-19 cases are provided in Section 14.

11.1.1.3. Severe COVID-19 Cases - Interim Analysis 1

Severe COVID-19 cases were reported in a total of 7 participants in Phase 3 interim analysis of 94 COVID-19 cases, all in the placebo group, as of the data cutoff date of 04 November 2020 (Table 21). Five of these cases were reported between Dose 1 and Dose 2, none were reported less than 7 days after Dose 2, and 2 cases were reported at least 7 days after Dose 2 (Appendix 16.2.8.3.1).

Table 21. Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=21617)	Placebo (N[a]=21633)
Efficacy Endpoint	n[b]	n[b]
Severe COVID-19 occurrence after Dose 1	0	7

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:48) Source Data: adc19ef Table Generation: 06NOV2020 (18:47)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File:
./nda2 unblinded ia/C4591001 IA 62/adc19ef sev cov d1 aai

11.1.1.4. Efficacy Conclusions - Interim Analysis 1

- The first primary efficacy objective met success criteria. BNT162b2 achieved vaccine efficacy of 95.5% with a 95% credible interval of 88.8% to 98.4% among participants without evidence of infection before and during vaccination regimen, and a >99.99% posterior probability for the true vaccine efficacy greater than 30% conditioning on available data.

- All 7 severe COVID-19 cases (after Dose 1) were observed in the placebo group, as of the interim analysis cutoff date.

11.1.2. Final Analysis

Efficacy data for the Phase 3 portion of Study C4591001 were analyzed for all enrolled participants who met the protocol-specified criteria for efficacy evaluation, with a final analysis cutoff date of 14 November 2020. Signs and symptoms of COVID-19 are presented first followed by efficacy results.

11.1.2.1. Signs and Symptoms of COVID-19

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

The signs and symptoms reported for cases contributing to the analysis for the first primary efficacy endpoint are summarized in Table 22. These include cases occurring at least 7 days after the second vaccination among participants in the evaluable efficacy population who had no evidence of SARS-CoV-2 infection before or during the vaccination regimen: 8 cases in the BNT162b2 group and 162 cases in the placebo group. Most of these participants reported new or increased cough, and other symptoms reported most frequently were new or increased

muscle pain, fever, and sore throat. New or increased shortness of breath was reported for 25 participants (15.4%) in the placebo group and for no participants who received BNT162b2. Most participants reported 2 or more symptoms consistent with COVID-19. Similar results were reported among cases in the evaluable efficacy population with or without evidence of SARS-CoV-2 infection before or during the vaccination regimen (Table 23).

Table 22. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=162)	Total (N[a]=170)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	76 (46.9)	78 (45.9)
New or increased cough	3 (37.5)	114 (70.4)	117 (68.8)
New or increased shortness of breath	0 (0.0)	25 (15.4)	25 (14.7)
Chills	2 (25.0)	57 (35.2)	59 (34.7)
New or increased muscle pain	1 (12.5)	81 (50.0)	82 (48.2)
New loss of taste or smell	5 (62.5)	43 (26.5)	48 (28.2)
Sore throat	3 (37.5)	68 (42.0)	71 (41.8)
Diarrhea	1 (12.5)	18 (11.1)	19 (11.2)
Vomiting	2 (25.0)	6 (3.7)	8 (4.7)
Subjects with specific number of signs and symptoms			
1	1 (12.5)	24 (14.8)	25 (14.7)
2	3 (37.5)	46 (28.4)	49 (28.8)
3	4 (50.0)	34 (21.0)	38 (22.4)
4	0 (0.0)	33 (20.4)	33 (19.4)
5	0 (0.0)	16 (9.9)	16 (9.4)
>5	0 (0.0)	9 (5.6)	9 (5.3)

Table 22. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=162)	Total (N[a]=170)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 wo eval

Table 23. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=9)	Placebo (N[a]=169)	Total (N[a]=178)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (22.2)	77 (45.6)	79 (44.4)
New or increased cough	3 (33.3)	120 (71.0)	123 (69.1)
New or increased shortness of breath	0 (0.0)	26 (15.4)	26 (14.6)
Chills	2 (22.2)	58 (34.3)	60 (33.7)
New or increased muscle pain	1 (11.1)	82 (48.5)	83 (46.6)
New loss of taste or smell	5 (55.6)	46 (27.2)	51 (28.7)
Sore throat	4 (44.4)	71 (42.0)	75 (42.1)
Diarrhea	1 (11.1)	19 (11.2)	20 (11.2)
Vomiting	2 (22.2)	6 (3.6)	8 (4.5)
Subjects with specific number of signs and symptoms			

Table 23. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=9)	Placebo (N[a]=169)	Total (N[a]=178)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
1	2 (22.2)	24 (14.2)	26 (14.6)
2	3 (33.3)	50 (29.6)	53 (29.8)
3	4 (44.4)	37 (21.9)	41 (23.0)
4	0 (0.0)	33 (19.5)	33 (18.5)
5	0 (0.0)	16 (9.5)	16 (9.0)
>5	0 (0.0)	9 (5.3)	9 (5.1)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_7d2_eval

Table 24 summarizes the signs and symptoms for all cases of COVID-19 occurring at any time after Dose 1 (50 cases in the BNT162b2 group and 275 cases in the placebo group). Most participants reported 2 or more symptoms, and the most frequently reported symptoms were similar to those for the primary efficacy analysis population.

Table 24. Summary of Signs and Symptoms for COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=50)	Placebo (N[a]=275)	Total (N[a]=325)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	20 (40.0)	122 (44.4)	142 (43.7)
New or increased cough	22 (44.0)	186 (67.6)	208 (64.0)
New or increased shortness of breath	4 (8.0)	44 (16.0)	48 (14.8)
Chills	10 (20.0)	86 (31.3)	96 (29.5)
New or increased muscle pain	12 (24.0)	121 (44.0)	133 (40.9)

Table 24. Summary of Signs and Symptoms for COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=50)	Placebo (N[a]=275)	Total (N[a]=325)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
New loss of taste or smell	24 (48.0)	91 (33.1)	115 (35.4)
Sore throat	18 (36.0)	111 (40.4)	129 (39.7)
Diarrhea	4 (8.0)	35 (12.7)	39 (12.0)
Vomiting	5 (10.0)	11 (4.0)	16 (4.9)
Subjects with specific number of signs and symptoms			
1	16 (32.0)	44 (16.0)	60 (18.5)
2	14 (28.0)	82 (29.8)	96 (29.5)
3	11 (22.0)	63 (22.9)	74 (22.8)
4	5 (10.0)	40 (14.5)	45 (13.8)
5	2 (4.0)	31 (11.3)	33 (10.2)
>5	2 (4.0)	15 (5.5)	17 (5.2)

a. N = number of subjects with COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_d1_aai

Four cases of severe COVID-19 occurred at least 7 days after the second vaccination among participants in the evaluable efficacy population without (Table 25) and with or without (Supplemental Table 14.310) evidence of SARS-CoV-2 infection before or during the vaccination regimen: 1 case in the BNT162b2 group and 3 cases in the placebo group. All 4 cases experienced clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg); respiratory failure and admission to an ICU were each reported for 1 participant in the placebo group.

Table 25. Summary of Signs and Symptoms for Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=3)	Total (N[a]=4)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	3 (100.0)	4 (100.0)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	1 (33.3)	1 (25.0)
Admission to an ICU	0 (0.0)	1 (33.3)	1 (25.0)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	2 (66.7)	3 (75.0)
3	0 (0.0)	1 (33.3)	1 (25.0)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate; ICU = intensive care unit; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with severe COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:49)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp sev cov 7d2 wo eval

Ten cases of severe COVID-19 occurred at any time after Dose 1: one case in the BNT162b2 group and 9 cases in the placebo group. All 10 cases experienced clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg); respiratory failure and admission to an ICU were each reported for 3 participants (33.3%) in the placebo group (Table 26).

Table 26. Summary of Signs and Symptoms for Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=9)	Total (N[a]=10)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	9 (100.0)	10 (100.0)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	3 (33.3)	3 (30.0)
Significant acute renal, hepatic, or neurologic dysfunction	0 (0.0)	1 (11.1)	1 (10.0)
Admission to an ICU	0 (0.0)	3 (33.3)	3 (30.0)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	5 (55.6)	6 (60.0)
2	0 (0.0)	2 (22.2)	2 (20.0)
3	0 (0.0)	1 (11.1)	1 (10.0)
5	0 (0.0)	1 (11.1)	1 (10.0)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate; ICU = intensive care unit; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.
a. N = number of subjects with severe COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:49)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp sev cov d1 aai

Signs and symptoms of COVID-19 frequency distributions were similar when analyzed by efficacy population (Dose 2 evaluable; Dose 1 and Dose 2 all-available), occurrence of COVID-19 after Dose 2 (7 days; 14 days), prior infection (without; with or without); age (12-15, 16-55; >55; ≥65 years); case definition (severe; CDC). Summary tables for signs and symptoms of COVID-19 are found in Supplemental Tables 14.311 to 14.351.

11.1.2.2. Primary Efficacy Endpoints – Final Analysis

For the first primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Cases were counted from 7 days after Dose 2. For the second primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in

participants with and without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Cases were counted from 7 days after Dose 2.

Secondary efficacy endpoints evaluated confirmed COVID-19 cases in participants either without or with and without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Cases were counted from 7 days after Dose 2 or from 14 days after Dose 2. Secondary efficacy endpoints are described in Table 2.

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

As noted above, overwhelming efficacy was declared at the first (and only) interim analysis for the first primary efficacy endpoint. A descriptive update based on 170 evaluable cases accrued at the time of the final analysis (of the other efficacy endpoints) is summarized below.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%, with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group (Table 27). The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%, indicating that the true VE is at least 90.3% with a 97.5% probability given the observed data.

The vaccine efficacy of BNT162b2 for the same primary efficacy endpoint based on the Dose 2 all-available efficacy population was 95.2%, with 8 and 165 cases in the BNT162b2 and placebo group (Table 28).

Table 27. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.3, 97.6)	>0.9999

Table 27. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]

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. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_wo_eval

Table 28. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18650)		Placebo (N[a]=18570)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	8	2.266 (17852)	165	2.244 (17746)	95.2	(90.6, 97.7)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_wo_aai

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

For the second primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants with or without evidence of prior SARS-CoV-2 infection through 7 days after Dose 2. Cases were counted from 7 days after Dose 2.

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%, indicating that the true VE is at least 89.9% with a 97.5% probability given the available data (Table 29). Note that with a posterior probability of 98.6%, the true vaccine efficacy is at least 89.2% given the available data.

The vaccine efficacy of BNT162b2 for the same primary efficacy endpoint based on the Dose 2 all-available efficacy population was 94.8%, with and 9 and 172 cases in the BNT162b2 and placebo group, respectively (Table 30).

Table 29. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First COVID-19 occurrence from 7 days after Dose 2	9	2.332 (18559)	169	2.345 (18708)	94.6	(89.9, 97.3)	>0.9999

Abbreviations: 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. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 eval

Table 30. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First COVID-19 occurrence from 7 days after Dose 2	9	2.389 (19049)	172	2.370 (18971)	94.8	(90.2, 97.4)	>0.9999

Table 30. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]

Abbreviations: 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. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_aai

11.1.2.2.3. All Confirmed Cases of COVID-19 After Dose 1

A number of confirmed cases of COVID-19 are not captured in the analyses of the first primary endpoint for the evaluable efficacy population because they occurred less than 7 days after Dose 2, or because they occurred in participants who were excluded from the evaluable efficacy population or who had evidence of infection before or during the vaccination regimen.

All reports of COVID-19 with onset at any time after Dose 1 are accounted for in Table 31, which provides a summary of cases for all participants in the Dose 1 all-available efficacy (modified intention-to-treat) population, regardless of evidence of infection before or during the vaccination regimen. Among these participants, 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 275 cases in the placebo group (Table 31). Notably, in the BNT162b2 group, most cases occurred before Dose 2. The estimated VE against confirmed COVID-19 occurring after Dose 1 was 82% (2-sided 95% CI: 75.6 %, 86.9%), with an estimated VE of 52.4% (2-sided 95% CI: 29.5%, 68.4%) against confirmed COVID-19 occurring after Dose 1 but before Dose 2.

Table 31. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
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	50	4.015 (21314)	275	3.982 (21258)	82.0	(75.6, 86.9)
After Dose 1 to before Dose 2	39		82		52.4	(29.5, 68.4)
Dose 2 to 7 days after Dose 2	2		21		90.5	(61.0, 98.9)
≥7 Days after Dose 2	9		172		94.8	(89.8, 97.6)

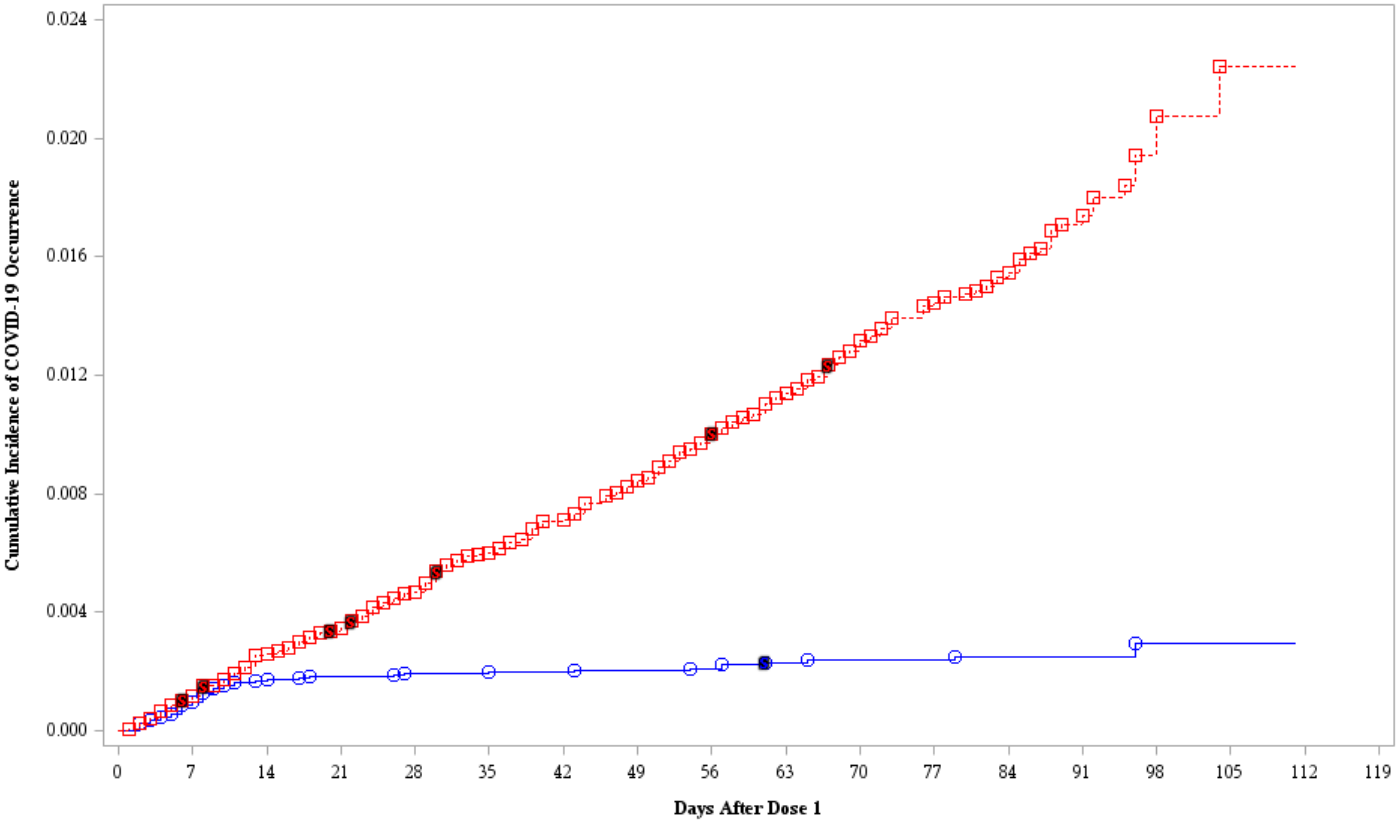
Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (17:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_pd1_aai

The early onset of protection is readily apparent in Figure 3, 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 14 days after Dose 1, at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat in the BNT162b2 group. The darker-appearing symbols for both BNT162b2 (blue circles) and placebo (red squares) curves in Figure 3 have an "S" written inside the open symbol, which denotes severe cases; note that 2 cases in the placebo group are "overlapping" relative to the placebo curve within the first 14 days. See Section 11.1.2.3.2 for more details on severe cases reported in the final analysis.

Cumulative incidence curves for the evaluable efficacy (7 days) population are presented in the following figures:

First COVID-19 Occurrence From 7 Days After Dose 2 - Subjects Without Evidence of Infection Prior to 7 Days After Dose 2	Supplemental Figure 14.27
First COVID-19 Occurrence From 7 Days After Dose 2 - Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2	Supplemental Figure 14.28

Figure 3. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population



Note: "S" indicates subjects with severe COVID-19 or COVID-19 leading to hospitalization.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adc19ef Table Generation: 17NOV2020 (21:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_f001_km_d1_aai

11.1.2.2.4. Vaccine Efficacy by Subgroup – Final Analysis

11.1.2.2.4.1. Subgroups of Age, Sex, Race/Ethnicity, and Country

For both primary endpoints, VE was also evaluated for subgroups of participants by age, sex race/ethnicity, and country in Table 32 (without evidence of prior infection) and Table 33 (with or without evidence of prior infection).

Among participants without prior evidence of SARS-CoV-2 infection before and during vaccination regimen, VE was >93% in all subgroups, with the exception of "all others" race group (89.3% VE) and Brazil (87.7% VE) (Table 32). Notably, VE was 94.7% (2-sided 95% CI: 66.7%, 99.9%) in participants ≥65 years of age (Table 32), and observed VE in participants ≥75 years of age was 100% (0 vs 5 cases in the BNT162b2 group vs the placebo group; 2-sided 95% CI: -13.1%, 100.0%) (Table 34).

Among participants with or without prior evidence of SARS-CoV-2 infection before and during vaccination regimen, VE was >93% in all subgroups, with the exception of "all others" race group (78.2% VE), Brazil (75.4% VE), and positive prior SARS-CoV-2 infection at baseline (-7.1% VE, 1 case in each BNT162 and placebo groups) (Table 33).

Results for the all-available population were similar; no clinically meaningful differences were observed in VE on the basis of subgroup. These data are presented in in the following tables:

First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup - Subjects Without Evidence of Infection Prior to 7 Days After Dose 2	Supplemental Table 14.352
First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup - Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2	Supplemental Table 14.353

Table 32. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
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						

Table 32. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Age group (years)						
16 to 55	5	1.234 (9897)	114	1.239 (9955)	95.6	(89.4, 98.6)
>55	3	0.980 (7500)	48	0.983 (7543)	93.7	(80.6, 98.8)
≥65	1	0.508 (3848)	19	0.511 (3880)	94.7	(66.7, 99.9)
Sex						
Male	3	1.124 (8875)	81	1.108 (8762)	96.4	(88.9, 99.3)
Female	5	1.090 (8536)	81	1.114 (8749)	93.7	(84.7, 98.0)
Race						
White	7	1.889 (14504)	146	1.903 (14670)	95.2	(89.8, 98.1)
Black or African American	0	0.165 (1502)	7	0.164 (1486)	100.0	(31.2, 100.0)
All others[f]	1	0.160 (1405)	9	0.155 (1355)	89.3	(22.6, 99.8)
Ethnicity						
Hispanic/Latino	3	0.605 (4764)	53	0.600 (4746)	94.4	(82.7, 98.9)
Non-Hispanic/non-Latino	5	1.596 (12548)	109	1.608 (12661)	95.4	(88.9, 98.5)
Country						
Argentina	1	0.351 (2545)	35	0.346 (2521)	97.2	(83.3, 99.9)
Brazil	1	0.119 (1129)	8	0.117 (1121)	87.7	(8.1, 99.7)
USA	6	1.732 (13359)	119	1.747 (13506)	94.9	(88.6, 98.2)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:55)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 wo sg eval

Table 33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
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	9	2.332 (18559)	169	2.345 (18708)	94.6	(89.6, 97.6)
Age group (years)						
16 to 55	6	1.309 (10653)	120	1.317 (10738)	95.0	(88.7, 98.2)
>55	3	1.022 (7892)	49	1.028 (7956)	93.8	(80.9, 98.8)
≥65	1	0.530 (4044)	19	0.532 (4067)	94.7	(66.8, 99.9)
Sex						
Male	4	1.183 (9457)	85	1.170 (9342)	95.3	(87.6, 98.8)
Female	5	1.149 (9102)	84	1.176 (9366)	93.9	(85.2, 98.1)
Race						
White	7	1.975 (15294)	153	1.990 (15473)	95.4	(90.3, 98.2)
Black or African American	0	0.187 (1758)	7	0.188 (1758)	100.0	(30.4, 100.0)
All others[f]	2	0.170 (1507)	9	0.167 (1477)	78.2	(-5.4, 97.7)
Ethnicity						
Hispanic/Latino	3	0.637 (5074)	55	0.638 (5090)	94.5	(83.2, 98.9)
Non-Hispanic/non-Latino	6	1.681 (13380)	114	1.693 (13509)	94.7	(88.1, 98.1)
Country						
Argentina	1	0.366 (2664)	36	0.367 (2684)	97.2	(83.5, 99.9)
Brazil	2	0.134 (1274)	8	0.132 (1257)	75.4	(-23.5, 97.5)
USA	6	1.816 (14141)	124	1.830 (14287)	95.1	(89.1, 98.2)
South Africa	0	0.015 (362)	1	0.015 (363)	100.0	(-3818.9, 100.0)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	1	0.056 (526)	1	0.060 (567)	-7.1	(-8309.9, 98.6)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.003 (27)	1	0.004 (34)	100.0	(-6004.9, 100.0)
Negative prior to 7 days after Dose 2[i]	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Unknown	0	0.059 (595)	5	0.060 (596)	100.0	(-9.6, 100.0)

Table 33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:55)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_sg_eval

Table 34. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
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						

Table 34. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Age group (years)						
12 to 15	0	0.000 (14)	0	0.000 (13)	NE	(NE, NE)
16 to 17	0	0.002 (52)	0	0.003 (55)	NE	(NE, NE)
18 to 64	7	1.703 (13497)	143	1.708 (13563)	95.1	(89.6, 98.1)
65 to 74	1	0.406 (3074)	14	0.406 (3095)	92.9	(53.1, 99.8)
≥75	0	0.102 (774)	5	0.106 (785)	100.0	(-13.1, 100.0)
Race						
White	7	1.889 (14504)	146	1.903 (14670)	95.2	(89.8, 98.1)
Black or African American	0	0.165 (1502)	7	0.164 (1486)	100.0	(31.2, 100.0)
American Indian or Alaska native	0	0.011 (100)	1	0.010 (96)	100.0	(-3429.0, 100.0)
Asian	1	0.092 (764)	4	0.093 (769)	74.6	(-156.6, 99.5)
Native Hawaiian or other Pacific Islander	0	0.006 (46)	1	0.003 (29)	100.0	(-2266.9, 100.0)
Multiracial	0	0.042 (414)	1	0.036 (359)	100.0	(-3231.3, 100.0)
Not reported	0	0.010 (81)	2	0.012 (102)	100.0	(-563.3, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 23NOV2020 (16:38)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 EUA FAEF RR/adc19ef ve cov 7pd2 worq sg eval

11.1.2.2.4.2. Subgroups of Risk Status

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

Post hoc analyses of efficacy by risk status were performed. For these analyses, at-risk participants were defined as those who had at least one Charlson Comorbidity Index condition or who were obese (defined as BMI ≥30 kg/m^2). For a summary of Charlson comorbidities among all participants at study entry, see Supplemental Table 14.295.

Among participants without prior evidence of SARS-CoV-2 infection before and during vaccination regimen,VE for participants at risk was 95.3%, as compared with 94.7% for those not at risk (Table 35). VE for participants ≥65 years of age and at risk was 91.7%, as compared with 100% for those ≥65 years of age and not at risk. VE was similar in obese (95.4%) and non-obese (94.8%) participants.

Table 35. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
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	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
At risk[f]						
Yes	4	1.025 (8030)	86	1.025 (8029)	95.3	(87.7, 98.8)
No	4	1.189 (9381)	76	1.197 (9482)	94.7	(85.9, 98.6)
Age group (years) and at risk						
16-64 and not at risk	4	0.962 (7671)	69	0.964 (7701)	94.2	(84.4, 98.5)
16-64 and at risk	3	0.744 (5878)	74	0.746 (5917)	95.9	(87.6, 99.2)
≥65 and not at risk	0	0.227 (1701)	7	0.233 (1771)	100.0	(29.0, 100.0)
≥65 and at risk	1	0.281 (2147)	12	0.279 (2109)	91.7	(44.2, 99.8)
Obese[g]						
Yes	3	0.763 (6000)	67	0.782 (6103)	95.4	(86.0, 99.1)
No	5	1.451 (11406)	95	1.439 (11404)	94.8	(87.4, 98.3)
Age group (years) and obese						
16-64 and not obese	4	1.107 (8811)	83	1.101 (8825)	95.2	(87.3, 98.7)

Table 35. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
16-64 and obese	3	0.598 (4734)	60	0.609 (4789)	94.9	(84.4, 99.0)
≥65 and not obese	1	0.343 (2582)	12	0.338 (2567)	91.8	(44.5, 99.8)
≥65 and obese	0	0.165 (1265)	7	0.173 (1313)	100.0	(27.1, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. At risk is defined as having at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2).
g. Obese is defined as BMI ≥30 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 24NOV2020 (17:41)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adc19ef_ve_cov_7pd2_wo_rg_eval

Results for the Dose 1 all-available efficacy population are presented by subgroup in Supplemental Table 14.354.

11.1.2.3. Secondary Efficacy Endpoints – Final Analysis

11.1.2.3.1. Vaccine Efficacy For COVID-19 Occurring ≥14 Days After Dose 2 – Final Analysis

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

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 14 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after

Dose 2 was 94.2%, with 8 and 139 cases in the BNT162b2 and placebo groups, respectively (Table 36). The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 88.7% to 97.2%, indicating that the true VE is at least 88.7% with a 97.5% probability given the available data.

Table 36. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 14 days after Dose 2	8	1.887 (16612)	139	1.893 (16663)	94.2	(88.7, 97.2)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_14pd2_wo_eval

Additional results are presented in the following tables:

Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population	Supplemental Table 14.355
Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 - Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 - Dose 2 All-Available Efficacy Population	Supplemental Table 14.356

Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup - Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 - Dose 2 All-Available Efficacy Population — Supplemental Table 14.357

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

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.4%, with 8 and 144 cases in the BNT162b2 and placebo groups respectively (Table 37). The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.1% to 97.3%, indicating that the true VE is at least 89.1% with a 97.5% probability given the available data.

Table 37. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 14 days after Dose 2	8	1.984 (17645)	144	1.995 (17746)	94.4	(89.1, 97.3)	>0.9999

Abbreviations: 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 eval

Additional results are presented in the following tables:

11.1.2.3.2. Vaccine Efficacy for Severe COVID-19 Cases – Final Analysis

11.1.2.3.2.1. Efficacy Against Severe COVID-19 (≥7 Days After Dose 2)

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

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, the estimated VE against severe COVID-19 occurring at least 7 days after Dose 2 was 66.4%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 38). The posterior probability for the true vaccine efficacy greater than 30% is 74.29%, which did not meet the prespecified success criterion of >98.6% for this endpoint due to the small number of severe cases observed after Dose 2 in the study. Consequently, statistical testing of subsequent secondary endpoints (ie, the additional secondary endpoints related to severe disease with pre-specified control of overall type 1 error) ended. However, descriptive summaries for the additional endpoints are provided.

Table 38. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	2.215 (17411)	3	2.232 (17511)	66.4	(-124.8, 96.3)	0.7429

Table 38. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]

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. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_sev_cov_7pd2_wo_eval

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

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against severe COVID-19 occurring at least 7 days after Dose 2 was 66.3%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 39). The posterior probability for the true vaccine efficacy greater than 30% is 74.19%.

Table 39. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	2.333 (18566)	3	2.358 (18733)	66.3	(-125.5, 96.3)	0.7419

Abbreviations: 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. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve sev cov 7pd2 eval

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

Among participants in the all-available efficacy population, 1 case of severe COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 9 severe COVID-19 cases in the placebo group (Table 40). The estimated VE against severe COVID-19 occurring after Dose 1 was 88.9% (2-sided 95% CI: 20.1%, 99.7%), with an estimated VE of 75.0% (1 case in BNT162b2 and 4 cases in placebo) against severe COVID-19 occurring at least 7 days after Dose 2.

Table 40. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence after Dose 1	1	4.021 (21314)	9	4.006 (21259)	88.9	(20.1, 99.7)
After Dose 1 to before Dose 2	0		4		100.0	(-51.5, 100.0)
Dose 2 to 7 days after Dose 2	0		1		100.0	(-3800.0, 100.0)
≥7 Days after Dose 2	1		4		75.0	(-152.6, 99.5)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (17:43)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve sev cov pd1 aai

11.1.2.3.2.2. Efficacy Against Severe COVID-19 (≥14 Days After Dose 2)

11.1.2.3.2.2.1. Participants Without Evidence of Infection Before and During Vaccination Regimen (14 Days) – Severe

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 14 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, the estimated VE against severe COVID-19 occurring at least 14 days after Dose 2 was 66.4%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 41). The posterior probability for the true vaccine efficacy greater than 30% is 74.32%.

Table 41. Vaccine Efficacy – First Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 14 days after Dose 2	1	1.888 (16612)	3	1.901 (16663)	66.4	(-124.7, 96.3)	0.7432

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 14 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 14 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_sev_cov_14pd2_wo_eval

11.1.2.3.2.2.2. Participants With or Without Evidence of Infection Before and During Vaccination Regimen (14 Days) – Severe

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against severe COVID-19 occurring at least 14 days after Dose 2 was 66.3%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 42). The posterior probability for the true vaccine efficacy greater than 30% is 74.18%.

Table 42. Vaccine Efficacy – First Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 14 days after Dose 2	1	1.985 (17652)	3	2.007 (17792)	66.3	(-125.6, 96.3)	0.7418

Abbreviations: 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve sev cov 14pd2 eval

11.1.2.3.3. Vaccine Efficacy for COVID-19 Cases per CDC Definition – Final Analysis

11.1.2.3.3.1. Efficacy Against COVID-19 Based on CDC-Defined Symptoms (≥7 Days After Dose 2)

11.1.2.3.3.1.1. Participants Without Evidence of Infection Before and During Vaccination Regimen – CDC Defined – 7 Days

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against CDC-defined COVID-19 occurring at least 7 days after Dose 2 was 95.1% (2-sided 95% CI: 90.2%, 97.9%), with 8 and 165 cases in the BNT162b2 and placebo groups, respectively (Table 43).

Table 43. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC-defined symptoms from 7 days after Dose 2	8	2.213 (17399)	165	2.220 (17495)	95.1	(90.2, 97.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 wo cdc eval

11.1.2.3.3.1.2. Participants With or Without Evidence of Infection Before and During Vaccination Regimen – CDC Defined – 7 Days

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against CDC-defined COVID-19 occurring at least 7 days after Dose 2 was 94.7% (2-sided 95% CI: 89.8%, 97.6%), with 9 and 172 cases in the BNT162b2 and placebo groups, respectively (Table 44).

Table 44. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)

Efficacy Endpoint	BNT162b2 (30 µg) (N[a]=19965) n1[b]	BNT162b2 (30 µg) (N[a]=19965) Surveillance Time[c] (n2[d])	Placebo (N[a]=20172) n1[b]	Placebo (N[a]=20172) Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC-defined symptoms from 7 days after Dose 2	9	2.330 (18544)	172	2.343 (18690)	94.7	(89.8, 97.6)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 cdc eval

11.1.2.3.3.2. Efficacy Against COVID-19 Based on CDC-Defined Symptoms (≥14 Days After Dose 2)

Among participants 1) without and 2) with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, observed VE results against CDC-defined COVID-19 occurring at least 14 days after Dose 2 were similar to those occurring at least 7 days after Dose 2.

These data are presented in the following tables:

Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population	Supplemental Table 14.361
Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population)	Supplemental Table 14.362

COVID-9 occurrence after Dose 1 based on CDC-defined symptoms is presented in Supplemental Table 14.363.

11.1.2.4. Efficacy Conclusions – Final Analysis

Evaluable Efficacy Population

In the final efficacy analysis, among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%, with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group. The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%.

For the second primary endpoint, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 in participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%.

Observed VE was very high for the first primary efficacy endpoint across subgroups of age, sex, race/ethnicity, and country, as VE was >93% in all subgroups, with the exception of "all others" race group (89.3% VE) and Brazil (87.7% VE).

For the secondary efficacy endpoints, observed VE against confirmed COVID-19 occurring at least 14 days after Dose 2 in participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, was 94.2%, with 8 and 139 cases in the BNT162b2 and placebo groups, respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 88.7% to 97.2%.

Similarly, among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.4%, with 8 and 144 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.1% to 97.3%.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, observed VE of 66.3% against severe COVID-19 occurring at least 7 days after Dose 2 did not meet the prespecified success criterion of the posterior probability >98.6%, due to the small number of severe cases (1 in the BNT162b2 group, 3 in the placebo group) observed within the prespecified timeframe of ≥7 days after Dose 2 in the study.

The efficacy analyses using CDC defined symptoms to identify a COVID-19 case gave similar efficacy results as the primary endpoints.

All-Available Efficacy Population

The early onset of protection is readily apparent from cumulative incidence curves, which show that disease onset tracks conjointly for BNT162b2 and placebo until approximately

14 days after Dose 1, at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat after BNT162b2.

Among all participants (regardless of evidence of infection before or during the vaccination regimen) 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared with 275 cases in the placebo group, indicating an estimated VE of 82% (2-sided 95% CI: 75.6%, 86.9%) against confirmed COVID-19 occurring after Dose 1, with VE of 52.4% (95% CI: 29.5%, 68.4%) between Dose 1 and Dose 2.

Among the total of 10 severe COVID-19 cases observed after Dose 1, only 1 severe case was seen in BNT162b2 recipients compared to 9 severe COVID-19 cases in placebo recipients; these results, as well as case splits between Dose 1 and Dose 2 and after Dose 2, were consistent with overall efficacy seen against COVID-19.

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

11.2. Immunogenicity Results

11.2.1. Phase 1

This Phase 1 interim CSR presents immunogenicity results for both adult age groups up to 1 month after Dose 2 for the BNT162b1 and BNT162b2 vaccine candidates at the 10-µg, 20-µg, and 30-µg dose levels, and up to 7 weeks after Dose 1 of BNT162b1 at the 100-µg dose level (younger age group only).

Results for the 7 days after Dose 1 time point are only analyzed and presented in the younger age group (18 to 55 years of age) for 10 µg and 30 µg BNT162b1 (Section 9.8).

11.2.1.1. SARS-CoV-2 Neutralizing Titers – Phase 1

11.2.1.1.1. GMTs

Overall, for both the BNT162b1 and the BNT162b2 recipients in both age groups, SARS-CoV-2 50% neutralizing GMTs modestly increased by Day 21 after Dose 1 and were substantially increased 7 days after Dose 2. Generally, GMTs in the older age group tended to be somewhat lower than the GMTs in the younger age group at most time points for both BNT162b1 and BNT162b2 recipients.

BNT162b1

In the younger age group, SARS-CoV-2 50% neutralizing GMTs modestly increased by Day 21 after Dose 1 and were substantially increased 7 days after Dose 2 (Day 28) of BNT162b1, with higher GMTs observed in the 30-µg dose group compared to the 10-µg and 20-µg dose groups (Figure 4 and Supplemental Table 14.65). GMTs increased at 14 days after Dose 2 (Day 35) for all dose groups, and although GMTs decreased at 1 month after Dose 2 (Day 52), the Day 52 GMTs remained substantially higher than those at the earlier time points after Dose 1.

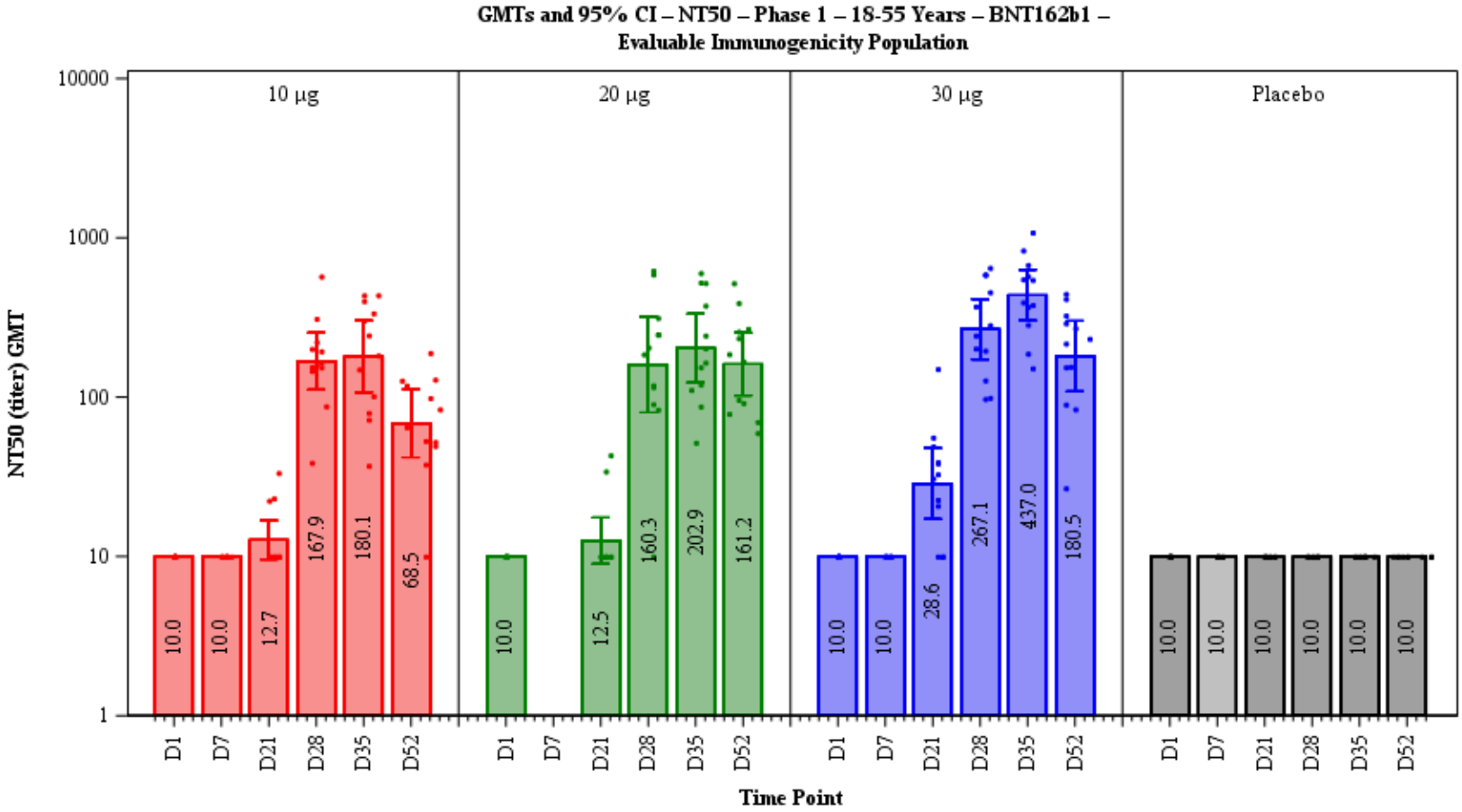
In the 100-µg dose group, SARS-CoV-2 50% neutralizing GMTs modestly increased by Day 21 after Dose 1 of BNT162b1 and decreased to a near baseline value by Day 52 (Supplemental Table 14.66).

Generally similar trends were observed in the older age group, with higher GMTs observed in the 20-µg and 30-µg dose groups of BNT162b1 compared to the 10-µg dose group (Figure 5 and Supplemental Table 14.67).

Similar trends were observed for the SARS-CoV-2 90% neutralizing GMTs:

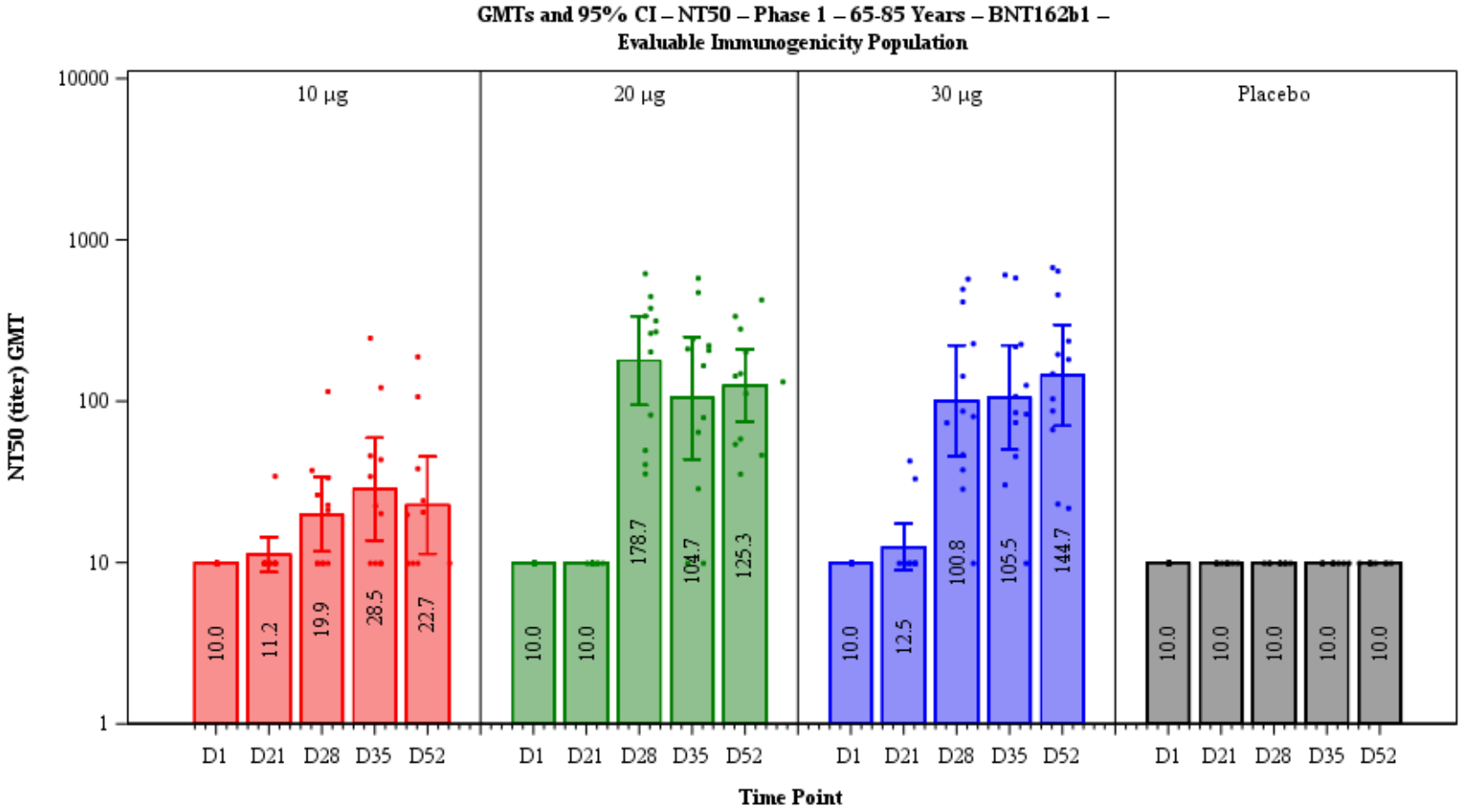
18-55 Years of Age – BNT162b1	Supplemental Table 14.65 and Supplemental Figure 14.1
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.66
65-85 Years of Age – BNT162b1	Supplemental Table 14.67 and Supplemental Figure 14.2

Figure 4. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_18_b1_p1

Figure 5. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: /nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_65_b1_p1

Results for the all-available immunogenicity population in the younger age and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in following tables:

18-55 Years of Age – BNT162b1	Supplemental Table 14.68
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.69
65-85 Years of Age – BNT162b1	Supplemental Table 14.70

RCDCs of SARS-CoV-2 50% and 90% neutralizing titers after BNT162b1 for the younger and older age groups are presented in Supplemental Figures 14.3 through 14.6. The RCDCs show that the majority of participants responded by 7 days after Dose 2 of BNT162b1.

BNT162b2

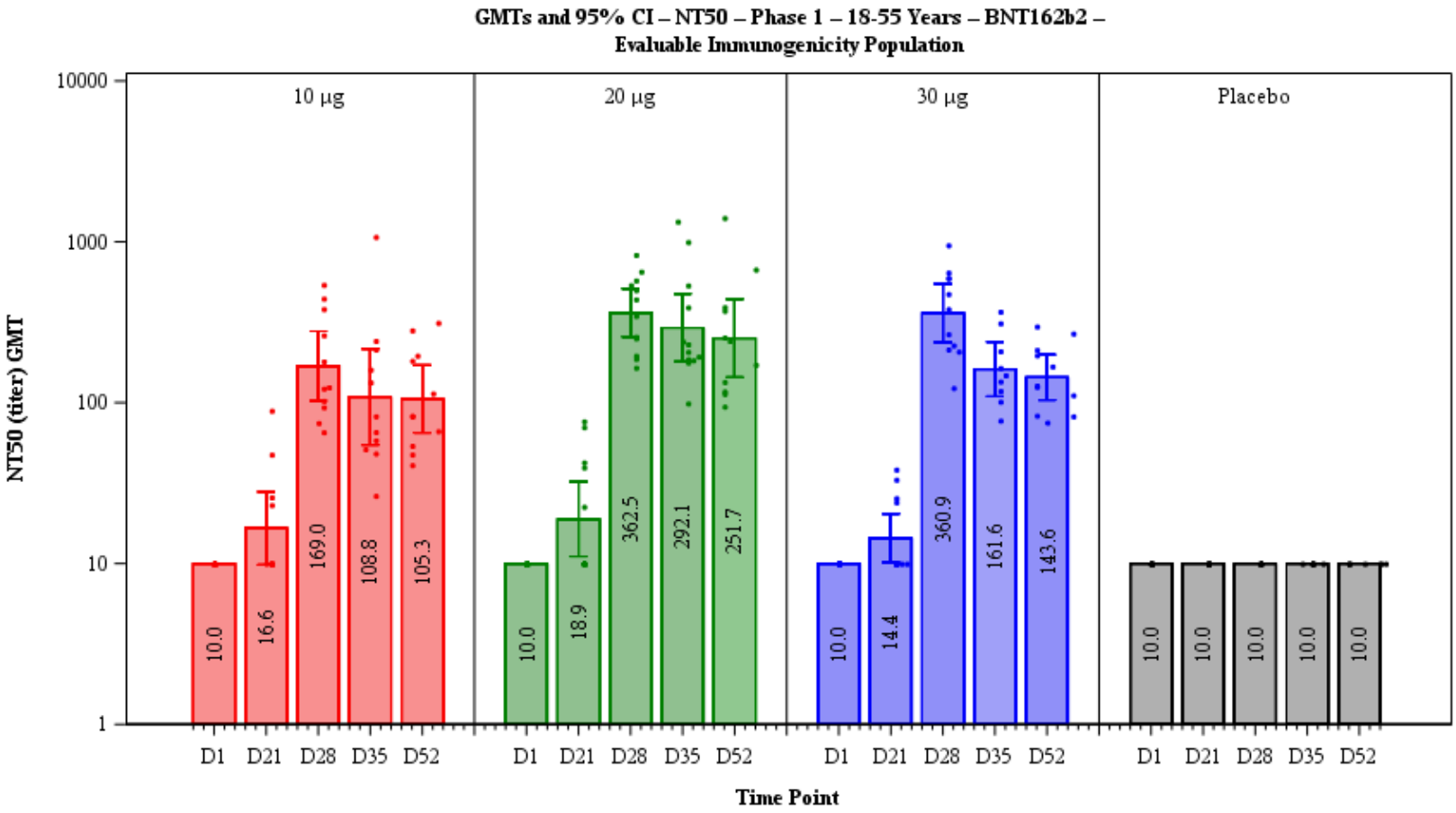
In the younger age group, SARS-CoV-2 50% neutralizing GMTs increased by Day 21 after Dose 1 and were substantially increased 7 days after Dose 2 (Day 28) of BNT162b2, with higher GMTs observed in the 20-µg and 30-µg dose groups compared to the 10-µg dose group (Figure 6 and Supplemental Table 14.71). The GMTs decreased at 14 days after Dose 2 (Day 35) and 1 month after Dose 2 (Day 52) of BNT162b2; however, the GMTs remained substantially higher than those at the earlier time points after Dose 1.

Similar trends were generally observed in the older age group, with higher GMTs observed in the 30-µg dose groups compared to the 20-µg and 10-µg dose groups (Figure 7 and Supplemental Table 14.72). SARS-CoV-2 50% neutralizing GMTs were increased 7 days after Dose 2 and were similar in the 10-µg and 20-µg dose groups and higher in the 30-µg dose group. At 1 month after Dose 2, GMTs remained substantially higher than those at the earlier time points after Dose 1. In the older age group, SARS-CoV-2 50% neutralizing GMTs were generally lower than the GMTs in the younger age group.

Similar trends were observed for the SARS-CoV-2 90% neutralizing GMTs:

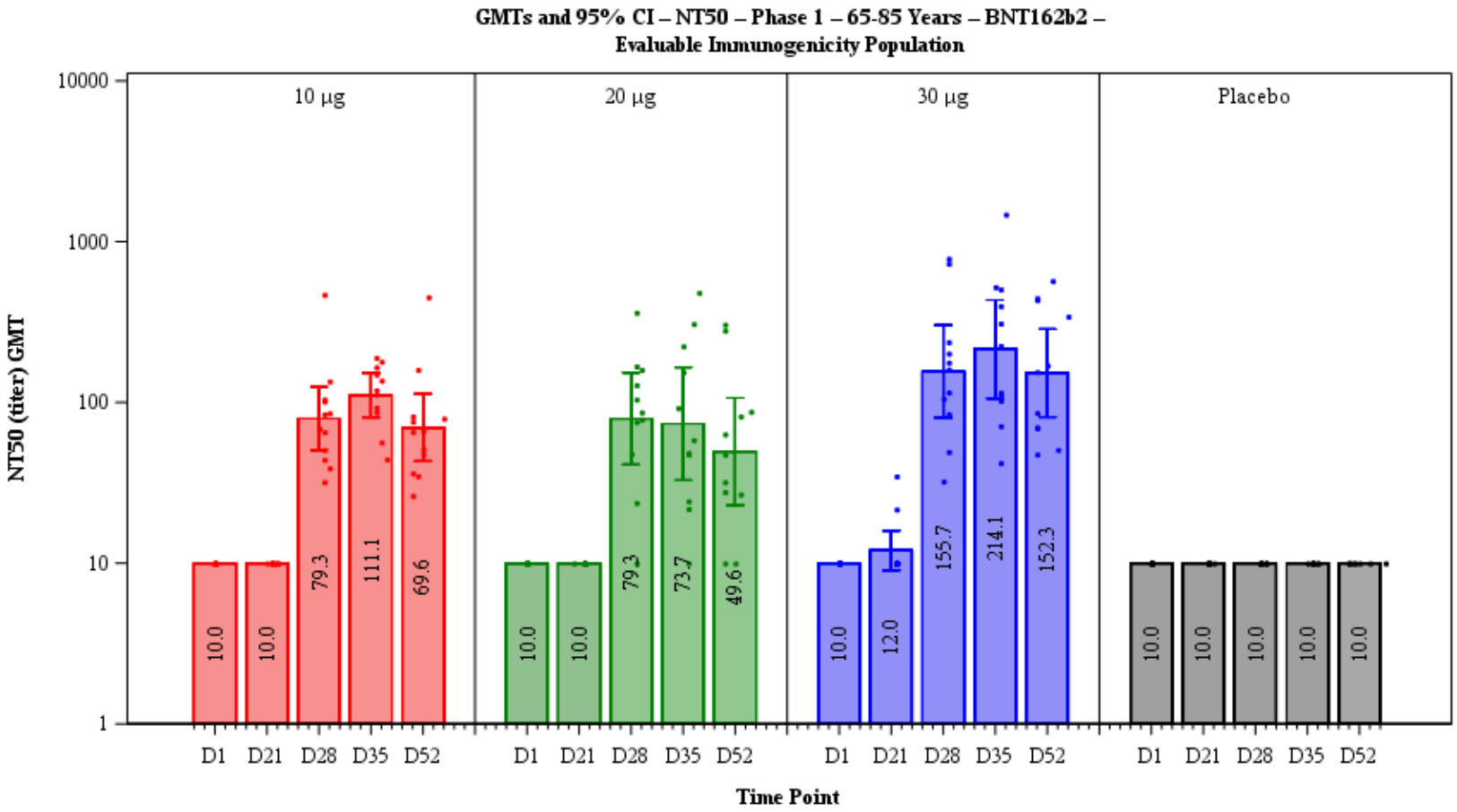
18-55 Years of Age – BNT162b2	Supplemental Table 14.71 and Supplemental Figure 14.7
65-85 Years of Age – BNT162b2	Supplemental Table 14.72 and Supplemental Figure 14.8

Figure 6. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_18_b2_p1

Figure 7. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_65_b2_p1

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in Supplemental Tables 14.73 and 14.74, respectively.

RCDCs of SARS-CoV-2 50% and 90% neutralizing titers for the younger and older age groups are presented in Supplemental Figures 14.9 through 14.12. The RCDCs show that the majority of participants responded by 7 days after Dose 2 of BNT162b2.

11.2.1.1.2. GMFRs

Overall, for both the BNT162b1 and the BNT162b2 recipients, and in both age groups, GMFRs of SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2 (Day 28) were substantially higher compared to the respective GMFRs after Dose 1. GMFRs in the older age group were generally lower than the those in the younger age group for both BNT162b1 and BNT162b2 recipients.

BNT162b1

In the younger age group, GMFRs of SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2 (Day 28) of BNT162b1 were substantially high compared to GMFRs at earlier time points after Dose 1 of BNT162b1 in all dose groups, with GMFRs being highest in the 30-µg dose group (Supplemental Table 14.75). At 1 month after Dose 2, the GMFRs remained higher than those at the earlier time points after Dose 1.

In the 100-µg dose group, the GMFRs of SARS-CoV-2 50% neutralizing titers were not substantially increased through Day 52 after Dose 1 of BNT162b1 (Supplemental Table 14.76).

In the older age group, GMFRs of SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2 (Day 28) of BNT162b1 were substantially high compared to GMFRs at the earlier time point after Dose 1 of BNT162b1 in the 20-µg and 30-µg dose groups with GMFRs being highest in the 20-µg dose group (Supplemental Table 14.77). The GMFRs remained high in the 20-µg and 30-µg dose groups at 1 month after Dose 2 (Day 52) of BNT162b1 compared to GMFRs at the earlier time point after Dose 1.

Similar trends were observed for GMFRs of SARS-CoV-2 90% neutralizing titers in the younger age group (Supplemental Table 14.75 and 14.76) and older age group (Supplemental Table 14.77).

Results for the all-available immunogenicity population in the younger age and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in following tables:

18-55 Years of Age – BNT162b1	Supplemental Table 14.78
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.79
65-85 Years of Age – BNT162b1	Supplemental Table 14.80

BNT162b2

In the younger age group, GMFRs of SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2 (Day 28) of BNT162b2 were substantially high compared to GMFRs at the earlier time point after Dose 1 of BNT162b2 for all dose groups, with GMFRs being similar and highest in the 20-µg and 30-µg dose groups (Supplemental Table 14.81). GMFRs remained high through 1 month after Dose 2 of BNT162b2 compared to GMFRs 21 days after Dose 1 of BNT162b2 .

In the older age group, GMFRs of SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2 (Day 28) of BNT162b2 were substantially high compared to GMFRs at the earlier time point after Dose 1 of BNT162b2 in all dose groups, with GMFRs being highest in the 30-µg dose group (Supplemental Table 14.82). GMFRs remained high through 1 month after Dose 2 of BNT162b2 compared to GMFRs at 21 days after Dose 1 of BNT162b2.

Similar trends were observed for GMFRs of SARS-CoV-2 90% neutralizing titers in the younger and older age groups (Supplemental Tables 14.81 and 14.82, respectively).

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population (Supplemental Tables 14.83 and 14.84, respectively).

11.2.1.1.3. Number (%) of Participants Achieving a ≥4-Fold Rise

Overall, for both the BNT162b1 and the BNT162b2 recipients, and in both age groups, most participants achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2, except in the older participants in the 10-µg BNT162b1 dose group.

BNT162b1

In the younger age group, from before vaccination to 21 days after Dose 1 of BNT162b1, no participants in the 10-µg dose group and ≤3 participants in the 20-µg and the 30-µg dose groups achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers (Supplemental Table 14.85). From before vaccination to both 7 days and 1 month after Dose 2 of BNT162b1 most or all participants in the 10-µg,20-µg, and 30-µg dose groups achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers.

The number of participants in the 100-µg dose group who achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers after Dose 1 are presented in Supplemental Table 14.86.

In the older age group, from before vaccination to 21 days after Dose 1 of BNT162b1, only 1 participant in the 30-µg dose group achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers (Supplemental Table 14.87). From before vaccination to both 7 days and 1 month after Dose 2 of BNT162b1, ≤2 participants in the 10-µg group and 9 to

11 participants in the 20-µg and 30-µg dose groups achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers.

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in following tables:

18-55 Years of Age – BNT162b1	Supplemental Table 14.88
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.89
65-85 Years of Age – BNT162b1	Supplemental Table 14.90

BNT162b2

In the younger age group, from before vaccination to 21 days after Dose 1 of BNT162b2, 2 (18.2%) participants in the 10-µg dose group, 3 (25.0%) participants in the 20-µg dose group, and none in the 30-µg group achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers (Supplemental Table 14.91). From before vaccination to 7 days after Dose 2 of BNT162b2, all participants achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers, which was maintained through 1 month after Dose 2 of BNT162b2.

In the older age group, from before vaccination to 21 days after Dose 1 of BNT162b2, no participants achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers in any dose group (Supplemental Table 14.92). From before vaccination to 7 days after Dose 2 of BNT162b2, 10 (83.3%), 9 (81.8%), and 10 (90.9%) participants achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers in the 10-µg, 20-µg, and 30-µg dose groups, respectively. From before vaccination to 1 month after Dose 2 of BNT162b2, 9 (75.0%), 6 (54.5%), and 11 (100.0%) participants achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers in the 10-µg, 20-µg, and 30-µg dose groups, respectively.

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population (Supplemental Tables 14.93 and 14.94, respectively).

11.2.1.2. SARS-CoV-2 Antigen-Specific Binding Antibody Levels – Phase 1

Vaccine candidate BNT162b1 encodes for the RBD of SARS-CoV-2. RBD-binding IgG responses for each dose level and age group for this candidate are described in this section. RBD-binding IgG levels were also assessed for candidate BNT62b2 which encodes the P2 S of SARS-CoV-2.

Vaccine candidate BNT162b2 encodes for the P2 S of SARS-CoV-2. S1-binding IgG responses for each dose level and age group for this candidate are described in this section. S1-binding IgG levels were also assessed for candidate BNT62b1 which encodes the RBD of SARS-CoV-2.

11.2.1.2.1. GMCs

Overall, for both the BNT162b1 and the BNT162b2 recipients, and in both age groups, RBD- and S1-binding GMCs increased substantially by Day 21 after Dose 1 and were further increased 7 days after Dose 2. Responses were maintained through Day 52. GMCs in the older age group were generally lower than the GMCs in the younger age group, with the exception of Day 28 in the 20-µg BNT162b1 dose group for both RBD- and S1-binding IgG levels.

BNT162b1

In the younger age group, RBD-binding GMCs increased substantially by Day 21 after Dose 1 of BNT162b1 and further increased 7 days after Dose 2 (Day 28) of BNT162b1, with higher GMCs observed in the 30-µg dose group compared to the 10-µg and 20-µg dose groups (Figure 8 and Supplemental Table 14.65). At 1 month after Dose 2 (Day 52), the GMCs remained substantially higher than at the earlier time points after Dose 1.

In the 100-µg BNT162b1 group, the RBD-binding GMC increased substantially by 21 days after BNT162b1 and remained higher through Day 52 compared to the Day 7 GMC (Supplemental Table 14.66).

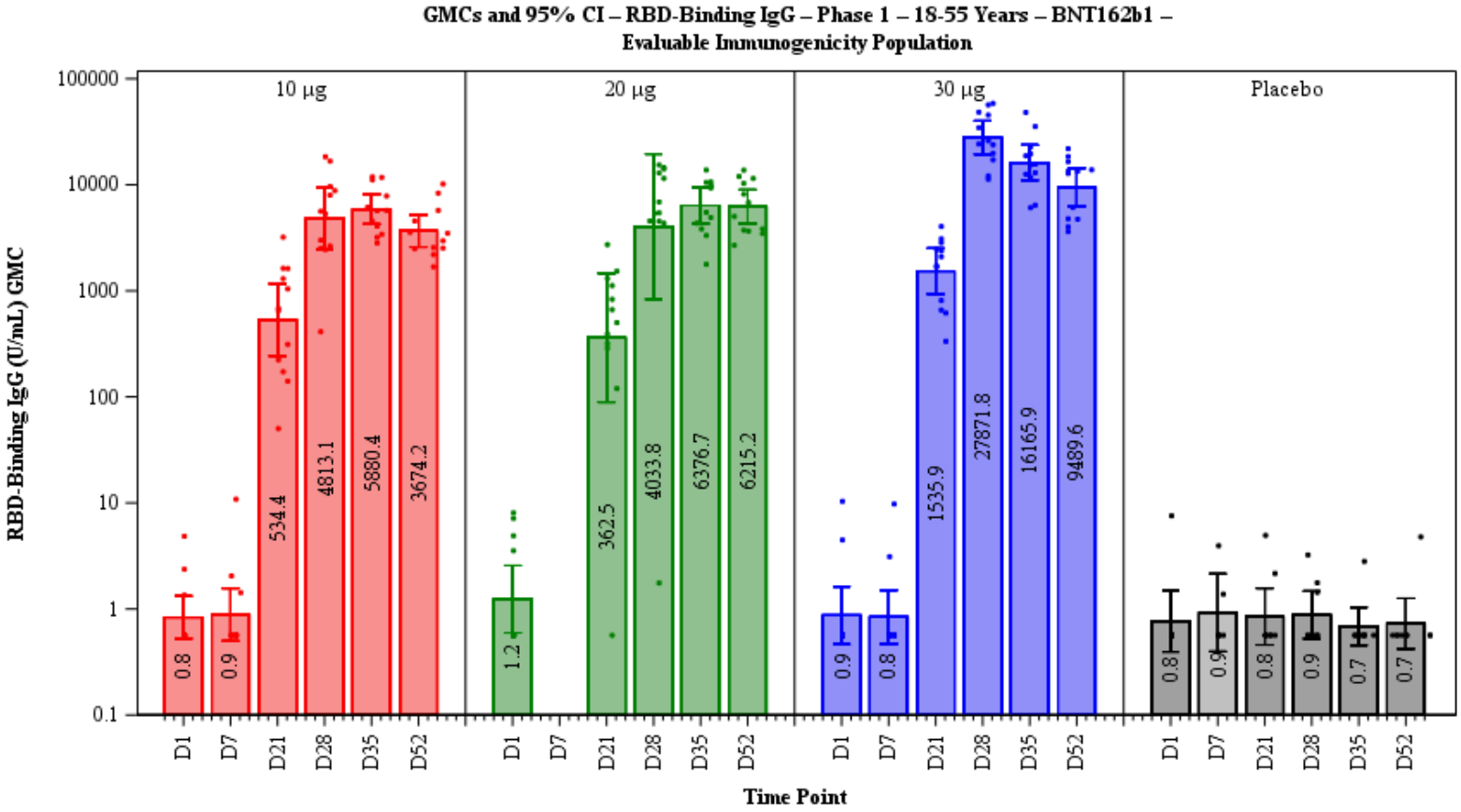
In the older age group, RBD-binding GMCs increased substantially by Day 21 after Dose 1 of BNT162b1 and further increased 7 days after Dose 2 (Day 28) of BNT162b1, with higher GMCs observed in the 20-µg and 30-µg dose groups compared to the 10-µg group (Figure 9 and Supplemental Table 14.67). At 1 month after Dose 2 (Day 52), the GMCs remained substantially higher than at the earlier time point after Dose 1.

S1-binding IgG GMC results for BNT162b1 were similar to those observed for RBD-binding IgG GMCs in the younger (Figure 10 and Supplemental Table 14.65) and older age groups (Figure 11 and Supplemental Table 14.67), and in the 100-µg BNT162b1 group (Supplemental Table 14.66).

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in following tables:

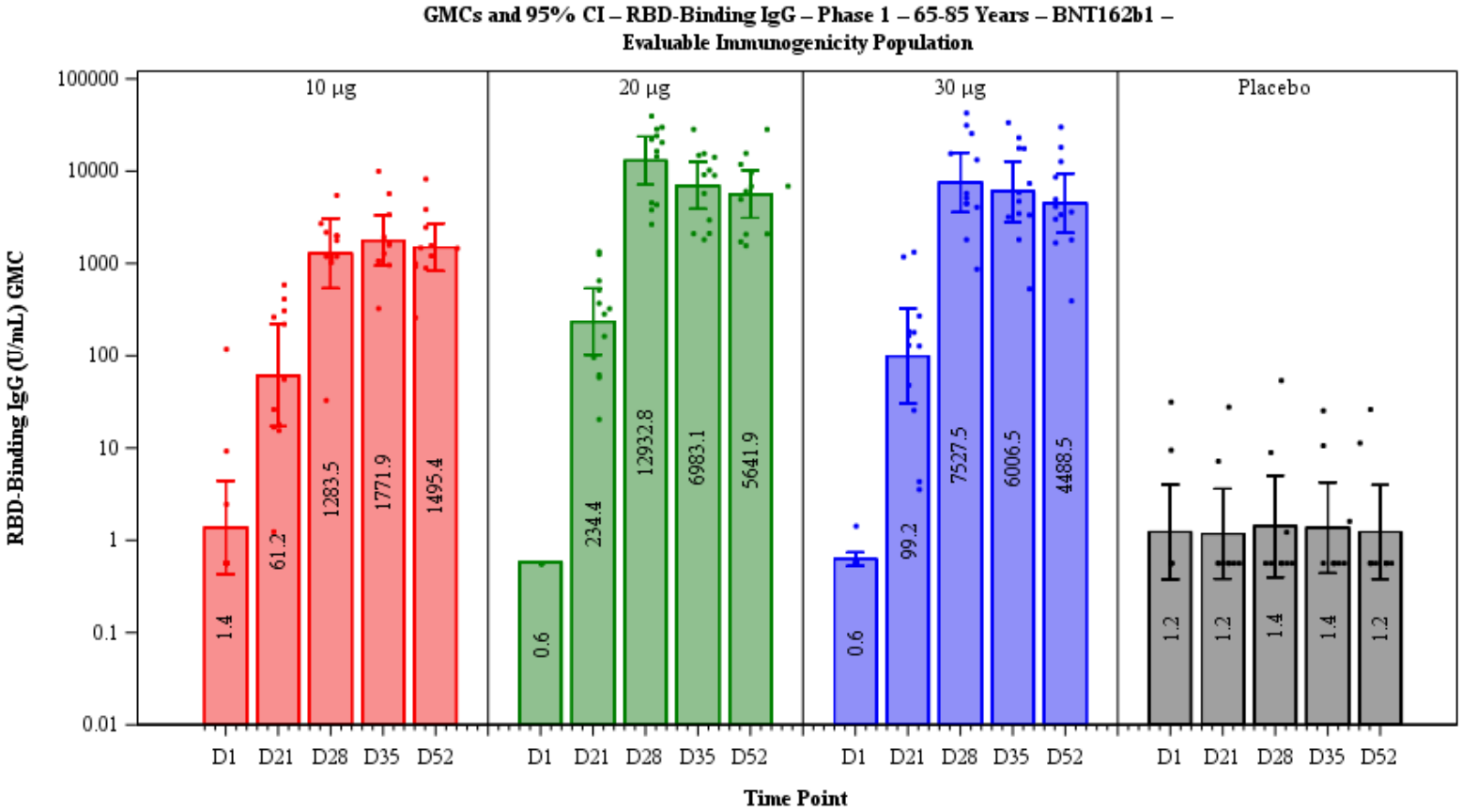
18-55 Years of Age – BNT162b1	Supplemental Table 14.68
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.69
65-85 Years of Age – BNT162b1	Supplemental Table 14.70

Figure 8. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 RBD-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



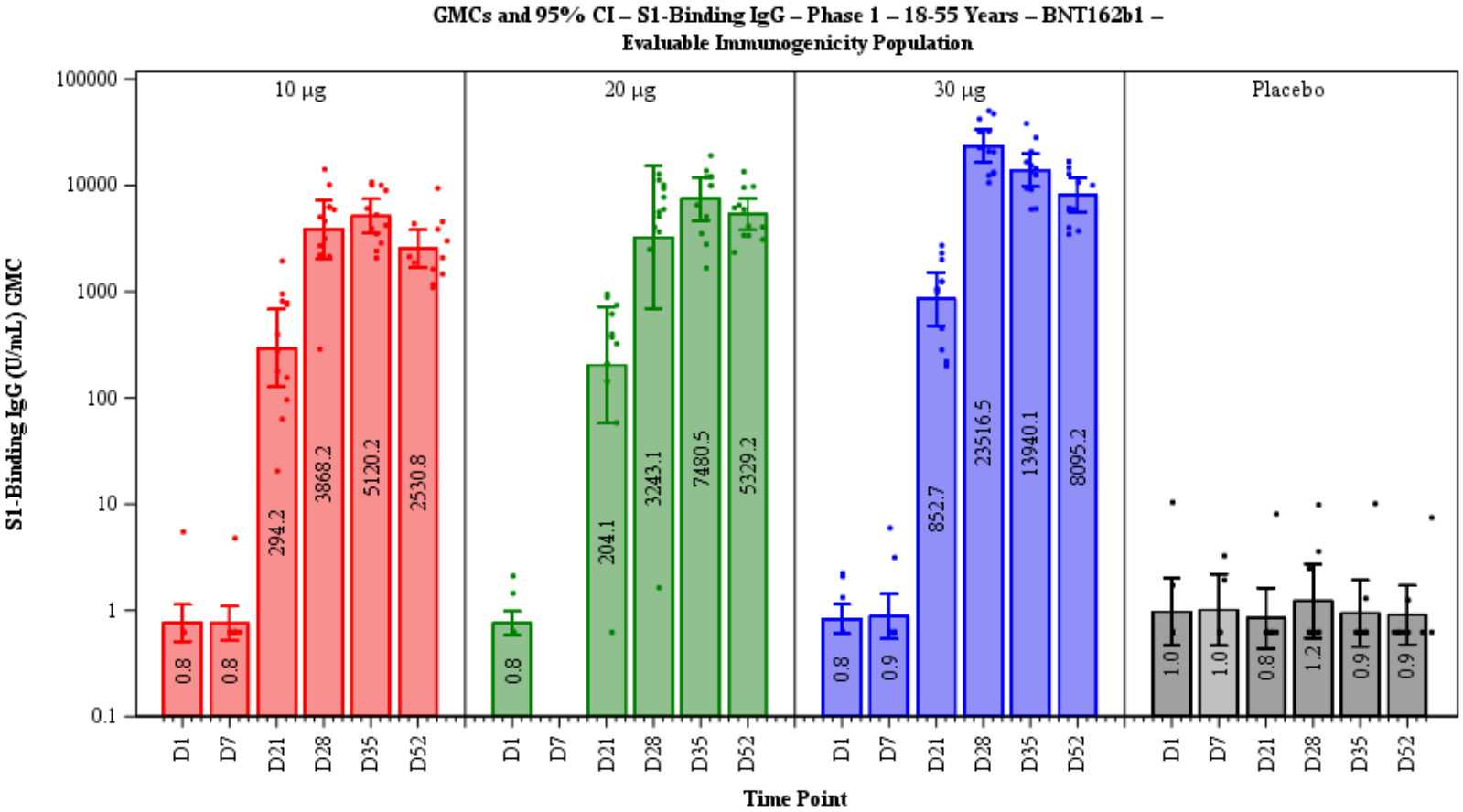
Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; RBD = receptor-binding domain.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_rbd_18_b1_p1

Figure 9. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 RBD-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age, BNT162b1 – Evaluable Immunogenicity Population



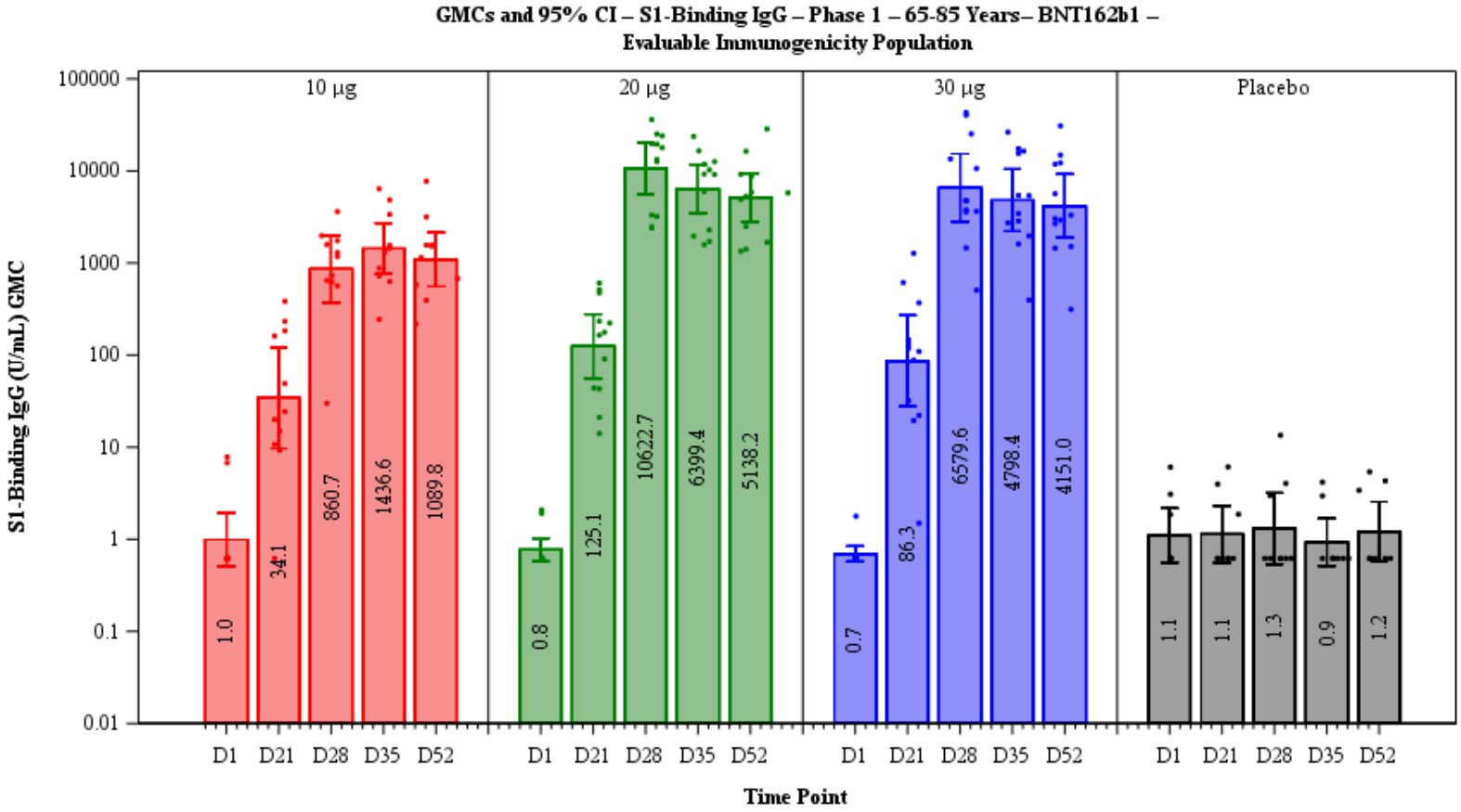
Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; RBD = receptor-binding domain.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_rbd_65_b1_p1

Figure 10. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 S1-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_s1_18_b1_p1

Figure 11. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 S1-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_s1_65_b1_p1

RCDCs of RBD- and S1-binding IgG levels are presented in Supplemental Figures 14.13 through 14.16. The RCDCs show that the majority of participants responded by 21 days after Dose 1 of BNT162b1.

BNT162b2

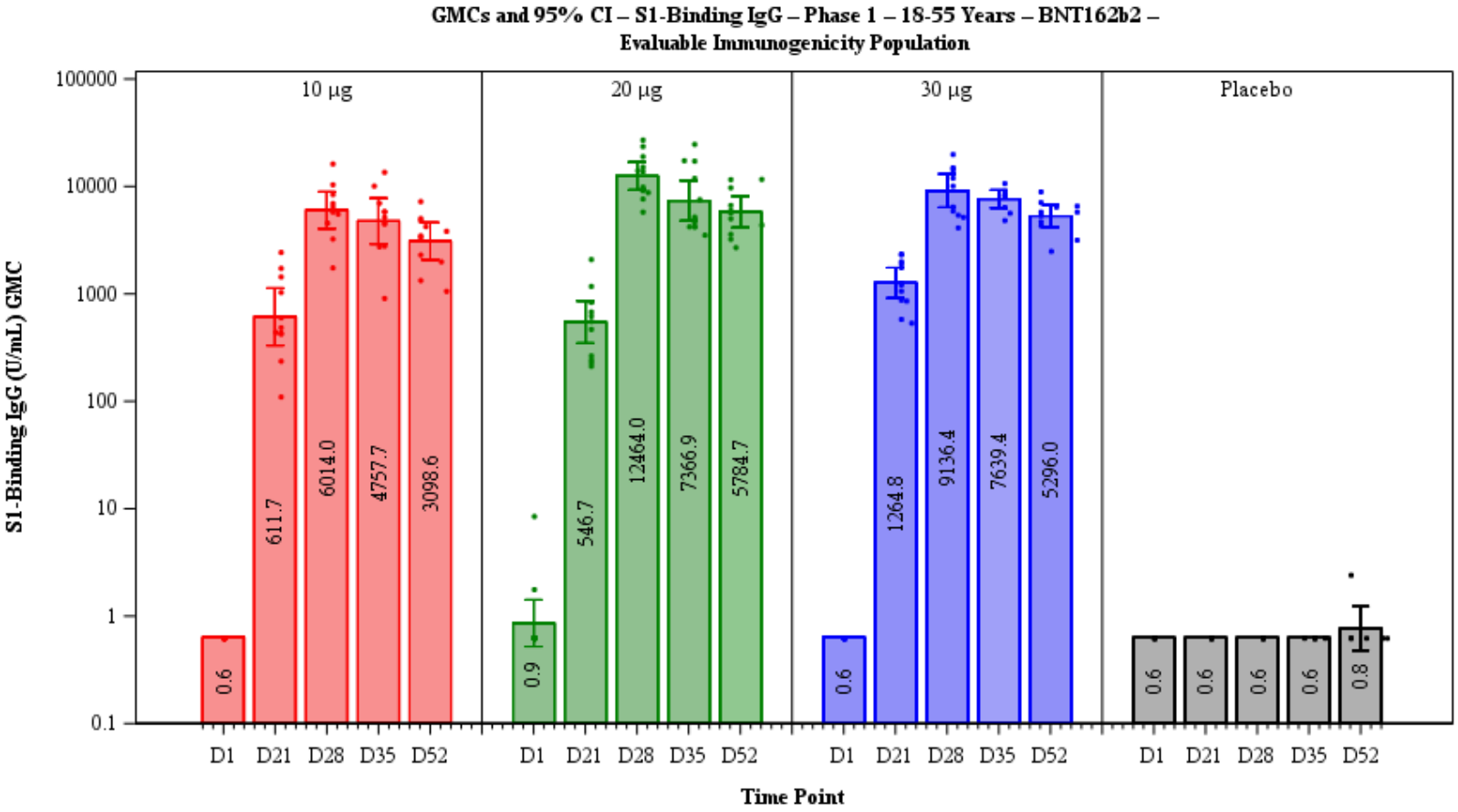
In the younger age group, S1-binding GMCs increased substantially by Day 21 after Dose 1 of BNT162b2 and were substantially increased by 7 days after Dose 2 (Day 28) of BNT162b2, with higher GMCs observed in the 20-µg and 30-µg dose groups compared to the 10-µg dose group (Figure 12 and Supplemental Table 14.71). At 1 month after Dose 2 (Day 52), the GMCs remained substantially higher than at the earlier time point after Dose 1.

Similar trends were observed in the older age group, with higher S1-binding GMCs observed in the 30-µg dose group compared to the 10-µg and 20-µg dose groups (Figure 13 and Supplemental Table 14.72).

RBD-binding IgG GMC results for BNT162b2 were similar to those observed for S1-binding IgG GMCs in the younger (Figure 14 and Supplemental Table 14.71) and older age groups (Figure 15 and Supplemental Table 14.72).

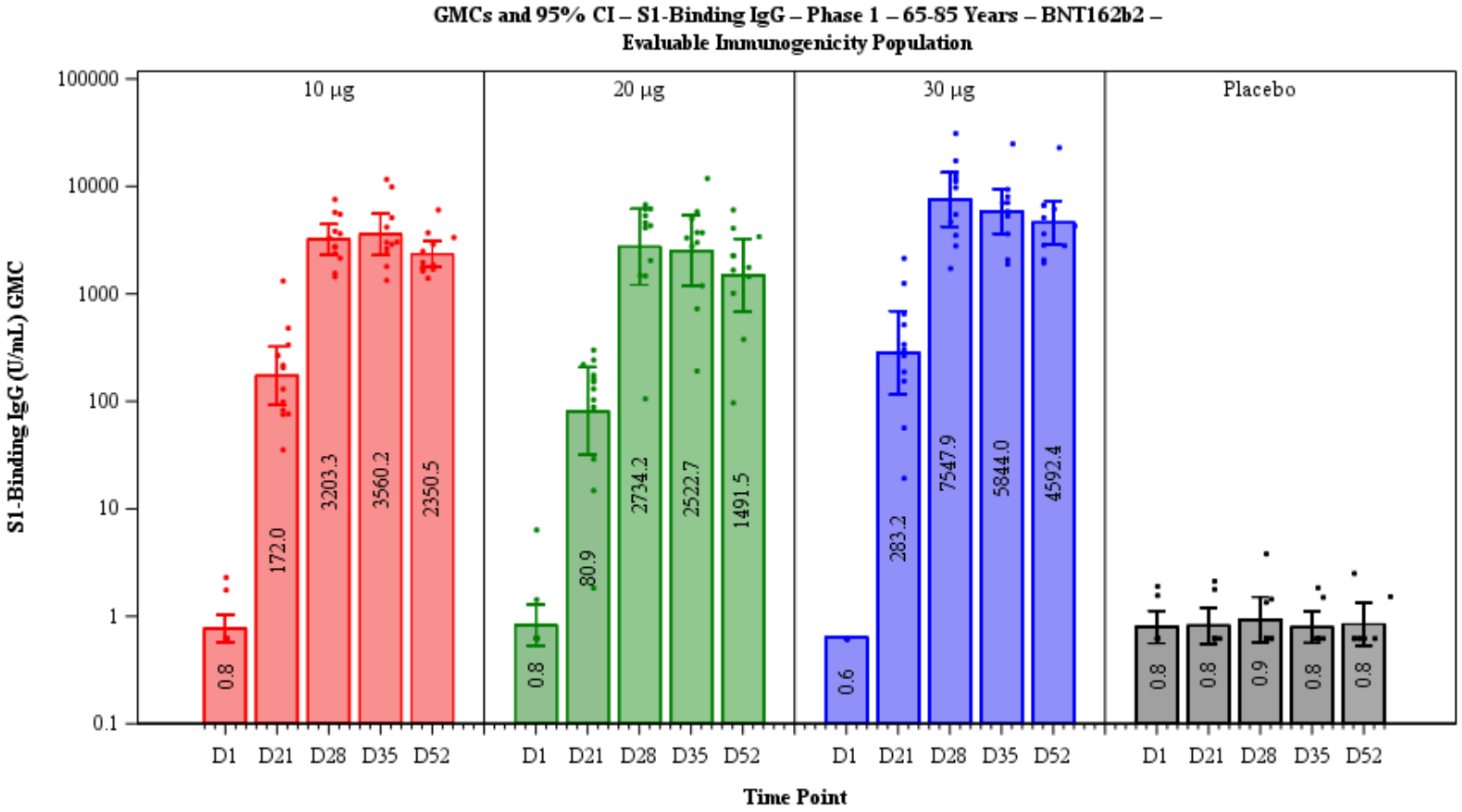
Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in Supplemental Tables 14.73 and 14.74, respectively.

Figure 12. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 S1-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



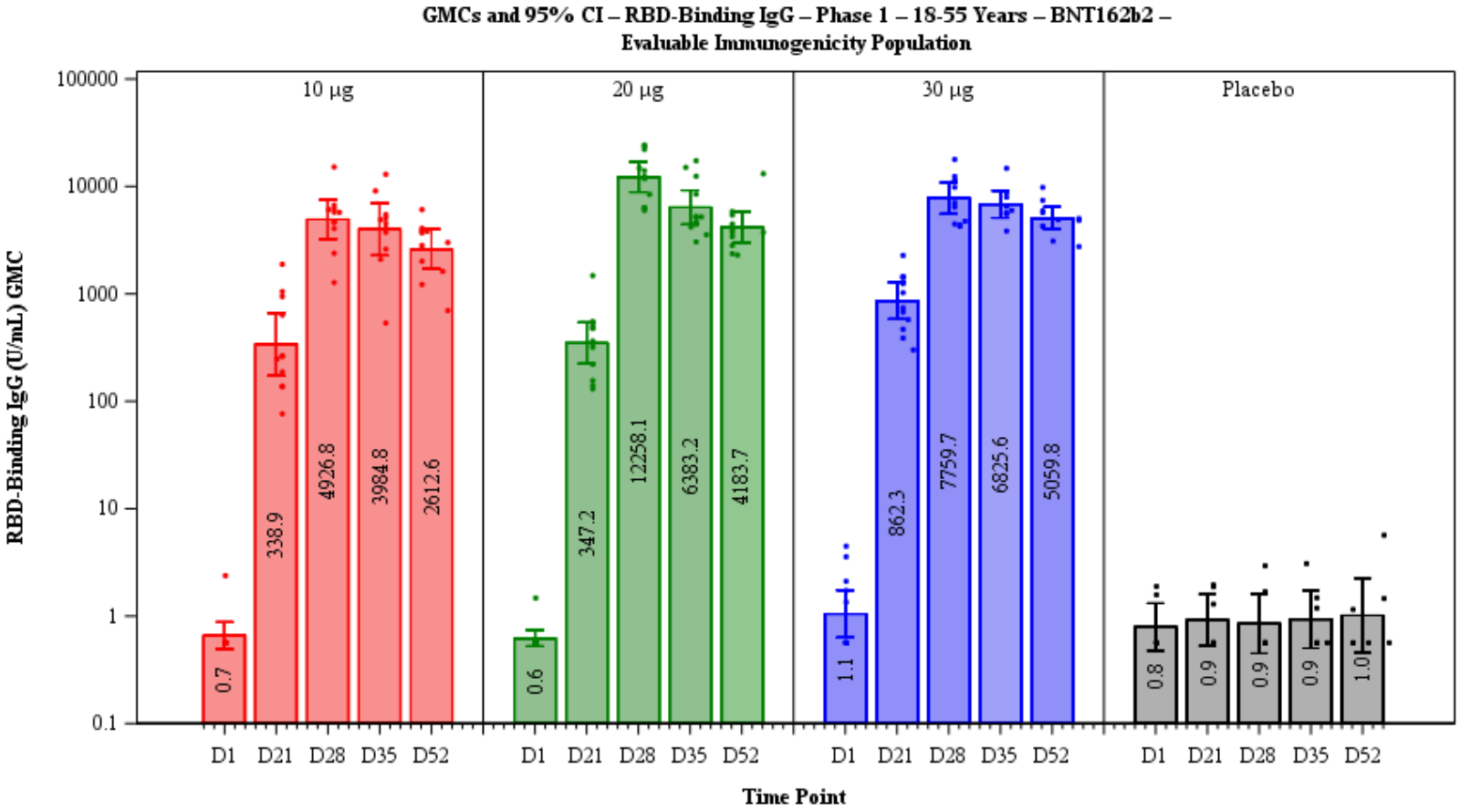
Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_s1_18_b2_p1

Figure 13. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 S1-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



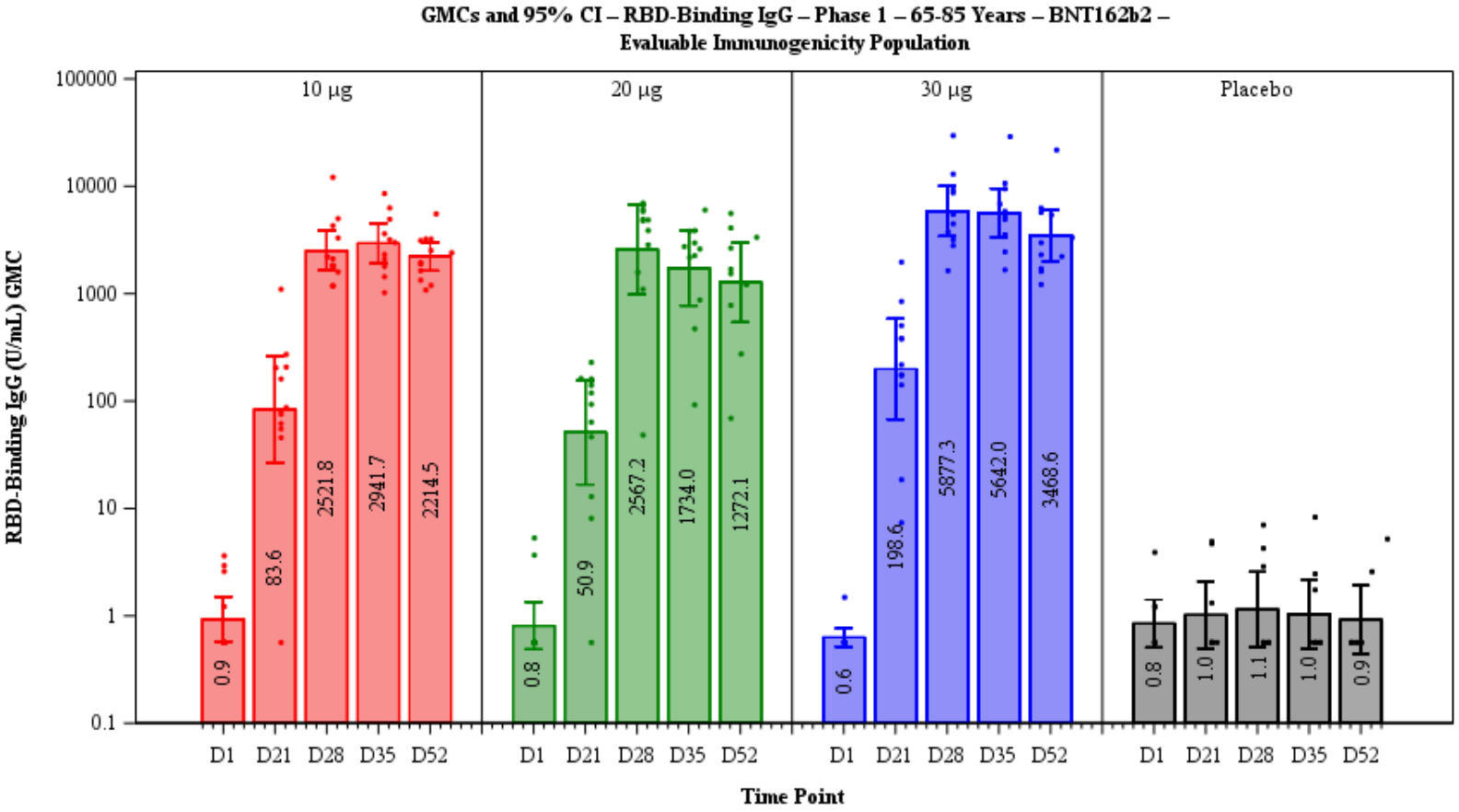
Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_s1_65_b2_p1

Figure 14. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 RBD-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; RBD = receptor-binding domain.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_rbd_18_b2_p1

Figure 15. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 RBD-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; RBD = receptor-binding domain.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_rbd_65_b2_p1

RCDCs of RBD- and S1-binding IgG levels after BNT162b2 are presented in Supplemental Figures 14.17 through 14.20. The RCDCs show that the majority of participants responded by 21 days after Dose 1 of BNT162b2.

11.2.1.2.2. GMFRs

Overall, for the BNT162b1 and the BNT162b2 recipients, and in both age groups, GMFRs of RBD-binding IgG levels and GMFRs of S1-binding IgG levels were substantially high from before vaccination to 21 days after Dose 1, with greater GMFRs observed from before vaccination to 7 days after Dose 2.

BNT162b1

GMFRs of RBD-binding IgG levels were substantially high from before vaccination to Day 21 (before Dose 2) after Dose 1 of BNT162b1, with greater GMFRs observed from before vaccination to 7 days after Dose 2 (Day 28) of BNT162b1 in both the younger and older age groups, for the 10-µg, 20-µg, and 30-µg dose groups (Supplemental Table 14.75 and Supplemental Table 14.77, respectively). GMFRs remained substantially high in the 10-µg, 20-µg, and 30-µg BNT162b1 groups from before vaccination to 1 month after Dose 2 compared to the earlier time points after Dose 1 for both age groups.

In the 100-µg BNT162b1 group, GMFR of RBD-binding IgG levels was substantially high from before vaccination by 21 days after BNT162b1 and remained higher through Day 52 compared to the Day 7 GMFR (Supplemental Table 14.76).

Similar trends were observed for GMFRs of S1-binding IgG levels for BNT162b1.

Results for the all-available immunogenicity population in the younger age and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in following tables:

18-55 Years of Age – BNT162b1	Supplemental Table 14.78
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.79
65-85 Years of Age – BNT162b1	Supplemental Table 14.80

BNT162b2

GMFRs of S1-binding IgG levels were substantially high from before vaccination to Day 21 (before Dose 2) after Dose 1 of BNT162b2, with greater GMFRs observed from before vaccination to 7 days after Dose 2 (Day 28) of BNT162b2 in both the younger and older age groups, for the 10-µg, 20-µg, and 30-µg dose groups (Supplemental Table 14.81 and Supplemental Table 14.82, respectively). GMFRs remained substantially high in all BNT162b2 groups from before vaccination to 1 month after Dose 2 compared to the earlier time point after Dose 1 for both age groups.

Similar trends were observed for GMFRs of RBD-binding IgG levels for BNT162b2.

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population (Supplemental Tables 14.83 and 14.84, respectively).

11.2.1.2.3. Number (%) of Participants Achieving a ≥4-Fold Rise

Overall, for the BNT162b1 and the BNT162b2 recipients, and in both age groups, all participants achieved a ≥4-fold rise in S1- and RBD-binding IgG levels from before vaccination to 7 days after Dose 2, with the exception of 1 participant in the younger 20-µg BNT162b1 group.

BNT162b1

In the younger age group, from before vaccination to 21 days following Dose 1 of BNT162b1, all participants (except 1 in the 20- µg dose group) across all dose groups achieved a ≥4-fold rise in RBD-binding IgG levels (Supplemental Table 14.85 and Supplemental Table 14.86 [100-µg group]). All participants in the 20-µg dose group achieved a ≥4-fold rise in RBD-binding IgG levels from before vaccination to 14 days after Dose 2 (Day 35).

In the older age group, from before vaccination to 21 days following Dose 1 of BNT162b1, all participants in the 20-µg and 30-µg dose groups and 8 (72.7%) participants in the 10-µg dose group achieved a ≥4-fold rise in RBD-binding IgG levels (Supplemental Table 14.87). All participants in the 10-µg dose group achieved a ≥4-fold rise in RBD-binding IgG levels from before vaccination to 7 days after Dose 2 (Day 28).

Similar trends were generally observed for participants achieving a ≥4-fold rise in S1-binding IgG levels for BNT162b1.

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in following tables:

18-55 Years of Age – BNT162b1	Supplemental Table 14.88
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.89
65-85 Years of Age – BNT162b1	Supplemental Table 14.90

BNT162b2

In the younger age group, from before vaccination to 21 days following Dose 1 of BNT162b2, all participants in each dose group achieved a ≥4-fold rise in S1-binding IgG levels (Supplemental Table 14.91).

In the older age group, from before vaccination to 21 days following Dose 1 of BNT162b2, all participants in the 10-µg, and 30-µg dose groups and 11 (91.7%) participants in the 20-µg dose group achieved a ≥4-fold rise in S1-binding IgG levels (Supplemental Table 14.92). All

participants in the 20-µg dose group achieved a ≥4-fold rise in S1-binding IgG levels from before vaccination to 7 days after Dose 2 (Day 28).

Similar trends were generally observed for participants achieving a ≥4-fold rise in RBD-binding IgG levels for BNT162b2.

Results for the all-available immunogenicity population, which were similar to those observed for the evaluable immunogenicity population in the younger and older age groups, are presented in Supplemental Tables 14.93 and 14.94, respectively.

11.2.1.3. GMRs of SARS-CoV-2-Neutralizing Titers to SARS-CoV-2 Antigen-Specific Binding Antibody Levels

Overall, for BNT162b1 and BNT162b2 recipients, GMRs of SARS-CoV-2 50% neutralizing titers to RBD- or S1-binding IgG levels show a more robust RBD- or S1-binding levels relative to neutralizing titers, which were similar within each age group.

BNT162b1

At 21 days after Dose 1 at 10 µg, 20 µg, or 30 µg, GMRs of SARS-CoV-2 50% neutralizing titers to RBD-binding IgG levels were ≤0.035 in the younger age group (Supplemental Table 14.95) and ≤0.183 in the older age group (Supplemental Table 14.96). At 14 days after Dose 2, the GMRs were ≤0.032 in the younger age group and ≤0.018 in the older age group.

For the 100-µg dose group, the GMR was 0.018 at 21 days after Dose 1 and 0.014 at 35 days after Dose 1 (Supplemental Table 14.97).

GMRs of SARS-CoV-2 50% neutralizing titers to S1-binding IgG levels were similar to GMRs of SARS-CoV-2 50% neutralizing titers to RBD-binding IgG levels in the younger (Supplemental Tables 14.95 and 14.97) and older (Supplemental Table 14.96) age groups after BNT162b1.

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in the following tables:

18-55 Years of Age – BNT162b1	Supplemental Table 14.98
18-55 Years of Age – BNT162b1 (100 µg)	Supplemental Table 14.99
65-85 Years of Age – BNT162b1	Supplemental Table 14.100

BNT162b2

At 21 days after Dose 1, GMRs of SARS-CoV-2 50% neutralizing titers to S1-binding IgG levels were ≤ 0.035 in the younger age group (Supplemental Table 14.101) and ≤0.124 in the older age group (Supplemental Table 14.102). At 14 days after Dose 2, the GMRs were ≤0.040 in the younger age group and ≤0.037 in the older age group.

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population and are presented in Supplemental Tables 14.103 and 14.104, respectively.

Evaluating BNT162b1 and BNT162b2 GMRs

In the younger age group at 21 days after Dose 1, GMRs of SARS-CoV-2 50% neutralizing titers to RBD-binding IgG levels were ≤0.035 after BNT162b21 (Supplemental Table 14.95) and ≤0.054 after BNT162b2 (Supplemental Table 14.101). At 14 days after Dose 2, the GMRs were ≤0.032 after BNT162b21 and ≤0.046 after BNT162b2.

In the older age group at 21 days after Dose 1, GMRs of SARS-CoV-2 50% neutralizing titers to RBD-binding IgG levels were ≤0.183 after BNT162b21 (Supplemental Table 14.96) and ≤0.196 after BNT162b2 (Supplemental Table 14.102). At 14 days after Dose 2, the GMRs were ≤0.018 after BNT162b21 and ≤0.043 after BNT162b2.

In the younger age group at 21 days after Dose 1, GMRs of SARS-CoV-2 50% neutralizing titers to S1-binding IgG levels were ≤0.061 after BNT162b21 (Supplemental Table 14.95) and ≤0.035 after BNT162b2 (Supplemental Table 14.101). At 14 days after Dose 2, the GMRs were ≤0.035 after BNT162b21 and ≤0.040 after BNT162b2.

In the older age group at 21 days after Dose 1, GMRs of SARS-CoV-2 50% neutralizing titers to S1-binding IgG levels were ≤0.328 after BNT162b21 (Supplemental Table 14.96) and ≤0.124 after BNT162b2 (Supplemental Table 14.102). At 14 days after Dose 2, the GMRs were ≤0.022 after BNT162b21 and ≤0.037 after BNT162b2.

11.2.2. Phase 1 Summary of Immunogenicity Results Evaluating BNT162b1 and BNT162b2

In general, a modest neutralizing immune response was observed in both the younger and older age groups after the first dose. A much more robust immune response was observed 7 days after the second dose of either BNT162b1 or BNT162b2 at all dose levels in both the younger and older age groups. Antibody levels at the last time point tested were still substantially above those at baseline.

In the younger age group:

- At 7 days after Dose 2, SARS-CoV-2 50% neutralizing GMTs in the 20-µg and 30-µg dose groups were higher for BNT162b2 recipients than for BNT162b1 recipients. The GMTs were similar in the 10-µg dose group for both recipients. At 1 month after Dose 2 (Day 52), GMTs remained substantially higher than those at the earlier time points after Dose 1 for both BNT162b1 and BNT162b2 recipients.

- From before vaccination to 7 days after Dose 2, GMFRs of SARS-CoV-2 50% neutralizing titers were substantially high for BNT162b1 and BNT162b2 recipients at the 30-µg dose level.

- From before vaccination to 7 days after Dose 2, all participants at the 30-µg dose level who received BNT162b1 or BNT162b2 achieved a ≥4-fold rise in SARS CoV-2 50% neutralizing titers.

In the older age group:

- At 7 days after Dose 2, SARS-CoV-2 50% neutralizing GMT in the 30-µg dose group was higher for BNT162b2 recipients than for BNT162b1 recipients. At 1 month after Dose 2 (Day 52), the SARS-CoV-2 50% neutralizing GMTs in the 30-µg dose group were similar for both BNT162b1 and BNT162b2 recipients.

- From before vaccination to 7 days after Dose 2, the GMFR of SARS-CoV-2 50% neutralizing titers were substantially high for BNT162b1 and BNT162b2 recipients at the 30-µg dose level.

- From before vaccination to 7 days after Dose 2, most participants who received BNT162b1 or BNT162b2 at the 30-µg dose level achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers.

11.2.3. Phase 1 Immunogenicity Conclusions

- Both BNT162b1 and BNT162b2 elicited robust SARS-CoV-2 neutralizing antibody response 7 days after Dose 2 in younger and older adults, based on GMTs, GMFRs, proportions of participants achieving a ≥4-fold rise in neutralizing titers, and RCDCs. Neutralizing antibody response was maintained through Day 52 and was similar for the candidates within the corresponding age and dose groups.

- Both BNT162b1 and BNT162b2 elicited substantial rises in antigen binding IgG levels 7 days after Dose 2, based on GMCs, GMFRs, and proportions of participants achieving a ≥4-fold rise in IgG-antigen specific binding. Responses were maintained through Day 52.

- In the 100-µg dose group, SARS-CoV-2 neutralizing antibody response modestly increased by 3 weeks after Dose 1 of BNT162b1, but neutralizing antibody response returned to levels similar to baseline by 7 weeks after Dose 1.

- These data support the need for a 2-dose vaccination series.

11.2.4. Phase 2

Results of immunogenicity analyses reported here are those for the Dose 2 evaluable immunogenicity population; note that baseline positive participants (by N-binding antibody or positive NAAT at Visit 1) were not excluded from these analyses.

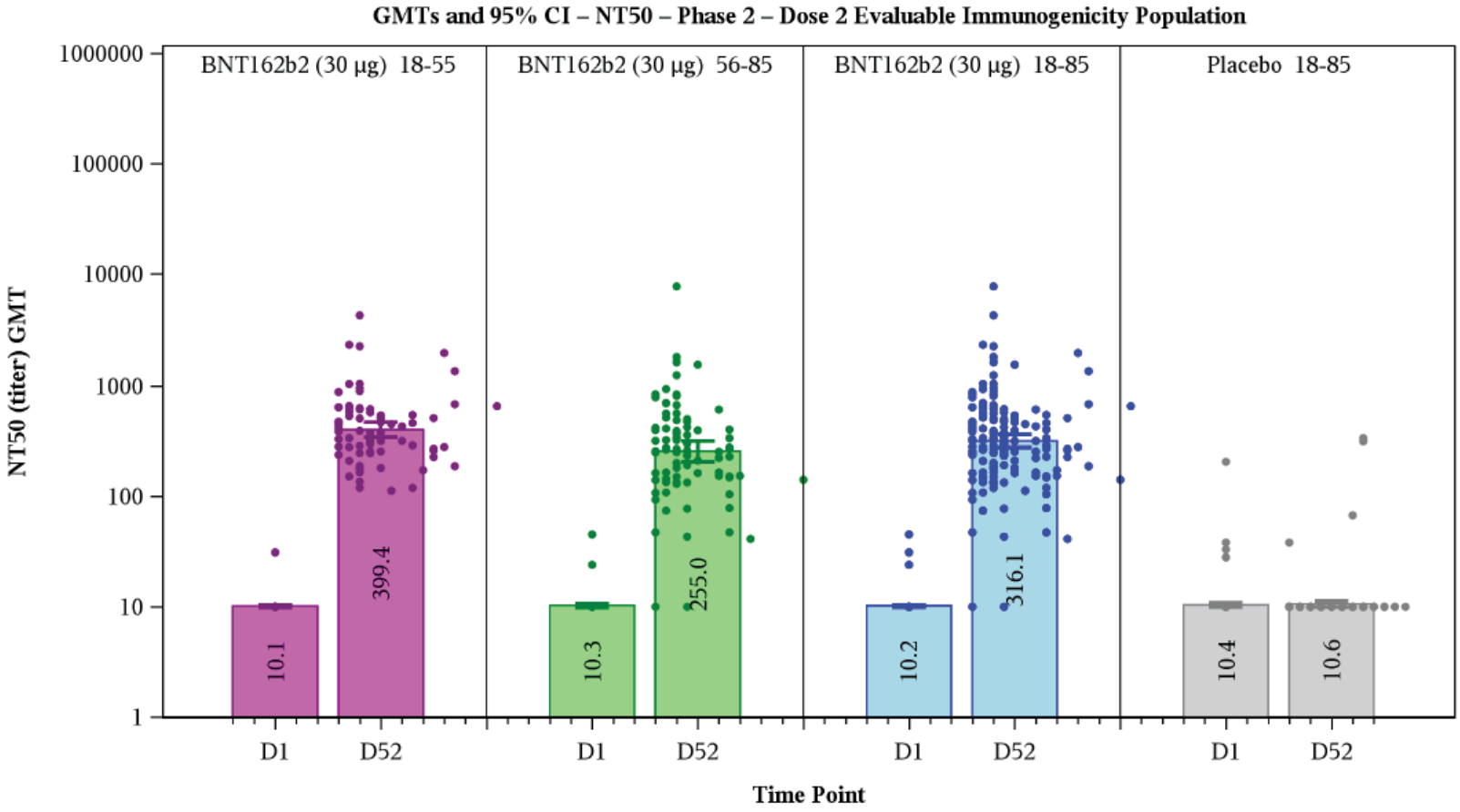
11.2.4.1. SARS-CoV-2 Neutralizing Titers and S1-Binding IgG Concentrations – Phase 2

11.2.4.1.1. GMTs/GMCs

At 1 month after Dose 2 (Day 52) of BNT162b2, there were substantial increases in SARS-CoV-2 50% neutralizing GMTs (Figure 16) and S1-binding IgG concentrations (GMCs) (Figure 17). GMTs/GMCs were higher in younger participants (18 to 55 years of age) than in older participants (56 to 85 years of age) (Supplemental Table 14.195).

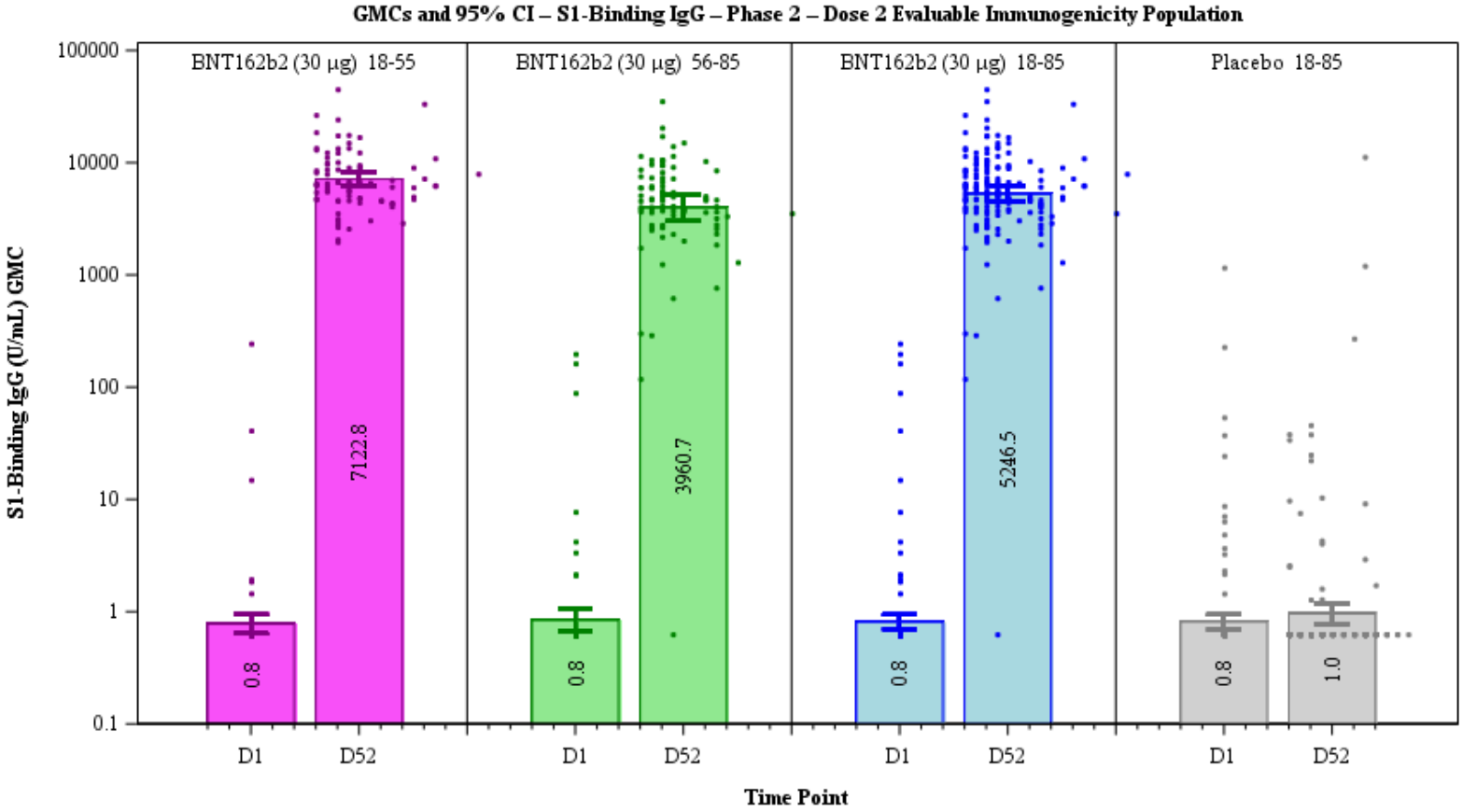
Similar trends were observed for the SARS-CoV-2 90% neutralizing GMTs (Supplemental Figure 14.21 and Supplemental Table 14.196).

Figure 16. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay – NT50 – Phase 2 – Dose 2 Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f002_sars_50_p2

Figure 17. Geometric Mean Concentrations and 95% CI: S1-Binding IgG Level Assay – Phase 2 Dose 2 Evaluable Immunogenicity Population



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f002_s1_p2

SARS-CoV-2 50% neutralizing titers/S1-binding IgG GMCs and 90% neutralizing GMTs for the Dose 2 all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Tables 14.197 and 14.198, respectively).

RCDCs of SARS-CoV-2 50% and 90% neutralizing titers and S1-binding GMCs are presented in Supplemental Figures 14.22 through 14.24.

11.2.4.1.2. GMFRs in Titers/Concentrations

GMFRs of SARS-CoV-2 50% serum neutralizing titers and S1-binding IgG concentrations from before vaccination to 1 month after Dose 2 (Day 52) of BNT162b2 were robust, with higher GMFRs observed in younger participants than in older participants (Supplemental Table 14.199).

Similar trends were observed for GMFRs of SARS-CoV-2 90% neutralizing titers (Supplemental Table 14.200).

GMFRs of SARS-CoV-2 50% neutralizing titers/S1-binding IgG GMCs and 90% neutralizing GMTs for the Dose 2 all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Tables 14.201 and 14.202).

11.2.4.2. SARS-CoV-2 Neutralizing Titers and S1-Binding IgG Concentrations by Baseline SARS-CoV-2 Status

11.2.4.2.1. GMTs/GMCs

A few participants in the Dose 2 evaluable immunogenicity population had a positive baseline SARS-CoV-2 status: a total of 9 participants with immunogenicity data at the pre-vaccination time point (5 who received BNT162b2 and 4 who received placebo) and 7 participants (3 who received BNT162b2 and 4 who received placebo) with immunogenicity data at the 1 month after Dose 2. These SARS-CoV-2 status positive participants were analyzed separately from the baseline negative participants (Supplemental Table 14.203). In general, at 1 month after Dose 2 among BNT162b2 recipients, SARS-CoV-2 50% neutralizing GMTs in participants with a positive baseline SARS-CoV-2 status (n=3) and S1-binding IgG GMCs in participants with a positive baseline SARS-CoV-2 status were numerically higher than those observed in participants with a negative baseline SARS-CoV-2 status (n=163) (Supplemental Table 14.203). Participants with baseline negative SARS-CoV-2 status had SARS-CoV-2 50% neutralizing GMTs and S1-binding IgG GMCs similar to those in the combined baseline positive and negative participant group (Section 11.2.4.1.1).

Similar trends were observed for SARS-CoV-2 90% neutralizing titers (Supplemental Table 14.204).

SARS-CoV-2 50% neutralizing titers/S1-binding IgG GMCs and 90% neutralizing GMTs for the Dose 2 all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.205 and 14.206).

SARS-CoV-2 neutralizing titers/S1-binding IgG GMCs with positive SARS-CoV-2 prior to 1 month after Dose 2 for the Dose 2 all-available immunogenicity population are presented in Supplemental Table 14.207.

11.2.4.2.2. GMFRs in Titers/Concentrations

When analyzing GMFRs stratified by SARS-CoV-2 status at 1 month after Dose 2, among BNT162b2 recipients (Supplemental Table 14.208), the GMFRs for SARS-CoV-2 50% neutralizing titers and S1-binding IgG were similar to those in the combined baseline positive and negative participant group (Section 11.2.4.1.2).

Similar trends were observed for GMFRs of SARS-CoV-2 90% neutralizing titers (Supplemental Table 14.209).

GMFRs of SARS-CoV-2 50% neutralizing titers/S1-binding IgG GMCs and 90% neutralizing titers for the Dose 2 all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.210 and 14.211).

GMFRs of SARS-CoV-2 neutralizing titers/S1-binding IgG GMCs with positive SARS-CoV-2 prior to 1 month after Dose 2 for the Dose 2 all-available immunogenicity population are presented in Supplemental Table 14.212.

11.2.5. Phase 2 Immunogenicity Conclusions

- Immunogenicity results from 360 participants in Phase 2 of this study demonstrated that BNT162b2 at 30 µg elicited robust SARS-CoV-2 neutralization and S1-binding IgG antibody responses at 1 month after Dose 2 similar to those previously observed in Phase 1 of the study. Notably, SARS-CoV-2 neutralizing titers were higher in the younger age cohort compared with the older age cohort.

- S1-binding GMCs were generally higher in the younger age cohort compared to the older age cohort, again concordant with observations in the Phase 1 portion of the study.

11.2.6. Phase 3

Immunogenicity is a secondary (12 to 15 year olds compared with 16 to 25 year olds) and an exploratory endpoint for the Phase 3 part of the study. These data will be reported at a later time and are not included in this interim CSR.

12. SAFETY EVALUATION

In this interim CSR, all participants in Phase 1 and a subset of 8183 participants in Phase 2/3 (360 participants from Phase 2 included) used an e-diary for reporting local reactions and systemic events.

Safety data for individuals 12 to 15 years of age who were later permitted to enroll in the study will be reported at a later time and are not included in this interim CSR.

12.1. Phase 1

Safety data are available up through the date cutoff date (24 August 2020) and are summarized at various time points relative to Dose 1 or Dose 2. Safety results for Phase 1 vaccine candidates BNT162b1 and BNT162b2 for both adult age groups are presented up to 1 month after Dose 2 (or data cutoff date) at the 10-µg, 20-µg, and 30-µg dose levels. Safety results for BNT162b1 at the 100-µg dose level in the younger age group are presented up to 3 weeks after Dose 1 or to before Dose 2 based on the data cutoff date. Note that the group of participants 18 to 55 years of age who received 100 µg BNT162b1 did not receive a second dose of 100 µg BNT162b2 per IRC decision (see Section 9.8) and instead, they were given 10 µg for Dose 2. At the time of the data cutoff date 11 of 12 participants in this group received Dose 2 of BNT162b1 at 10 µg (24 August 2020), but results for Dose 2 are not yet available at the time of this report. Additionally, long-term follow-up (approximately 4 months after Dose 2 [as of cutoff date 14 November 2020]) of AEs for Phase 1 participants who received BNT162b2 30-µg are presented.

12.1.1. Local Reactions – Phase 1

Overall, for both the BNT162b1 and the BNT162b2 recipients, and in both age groups, pain at the injection site was the most frequent local reaction. Redness and swelling occurred less frequently in the BNT162b2 group and in the BNT162b1 group. In both the BNT162b1 and BNT162b2 groups, the frequency of local reactions was lower in the older age group compared to the younger age group, and there was a trend of a higher frequency of local reactions with increased dose.

BNT162b1

In the younger age group, pain at the injection site was the most frequently reported local reaction within 7 days after Dose 1 of BNT162b1. As dose level increased from 10 µg to 30 µg, increasing frequencies of pain at the injection site (58.3% to 100.0%, 7 and 12 participants, respectively) were observed compared to none in the placebo group (Figure 18 and Supplemental Table 14.105). Redness was reported in 2 (16.7%) participants in the 30-µg dose group, and swelling was reported in 3 (25.0%) participants in the 20-µg dose group and 2 (16.7%) participants in the 30-µg dose group. In the 100-µg dose group, pain at the injection site (12 [100.0%] participants), swelling (5 [41.7%] participants), and redness (4 [33.3%] participants) were reported, and 1 [8.3%] participant had severe injection site pain (Supplemental Table 14.106) (note: per IRC decision, Dose 2 was later administered to participants at the 10-µg dose level).

Within 7 days after Dose 2 of BNT162b1 in the younger age group, pain at the injection site remained the most frequently reported local reaction reaching 12 (100.0%) participants with the 30-µg dose group compared to the placebo group (2 [22.2%] participants), while the proportions of participants with redness (2 [16.7%] participants) and swelling (3 [25.0%] participants) were highest in the 30-µg dose group (Figure 18 and Supplemental Table 14.105). No redness or swelling was reported in the placebo group.

In the older age group, pain at the injection site was the most frequently reported local reaction within 7 days after Dose 1 of BNT162b1 in both the 20-µg and 30-µg dose groups

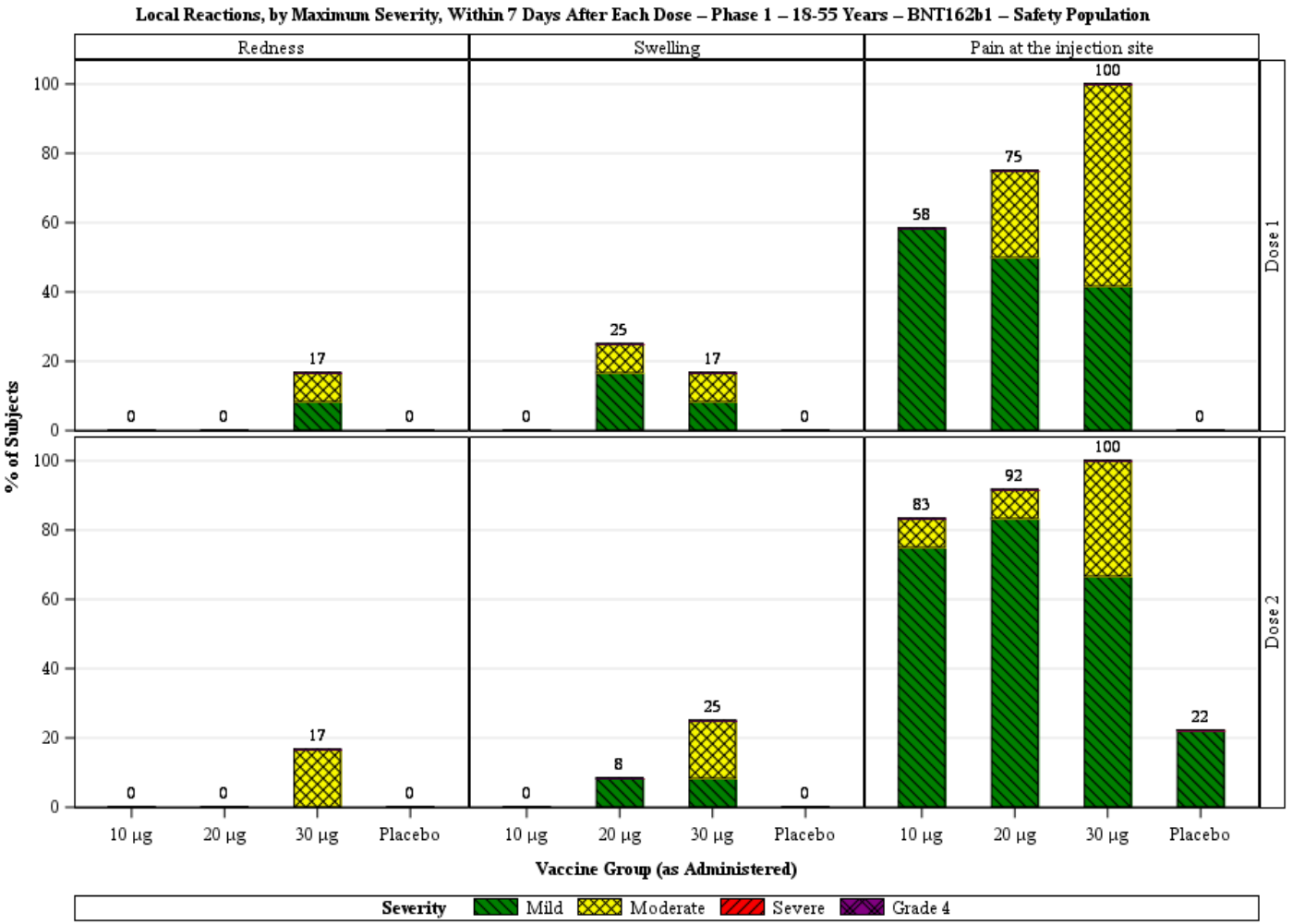
(11 [91.7%] participants each) compared to the placebo group (1 [11.1%] participant) (Figure 19 and Supplemental Table 14.107). No redness was reported, and the maximal frequency of swelling (2 [16.7%] participants) was in the 30-µg group. No redness or swelling was reported in the placebo group.

Within 7 days after Dose 2 of BNT162b1 in the older age group, pain at the injection site was the most frequently reported local reaction in both the 20-µg and 30-µg dose groups (9 [75.0%] participants each). The frequency of swelling (3 [25.0%] participants) was maximal at 30 µg, while redness (1 [8.3%] participant each) was reported in the 20-µg and 30-µg dose groups. No redness or swelling was reported in the placebo group.

After the first and second dose and in both age groups, the majority of local reactions were mild or moderate in severity, and no Grade 4 local reactions were reported.

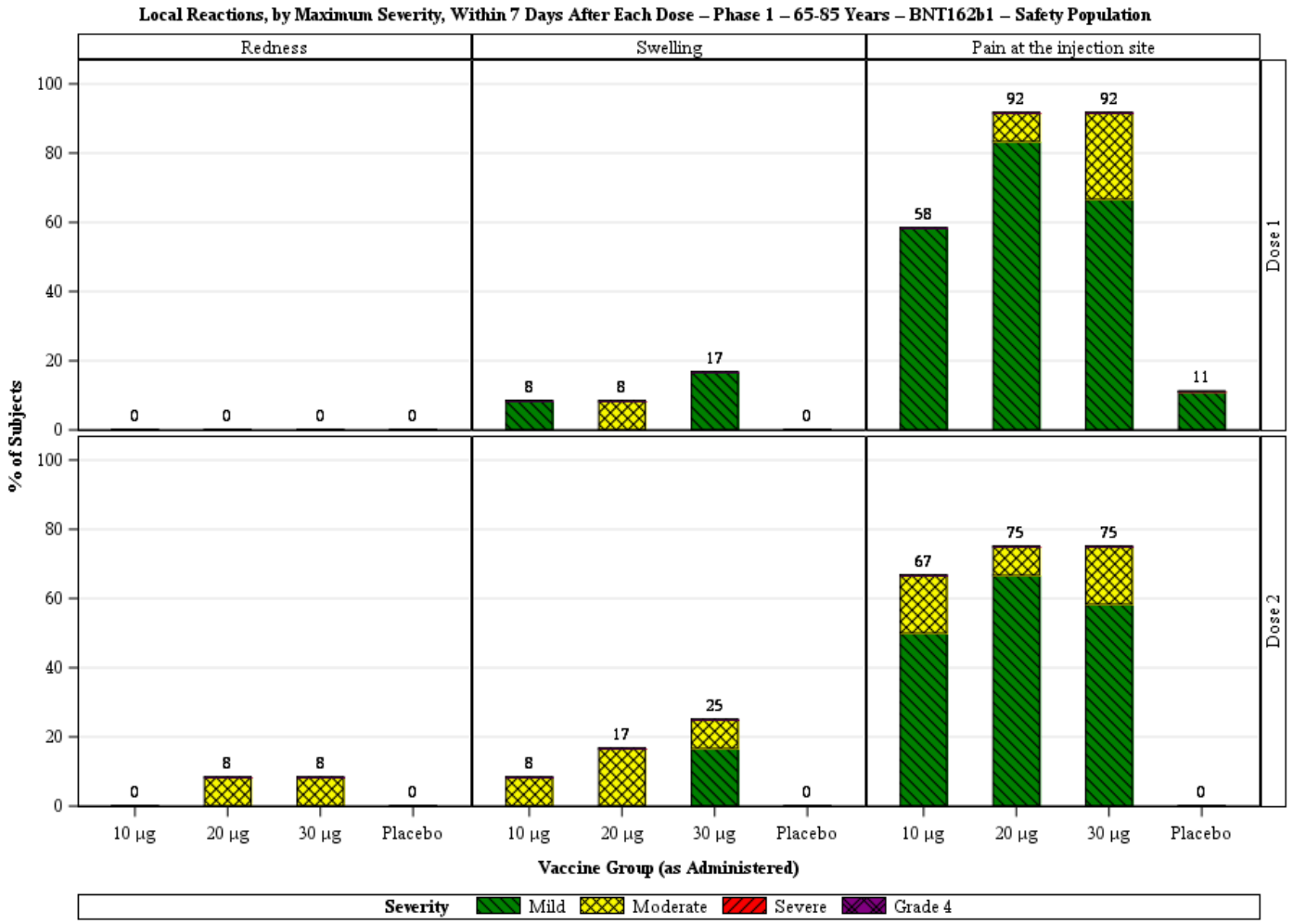
Overall, for BNT162b1 recipients and in both age groups, pain at the injection site was the most frequent local reaction (58.3% to 100.0%), and redness (0% to 16.7%) and swelling (0% to 25.0%) occurred at a lower frequency. Notably, the frequency of local reactions was lower in the older age group compared to the younger age group, and there was a trend of a higher frequency of local reactions with increased dose.

Figure 18. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:52)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_lr_maxsev_18_b1_p1

Figure 19. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:51)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_lr_maxsev_65_b1_p1

In the younger age group, pain at the injection site had median onset day of Day 1.0 (day of vaccination) after either dose of BNT162b1 across doses 10 µg to 30 µg and after Dose 1 of BNT162b1 100 µg (Supplemental Tables 14.108 and 14.109, respectively). Median onset day for redness and swelling was between Day 1.0 and Day 3.0 in all dose groups.

In the older age group, pain at the injection site had median onset day of Day 1.0 (day of vaccination) after Dose 1 of BNT162b1 across all dose groups and after Dose 2 for the 20-µg and 30-µg dose groups (median onset day was on Day 1.5 in the 10-µg dose group after Dose 2) (Supplemental Table 14.110). With the exception of redness on Day 4 (20-µg dose group) and Day 5 (30-µg dose group) in 1 participant each after Dose 2, all other local reactions of redness or swelling reported had median onset day between Day 1.0 and Day 3.0 for all dose groups.

Local reactions resolved with median durations between 1.0 and 4.0 days in the younger age group (Supplemental Tables 14.111 and 14.112) and older age group (Supplemental Table 14.113) across dose levels.

BNT162b2

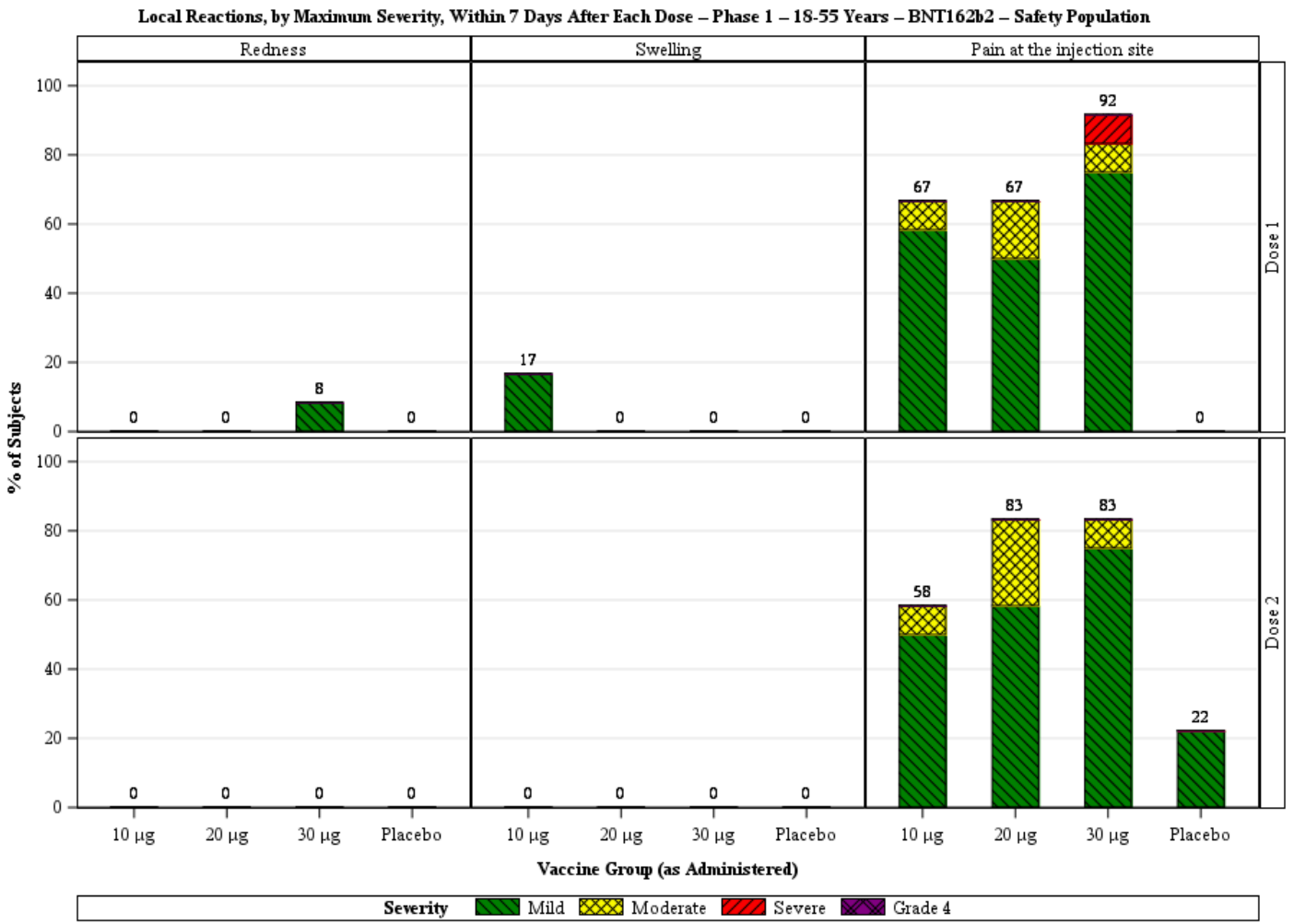
In the younger age group, pain at the injection site was the most frequently reported local reaction within 7 days after Dose 1, which was maximal in the 30-µg dose group (11 [91.7%] participants) (Figure 20 and Supplemental Table 14.114). One [8.3%] participant had severe injection site pain after Dose 1 of 30 µg. Most participants did not report swelling and redness. After Dose 2, pain at the injection site remained the most frequently reported local reaction (83.3%, 10 participants in each) in the 20-µg and 30-µg dose groups compared to the placebo group (2 [22.2%] participants). No participants reported redness and swelling for any dose group including placebo.

In the older age group, pain at the injection site was reported within 7 days after Dose 1 of BNT162b2 in all dose groups and was maximal in the 30-µg dose group (75.0%, 9 participants), while no redness and swelling was reported in any group (Figure 21 and Supplemental Table 14.115). Local reactions were not reported in the placebo group. After Dose 2, pain at the injection site (8 [66.7%] participants) was reported in the 30-µg group compared to the placebo group (9 [11.1%] participants); no participants who received BNT162b2 or placebo reported redness and swelling.

After the first and second dose and in both age groups, the majority of local reactions were mild or moderate in severity, and no Grade 4 local reactions were reported.

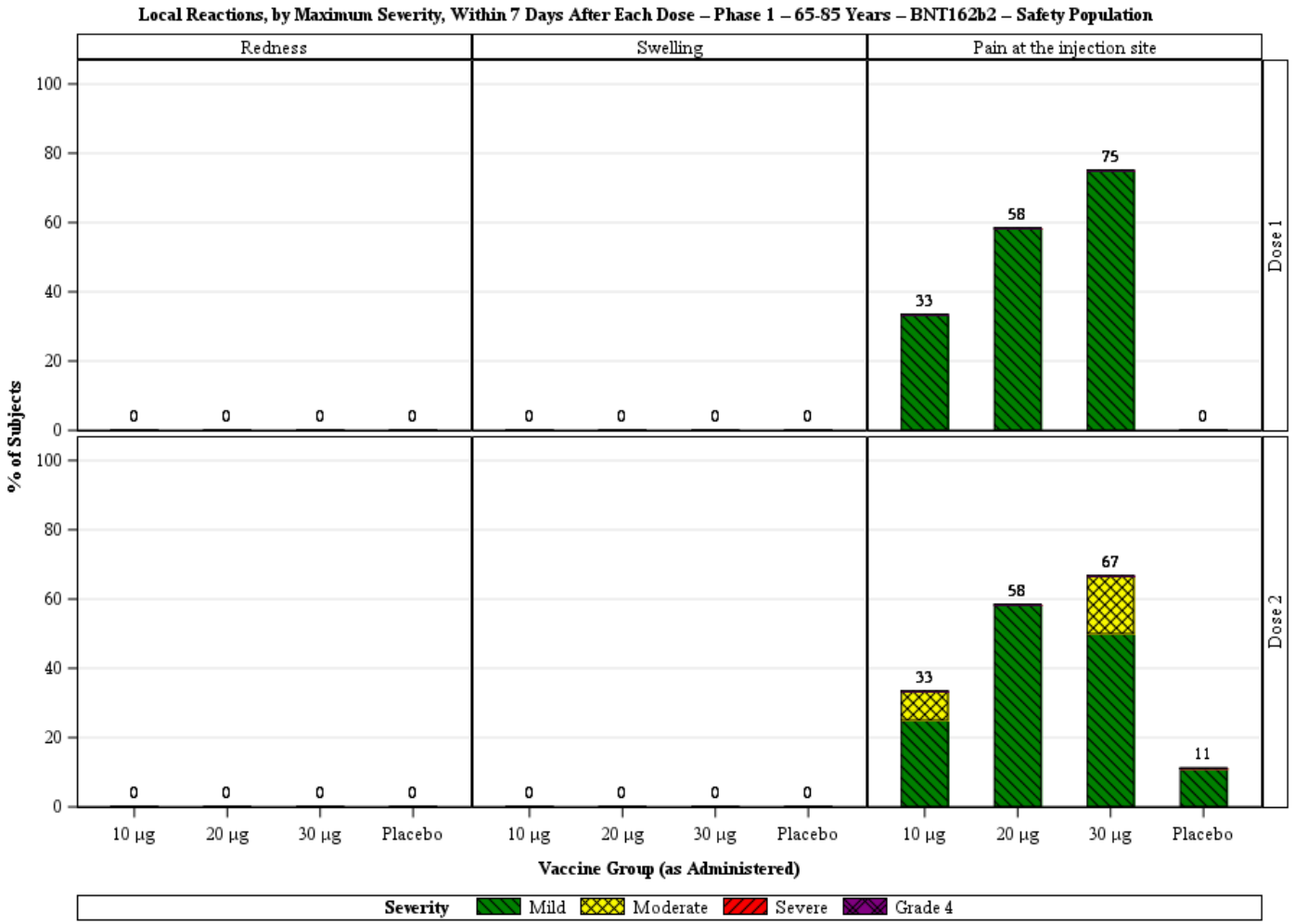
Overall, for BNT162b2 recipients and in both age groups, pain at the injection site was the most frequent local reaction (33.3% to 91.7%), and redness (0% to 8.3%) and swelling (0% to 16.7%) were infrequent. The frequency of local reactions was lower in the older age group compared to the younger age group, and there was a trend of a higher frequency of local reactions with increased dose.

Figure 20. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:51)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_lr_maxsev_18_b2_p1

Figure 21. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:51)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_lr_maxsev_65_b2_p1

In the younger age group, median onset day for local reactions occurred between Day 1.0 (day of vaccination) to Day 2.0 after any dose of BNT162b2 across any dose level (Supplemental Table 14.116). In the older age group, median onset day for local reactions occurred between Day 1.0 (day of vaccination) to Day 2.0 after any dose of BNT162b2 across any dose level (Supplemental Table 14.117). Local reactions generally resolved with median durations between 1.0 to 2.0 days in the younger and older age groups across dose levels (Supplemental Tables 14.118 and 14.119, respectively).

12.1.2. Systemic Events – Phase 1

Overall, within 7 days after Dose 1, fatigue was generally the most frequently reported systemic event in the both the younger and older BNT162b1 groups and in the older BNT162b2 group; while headache and fatigue were most frequently reported in the younger BNT162b2 dose group. Overall, within 7 days after Dose 2, headache was the most frequently reported systemic event in the both the younger and older BNT162b1 groups and fatigue was the most frequently reported systemic event in the both the younger and older BNT162b2 groups. Chills was generally reported at a higher frequency after Dose 2 and at a higher frequency in the BNT162b1 group than in the BNT162b2 group. Fever was reported more frequently in the younger BNT162b1 group after Dose 2 than in the older BNT162b2 group. For both the BNT162b1 and the BNT162b2 recipients, after the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity, and no Grade 4 systemic events were reported.

BNT162b1

In the younger age group, fatigue was the most frequently reported systemic event within 7 days after Dose 1 of BNT162b1, reported by 4 (33.3%), 8 (66.7%), and 6 (50.0%) participants in the 10-µg, 20-µg, and 30-µg dose groups, respectively (Figure 22 and Supplemental Table 14.120), compared to the placebo group (2 [22.2%] participants). Headache (6 [50.0%] participants) and chills (7 [58.3%] participants) were reported in the 30-µg dose group, and ≤1 (8.1%) participant reported fever in each group through 30 µg. In the placebo group, headache (1 [11.1%]) participant) was reported and none reported fever or chills. In the 100-µg dose group, higher frequencies were reported compared to the 30-µg dose group: fatigue (10 [83.3%] participants), headache (9 [75.0%] participants), chills (10 [83.3%] participants), and fever (6 [50.0%] participants) (Supplemental Table 14.121).

Within 7 days after Dose 2 of BNT162b1 in the younger age group, headache was the most frequently reported systemic event, reported by all 12 (100.0%) participants in the 30-µg dose group compared to none in the placebo group, while fatigue and chills were reported by 10 (83.3% participants) and 8 (66.7%) participants in the 30-µg dose group, respectively. Fever was reported in 17% and 75% of participants in the 20-µg and 30-µg dose groups, respectively. In the placebo group, 2 (22.2%) participants reported fatigue, and none reported fever and chills.

In the older age group, fatigue was the most frequently reported systemic event within 7 days after Dose 1 of BNT162b1, with 7 (58.3%) and 6 (50.0)% of participants reporting fatigue in the 20-µg and 30-µg dose groups, respectively (Figure 23 and Supplemental Table 14.122),

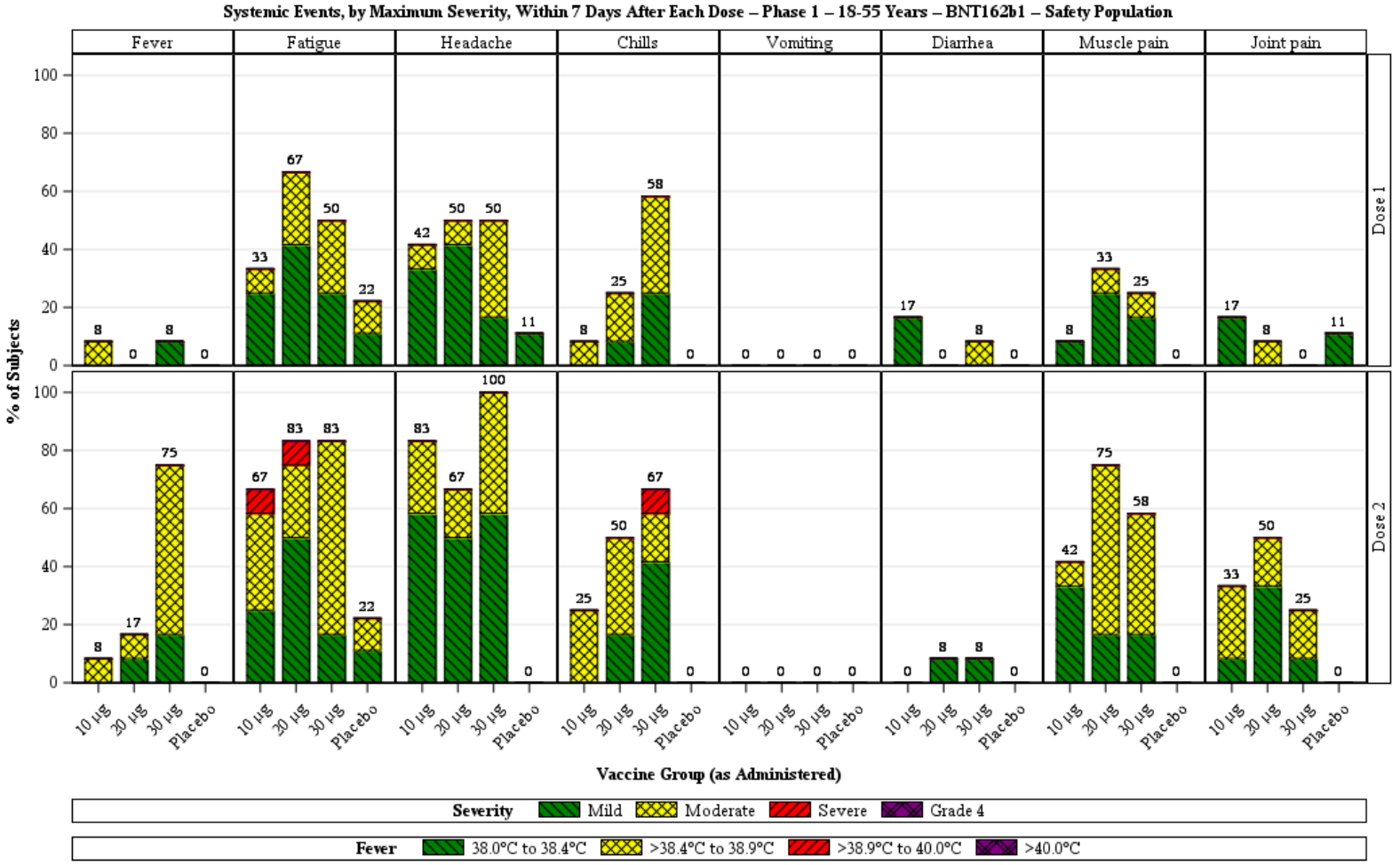
compared to 4 (44.4%) participants in the placebo group. Headache (6 [50.0%] participants) and chills (2 [16.7%] participants) were reported in the 30-µg dose group, and fever (3 [25.0%] participants) was reported only in the 30-µg dose group. In the placebo group, chills (2 [22.2%] participants) was reported and none reported headache or fever. One participant each reported severe muscle pain (20-µg dose group) and severe fatigue (30-µg dose group) (the former was pain related to onset of herpes zoster).

Within 7 days after Dose 2 of BNT162b1 in the older age group, headache was the most frequent systemic event reported in both the 20-µg and 30-µg dose groups (9 [75.0%] participants each) compared to the placebo group (1 [11.1%] participant). Chills was reported in 7 (58.3%) and 4 (33.3%) participants at the 20-µg and 30-µg dose groups, respectively. Fever was reported in 6 (50.0%) participants in the 20-µg dose group and in 4 (33.3%) participants in the 30-µg dose group, with 1 participant reporting fever >38.9°C to 40.0°C. In the placebo group, fatigue (2 [22.2%] participants) was reported and none reported fever and chills.

After the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity, and no Grade 4 systemic events were reported. In the older age group, prompted systemic events after each dose were milder and less frequent than those observed in the younger age group.

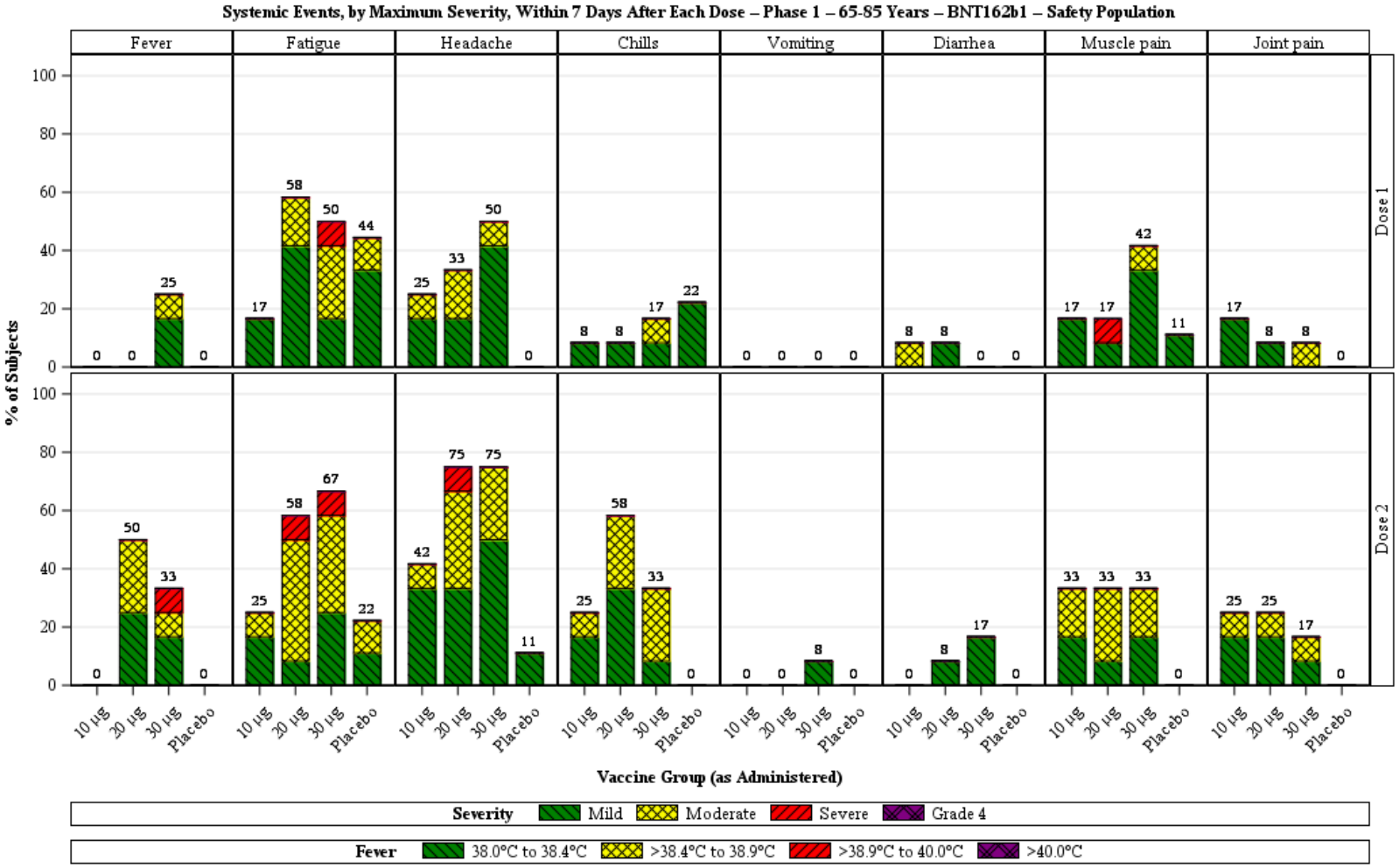
Systemic events had the highest frequency and/or severity with the 100-µg dose group after Dose 1. Use of antipyretic/pain medication also increased with increasing dose level and number of doses in both age groups. For these reasons, the IRC decided that the younger age group participants should not receive a second dose of 100 µg of BNT162b1.

Figure 22. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:51)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_se_maxsev_18_b1_p1

Figure 23. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:51)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_se_maxsev_65_b1_p1

In the younger age group, median onset day for most systemic events after either dose of BNT162b1 across doses 10 µg to 30 µg and after Dose 1 of BNT162b1 100 µg was between Day 1.0 and Day 2.0 (Supplemental Table 14.123 and 14.124, respectively). Most systemic events generally resolved with median durations between 1.0 to 2.0 days (Supplemental Table 14.125 and 14.126). For fatigue, median duration after Dose 1 was 4.0 days in the 10-µg dose group compared with 2.0 days in the 30-µg dose group. The median duration of fever and chills was 1.0 day for participants in the 30 µg group.

In the older age group, median onset day for most systemic events after either dose of BNT162b1, and across any dose group, was between Day 1.0 and Day 3.5 (Supplemental Table 14.127). Most systemic events generally resolved with median durations between 1.0 to 3.0 days (Supplemental Table 14.128). The median duration of fever was 1.0 day for participants in the 30 µg group. The median duration of chills was 2.0 days in 2 participants after Dose 1 and 1.5 days in 4 participants after Dose 2 in the 30 µg group.

BNT162b2

In the younger age group, headache (4 [33.3%] to 6 [50.0%] participants) and fatigue (3 [25.0%] to 5 [41.7%] participants) were the most frequently reported systemic events within 7 days after Dose 1 of BNT162b2 compared to the placebo group (3 [33.3%] participants each) (Figure 24 and Supplemental Table 14.129). Fever (2 [16.7%] participants) and chills (4 [33.3%] participants) were reported only in the 30-µg dose group. One participant in the 30-µg group with a prior history of migraine reported a severe migraine headache on Day 7 after Dose 1 (Section 12.1.3.2.4).

Within 7 days after Dose 2 of BNT162b2 in the younger age group, fatigue was the most frequently reported systemic event in the 20-µg and 30-µg dose groups (7 [58.3%] and 9 [75.0%] participants, respectively) compared to the placebo group (5 [55.6%] participants). Headache (8 [66.7%] participants), chills (7 [58.3%] participants), and muscle pain (7 [58.3%] participants), and fever (2 [16.7%] participants) were reported in the 30-µg dose group. Of these events, fatigue (5 [55.6%] participants), headache (1 [11.1%] participant), and chills (1 [11.1%] participant) were reported in the placebo group, and none were reported for muscle pain.

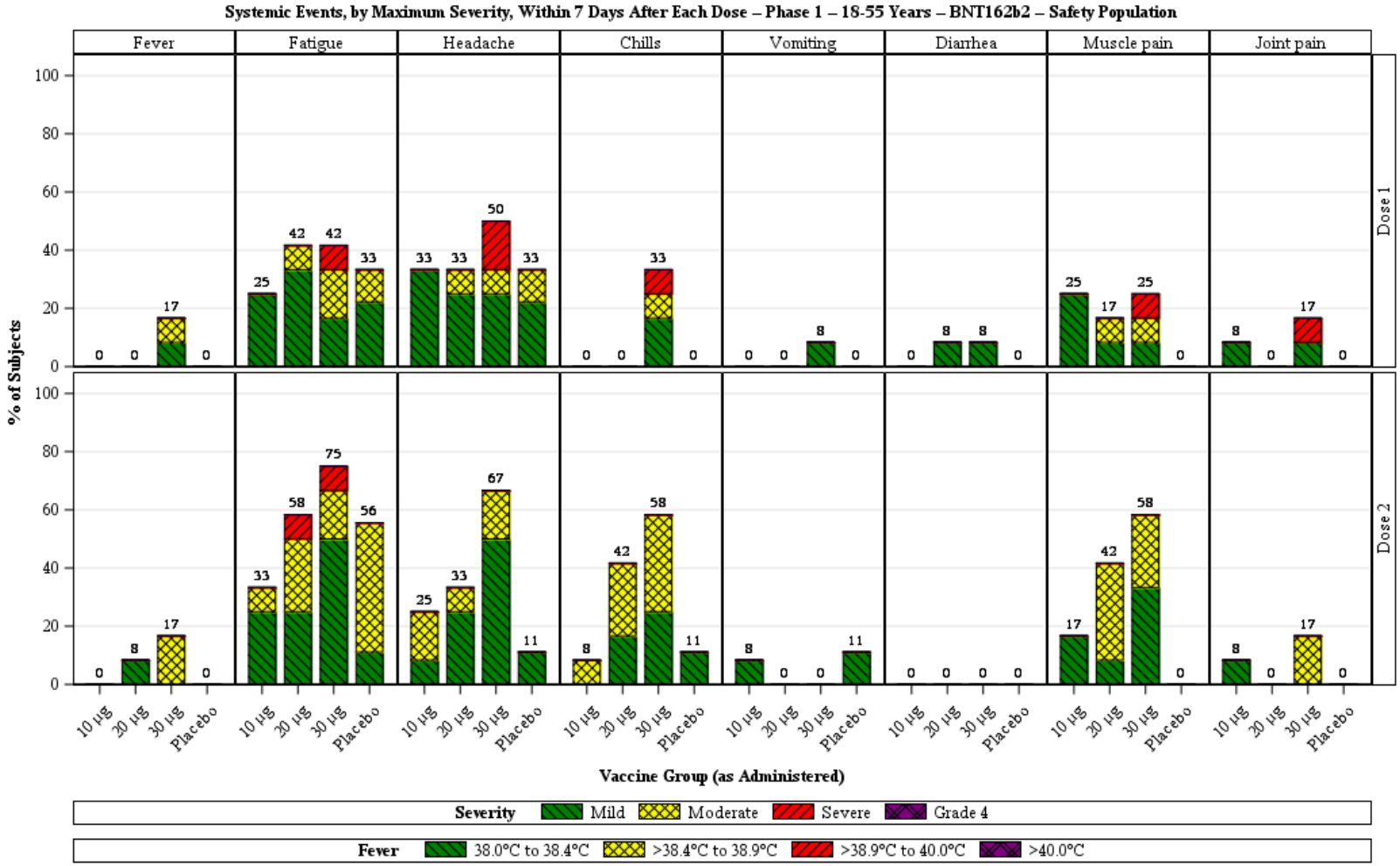
In the older age group, the most frequently reported systemic event within 7 days after Dose 1 of BNT162b2 was fatigue in the 20-µg and at 30-µg dose groups (4 [33.3%] and 3 [25.0%] participants, respectively) compared to the placebo group (2 [22.2%] participants) (Figure 25 and Supplemental Table 14.130). Headache (3 [25.0%] participants), chills (2 [16.7%] participants), and muscle pain (1 [8.3%] participant) were maximal in the 20-µg dose group. Of these events, only headache (1 [11.1%] participant) and muscle pain (2 [22.2%] participants) were reported in the placebo group. Fever was not reported.

Within 7 days after Dose 2 of BNT162b2 in the older age group, fatigue remained the most frequent systemic event in the 20-µg and 30-µg dose groups (6 [50.0%] and 5 [41.7%] participants, respectively), compared to the placebo group (1 [11.1%] participant). Headache was reported in the 20-µg and 30-µg dose groups (4 [33.3%] and 3 [25.0%] participants, respectively), while muscle pain and chills were reported in the 30-µg

dose group (3 [25.0%] and 2 [16.7%] participants, respectively). Fever (1 [8.3%] participant) was reported in the 30-µg dose group. Of these events, headache and muscle pain were reported in the placebo group (1 [11.1%] participant each).

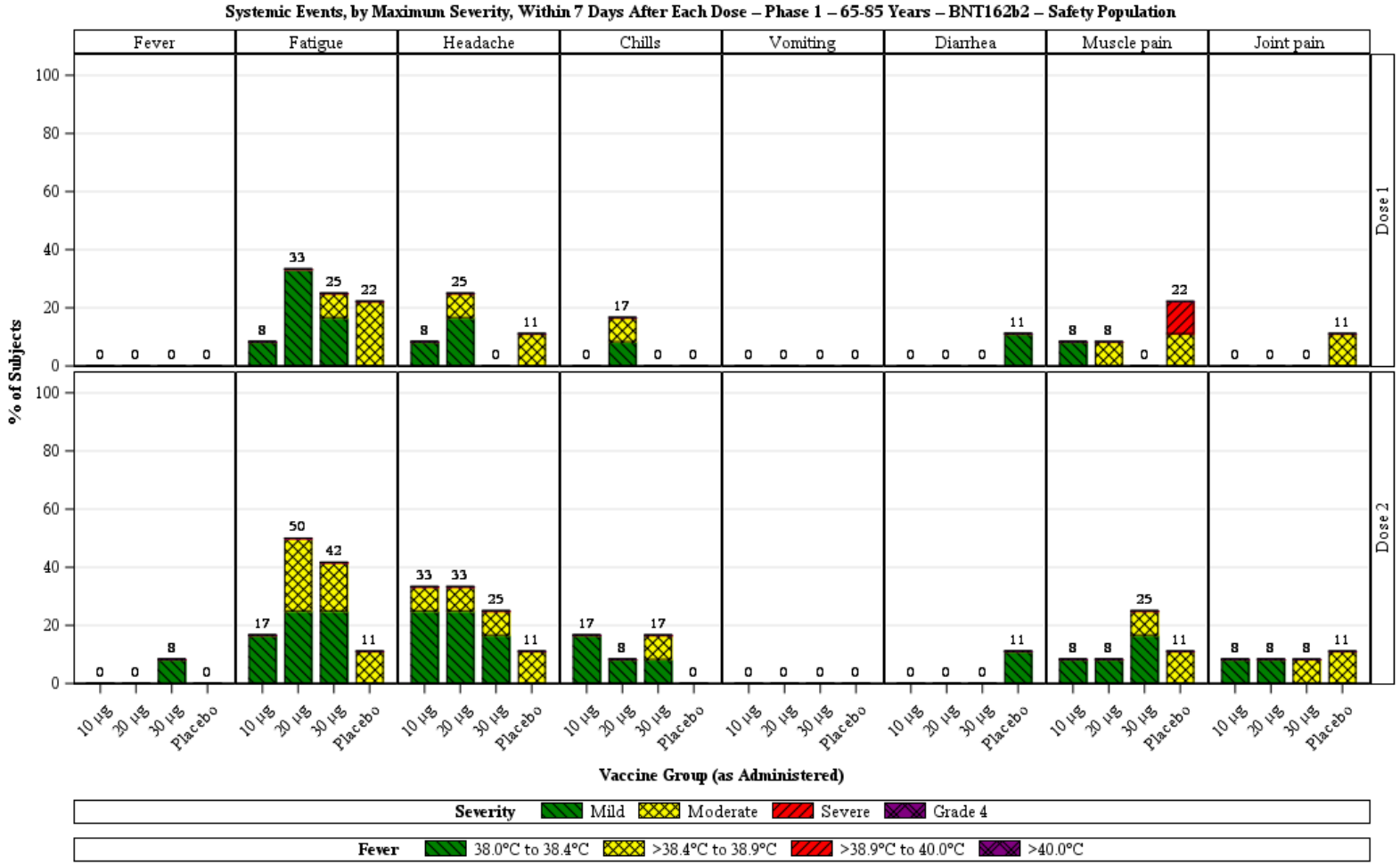
After the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity, and no Grade 4 systemic events were reported.

Figure 24. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:51)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_se_maxsev_18_b2_p1

Figure 25. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:52)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_f001_se_maxsev_65_b2_p1

In the younger age group, median onset day for most systemic events after either dose of BNT162b2, and across any dose group, was between Day 1.0 and Day 4.0 (Supplemental Table 14.131). Most systemic events generally resolved with median durations between 1.0 to 2.5 days (Supplemental Table 14.132). The median duration of fever and chills was 1.0 day for participants in the 30 µg group.

In the older age group, median onset day for any systemic event after either dose of BNT162b2, and across any dose level, was between Day 1.5 and Day 2.0, except for systemic events in the 10-µg dose group after Dose 1, which had a median onset day of Day 5.5 (Supplemental Table 14.133). Most systemic events generally resolved with median durations between 1.0 to 3.0 days (Supplemental Table 14.134). The median duration of fever was 1.0 day for participants in the 30 µg group. The median duration of chills was 2 days in 2 participants in the 30 µg group.

12.1.3. Adverse Events – Phase 1

12.1.3.1. Summary of Adverse Events – Phase 1

This section summarizes AEs reported up to 1 month after Dose 2 (as of 24 August 2020) for BNT162b1 and BNT162b2 (all dose levels). Additionally, long-term follow-up (approximately 4 months after Dose 2 [as of cutoff date 14 November 2020]) are presented for BNT162b2 30-µg. AEs reported up to 1 month after Dose 2 (as of 24 August 2020) are summarized first, followed by additional safety follow-up for BNT162b2 30-µg.

12.1.3.1.1. Up to 1 Month After Dose 2

All AEs from Dose 1 through the data cutoff date of 24 August 2020 were included in the summary for all dose levels for each vaccine candidate and age group other than BNT162b1 100-µg group for which AEs from Dose 1 to before Dose 2 were summarized.

Overall, fewer participants reported at least 1 AE after Dose 1 in the older BNT162b2 group (8.3% to 25.0%) compared to the younger (41.7% to 50.0%) and older (25.0% to 58.3%) BNT162b1 groups and the younger BNT162b2 group (33.3% to 41.7%).

BNT162b1

In the younger age group, 5 (41.7%) to 6 (50%) participants reported at least 1 AE after Dose 1 of BNT162b1 up to 30 µg, compared to 2 (22.2%) participants in the placebo group (Supplemental Table 14.135). Related AEs increased with increasing BNT162b1 dose level (25.0% to 50.0%); six (50%) participants reported at least 1 related AE in the 30-µg dose group. One (8.3%) participant reported a severe AE (pyrexia) in the 30-µg dose group (Section 12.1.3.2.4).

In the 100-µg dose group, 8 (66.7%) participants reported at least 1 AE after Dose 1 to before Dose 2 of BNT162b1, compared to 1 (33.3%) participant in the placebo group (Supplemental Table 14.136). Six (50.0%) participants had at least 1 related AE, and 1 (8.3%) participant reported a severe AE (sleep disorder) (Section 12.1.3.2.4).

In the older group, 3 (25.0%) participants (30-µg dose group) and 7 (58.3%) participants each (10-µg and 20-µg dose groups) reported at least 1 AE after Dose 1 of BNT162b1, compared to 4 (44.4%) participants in the placebo group (Supplemental Table 14.137). Two (16.7%) to 4 (33.3%) participants reported at least 1 related AE, with the highest frequency in the 20-µg dose group. One participant each reported a severe AE in the 20-µg (herpes zoster) and 30-µg (fatigue) dose groups (Section 12.1.3.2.4).

No SAEs, AEs leading to withdrawals, or deaths were reported in either age group.

BNT162b2

In the younger age group, 4 (33.3%) to 5 (41.7%) participants reported at least 1 AE after Dose 1 of BNT162b2, compared to 2 (22.2%) participants in the placebo group (Supplemental Table 14.138). Two (16.7%) to 4 (33.3%) participants reported at least 1 related AE, with the highest frequency in the 20-µg dose group. One participant reported a severe AE (migraine) in the 30-µg dose group (Section 12.1.3.2.4).

In the older group, 1 (8.3%) to 3 (25.0%) participants reported at least 1 AE after Dose 1 of BNT162b2, compared to 2 (22.2%) participants in the placebo group (Supplemental Table 14.139). Only 1 (8.3%) participant reported at least 1 related AE (20-µg dose group). One participant each reported a severe AE in the 30-µg dose group (muscle spasms) and placebo group (radiculopathy) (Section 12.1.3.2.4).

No SAEs, AEs leading to withdrawals, or deaths were reported in either age group.

12.1.3.1.2. Through the Data Cutoff Date (BNT162b2 30-µg)

A summary of the number of participants reporting at least 1 AE from Dose 1 through the data cutoff date (14 November 2020) for younger and older participants who received BNT162b2 30-µg is presented in Supplemental Tables 14.140 and 14.141, respectively. During the additional follow-up from 1 month after to 4 months after Dose 2 to the data cutoff date (14 November 2020), 1 severe SAE (neuritis; due to an antecubital fossa blood draw) was reported in the younger age group (Section 12.1.3.2.1.2). No additional AEs were reported in the younger or older age group during the time period of 1 month after Dose 2 (29 August 2020) through approximately 4 months after Dose 2 (data cutoff 14 November 2020).

12.1.3.2. Analysis of Adverse Events – Phase 1

12.1.3.2.1. Adverse Events by System Organ Class and Preferred Term – Phase 1

12.1.3.2.1.1. Up to 1 Month After Dose 2/3 Weeks After Dose 1 (BNT162b2 100 µg Group)

AE by SOC and PT summaries in this section included AEs from Dose 1 to 1 month after Dose 2 for all groups other than BNT162b1 100-ug group for which AEs from Dose 1 to 3 weeks after Dose 1 or from Dose 1 to before Dose 2 were summarized.

General disorders and administration site conditions was the most commonly reported SOC in the older BNT162b1 group and the younger BNT162b2 group. The most commonly

reported SOC was gastrointestinal disorders in the younger BNT162b1 group and nervous system disorders in the older BNT162b2 group. Generally, most PTs were reported by ≤2 participants per dose group.

BNT162b1

In the younger age group, from Dose 1 to 1 month after Dose 2 of BNT162b1, gastrointestinal disorders was the most commonly reported SOC (2 [16.7%] participants each dose group) in the BNT162b1 groups up to 30 µg (Supplemental Table 14.142). In the 20-µg dose group only, paraesthesia (3 [25.0%]) was the most common AE by PT. All other AEs were reported by ≤2 participants per dose group, including those in the placebo group.

In the 100-µg dose group, from Dose 1 to 3 weeks after Dose 1 of BNT162b1, psychiatric disorders was the most commonly reported SOC (3 [25.0%] participants), and sleep disorder (3 [25%] participants) was the most common AE by PT (Supplemental Table 14.143). All other AEs were reported by ≤2 participants, including those in the placebo group.

In the older age group, from Dose 1 to 1 month after Dose 2 of BNT162b1, general disorders and administration site conditions was the most commonly reported SOC in the BNT162b1 groups, reported in a total of 6 participants: 1 (8.3%) participant in the 10-µg dose group, 2 (16.7%) participants in the 20-µg dose group, and 3 (25.0%) participants in the 30-µg dose group (Supplemental Table 14.144). Any AEs by PT were reported by no more than 1 participant per dose group.

BNT162b2

In the younger age group, general disorders and administration site conditions was the most commonly reported SOC (Supplemental Table 14.145). These events included injection site pain and injection site erythema. Any AEs by PT were reported by no more than 1 participant per dose group.

In the older age group, nervous system disorders was the most commonly reported SOC, reported in 1 participant each in the 30-µg group (sciatica) and the placebo group (radiculopathy) (Supplemental Table 14.146). Any AEs by PT were reported by no more than 1 participant per dose group.

12.1.3.2.1.2. Through the Data Cutoff Date (BNT162b2 30-µg)

The number of participants reporting at least 1 AE from Dose 1 to the data cutoff date (14 November 2020) by SOC and PT for younger and older participants who received BNT162b2 30-µg is presented in Supplemental Tables 14.147 and 14.148, respectively.

Additional follow-up from 1 month to 4 months after Dose 2 to the data cutoff date (14 November 2020) included 1 severe SAE (neuritis) reported by 1 participant in the younger BNT162b2 30-µg group; per the participant's medical examination and history, this event was linked to a blood draw, and the investigator considered there was a reasonable possibility that the event neuritis was related to clinical trial procedure (blood draw) but unrelated to vaccination. The AE profile for remaining non-serious events was unchanged.

12.1.3.2.2. Related Adverse Events – Phase 1

12.1.3.2.2.1. Up to 1 Month After Dose 2/3 Weeks After Dose 1 (BNT162b2 100 µg Group)

Overall, general disorders and administration site conditions was the most commonly reported SOC for the younger and older BNT162b1 groups and the younger BNT162b2 group. In the older BNT162b2 group, nausea, reported in 1 (8.3%) participant, was the only related AE.

BNT162b1

In the younger age group, general disorders and administration site conditions was the most commonly reported SOC (injection site pain, pyrexia, chills, fatigue, and injection site swelling) (Supplemental Table 14.149). Two (16.7%) participants each in the 30-µg dose group reported related AEs of tachycardia and pyrexia. All other related AEs were reported by ≤2 participants per dose group.

In the 100-µg BNT162b1 group, psychiatric disorders were the most commonly reported SOC (Supplemental Table 14.150). Three (25.0%) participants reported sleep disorder as their psychiatric disorder. All other related AEs were reported by ≤2 participants each.

In the older age group, general disorders and administration site conditions was the most commonly reported SOC (fatigue, injection site bruising, injection site pain, and peripheral swelling) (Supplemental Table 14.151). Any related AEs by PT were reported by no more than 1 participant per dose group.

BNT162b2

In the younger age group, general disorders and administration site conditions was the most commonly reported SOC (injection site pain and injection site erythema) (Supplemental Table 14.152). Any related AEs by PT were reported by no more than 1 participant per dose group, including those in the placebo group.

In the older age group, only 1 (8.3%) participant reported a related AE of nausea in the 20-µg dose group (Supplemental Table 14.153).

12.1.3.2.2.2. Through the Data Cutoff Date (BNT162b2 30-µg)

Additional follow-up from 1 month after to 4 months after Dose 2 to the data cutoff date (14 November 2020) did not identify any additional participants with related AEs.

12.1.3.2.3. Immediate Adverse Events – Phase 1

BNT162b1

In the younger age group, 1 participant reported an immediate AE of paraesthesia after Dose 1 of 20 µg BNT162b1 (Supplemental Table 14.154). In the 100-µg group, no participants reported an immediate AE after Dose 1.

In the older age group, 1 participant reported an immediate AE of eye paraesthesia after Dose 1 of 10 µg BNT162b1 (Supplemental Table 14.155).

There were no participants in either age group who reported any immediate AEs after Dose 2 of BNT162b1 (Appendix 16.2.7.4.1).

BNT162b2

In the younger age group, after Dose 1 of BNT162b2, there were 3 participants who reported an immediate AE: injection site erythema (10-µg dose group), ageusia (20-µg dose group), and injection site pain (30-µg dose group) (Supplemental Table 14.156). After Dose 2 of BNT162b2, there was 1 participant who reported an immediate AE of taste disorder (20-µg dose group) (Supplemental Table 14.157).

There were no participants in the older age group who reported any immediate AE after any dose of BNT162b2 (Appendix 16.2.7.4.1).

12.1.3.2.4. Severe Adverse Events – Phase 1

12.1.3.2.4.1. Up to 1 Month After Dose 2/3 Weeks After Dose 1 (BNT162b2 100 µg Group)

BNT162b1

In the younger age group, there was 1 participant who reported a severe AE of pyrexia (102.4°F) 2 days after Dose 2 (30-µg dose group) (Supplemental Table 14.158 and Appendix 16.2.7.4.1) and 1 participant who reported a severe AE of sleep disorder 1 day after Dose 1 (100-µg dose group) (Supplemental Table 14.159 and Appendix 16.2.7.4.1.1). Both AEs were determined by the investigator to be related to study intervention.

In the older age group, 2 participants reported a severe AE: herpes zoster which occurred 2 days after Dose 1 (20-µg dose group, considered unrelated to BNT162b1) and fatigue 1 day after Dose 2 (30-µg dose group, considered related to BNT162b1) (Supplemental Table 14.160 and Appendix 16.2.7.4.1).

BNT162b2

In the younger age group, 1 participant with a history of migraines reported a severe migraine 7 days after Dose 1 (30-µg dose group, considered unrelated) (Supplemental Table 14.161 and Appendix 16.2.7.4.1). In the older age group, 2 participants reported a severe AE: muscle spasms 2 days after Dose 2 (30-µg dose group, considered unrelated to BNT162b2) and radiculopathy 3 days after Dose 1 (placebo), considered unrelated to study intervention (Supplemental Table 14.162 and Appendix 16.2.7.4.1).

12.1.3.2.4.2. Through the Data Cutoff Date (BNT162b2 30-µg)

From additional follow-up from 1 month after to 4 months after Dose 2 to the data cutoff date (14 November 2020), 1 severe SAE (neuritis; due to an antecubital fossa blood draw) was reported in the younger age group (Section 12.1.3.2.1.2).

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

12.1.4.1. Deaths – Phase 1

There were no Phase 1 participants who died through the data cutoff date of 24 August 2020 in this interim CSR (Appendix 16.2.7.7.1 and Appendix 16.2.7.7.1.1).

12.1.4.2. Serious Adverse Events – Phase 1

There were no Phase 1 participants who reported any SAEs from Dose 1 through the data cutoff date of 24 August 2020 (Appendix 16.2.7.5.1 and Appendix 16.2.7.5.1.1). From additional follow-up from 1 month after to 4 months after Dose 2 to the data cutoff date (14 November 2020), 1 severe SAE (neuritis) was reported in the younger age group (Section 12.1.3.2.1.2).

12.1.4.3. Safety-Related Participant Withdrawals – Phase 1

There were no Phase 1 participants with any AEs leading to withdrawal from the study through the data cutoff date of 24 August 2020 in this interim CSR (Appendix 16.2.7.6.1 and Appendix 16.2.7.6.1.1).

12.1.4.4. Other Significant Adverse Events – Phase 1

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

12.1.4.5. Other Safety Assessments – Phase 1

12.1.4.5.1. Severe COVID-19 Illness – Phase 1

There were no COVID-19 cases reported in the Phase 1 participants through the data cutoff date of 24 August 2020.

12.1.4.5.2. Pregnancy – Phase 1

Pregnancy was not reported in any Phase 1 participants through the data cutoff date of 24 August 2020.

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

During the period covered in this interim CSR, there were no SAEs, AEs leading to withdrawals, or deaths reported in either age group.

12.1.5. Clinical Laboratory Evaluation – Phase 1

Overall, 1 to 3 days after Dose 1, there were transient decreases in lymphocytes (<0.8 × LLN), which returned to normal by 6 to 8 days after Dose 1, in the younger and older BNT162b1 and BNT162b2 groups. Most shifts were from normal or Grade 1 to Grade 1, 2, or 3 decrease in lymphocyte counts, which returned to normal by 6 to 8 days after Dose 1 and were observed in all age and dose groups. The incidence of decreased lymphocyte counts was lower for BNT162b2 recipients compared with BNT162b1 recipients. Shifts from

normal to Grade 1 (younger BNT162b1 group) or Grade 2 (older BNT162b2 group) neutrophil decrease were also observed but were infrequent.

Overall, clinical chemistry and other hematology abnormalities reported or shifts of laboratory results were infrequent. None of the laboratory abnormalities were associated with clinical findings.

BNT162b1

In the younger age group, laboratory abnormalities of transient decreases in lymphocytes (<0.8 × LLN) were observed in 1 (8.3%), 4 (33.3%), and 6 (54.5%) of participants 1 to 3 days after Dose 1 of BNT162b1 10 µg, 20 µg, or 30 µg, respectively, which returned to normal by 6 to 8 days after Dose 1 (Supplemental Table 14.163). A shift from normal to Grade 3 decrease in lymphocyte counts was observed in 1 participant each in the 10-µg and 30-µg dose groups and 2 (16.7%) participants the 20-µg dose group (Supplemental Table 14.164). No Grade 3 decrease in lymphocyte counts was observed by 6 to 8 days after Dose 1. After Dose 1, a shift from normal to Grade 2 neutrophil decrease was observed in 1 (11.1%) participant in the placebo group, which was not observed by 19 to 23 days after Dose 1. At 6 to 8 days after Dose 2, a shift in neutrophil decrease was observed in 1 participant each in the 10-µg dose group (Grade 1 to Grade 2) and in the 30-µg dose group (normal to Grade 2). Both participants had a shift to Grade 1 at the unplanned visit approximately 1 month after Dose 2 (Appendix 16.2.8.1.1).

In the 100-µg BNT162b1 group, laboratory abnormalities of transient decreases in lymphocytes (<0.8 × LLN) were observed in 9 (75.0%) participants 1 to 3 days after Dose 1, which returned to normal by 6 to 8 days after Dose 1 (Supplemental Table 14.165). A shift from normal to Grade 3 decrease in lymphocyte counts was observed in 4 (33.3%) participants 1 to 3 days after Dose 1, which returned to normal by 6 to 8 days after Dose 1 (Supplemental Table 14.166). A shift from normal to Grade 1 neutrophil decrease was observed in 3 (25.0%) participants at 6 to 8 days after Dose 1, which returned to normal by 19 to 23 days after Dose 1.

In the older age group, laboratory abnormalities of transient decreases in lymphocytes (<0.8 × LLN) were also observed in 1 (8.3%), 3 (25.0%), and 2 (16.7%) participants 1 to 3 days after Dose 1 of BNT162b1 10 µg, 20 µg, or 30 µg, respectively, which returned to normal by 6 to 8 days after Dose 1 (Supplemental Table 14.167). At 1 to 3 days after Dose 1 of BNT162b1, shifts from normal to Grade 3 or Grade 4 decrease in lymphocyte counts were observed in 1 (8.3%) participant each in the 30-µg and 10-µg dose groups, respectively, and both returned to normal by 6 to 8 days after Dose 1 (Supplemental Table 14.168).

Overall, clinical chemistry and other hematology abnormalities reported or shifts of laboratory results were infrequent. None of the abnormalities were associated with clinical findings.

BNT162b2

In the younger age group, laboratory abnormalities of transient decreases in lymphocytes (<0.8 × LLN) were observed in 1 (8.3%) participant each 1 to 3 days after Dose 1 of BNT162b2 in the 20-µg and 30-µg dose groups, which returned to normal by 6 to 8 days after Dose 1 (Supplemental Table 14.169). At 1 to 3 days after Dose 1 of BNT162b2, shifts from normal to Grade 1 decrease in lymphocyte counts were observed in 3 (25.0%), 2 (16.7%), and 4 (33.3%) participants in the 10-µg, 20-µg, and 30-µg dose groups, respectively, and shifts from normal to Grade 2 decrease in lymphocyte counts were observed in 1 (8.3%) participant each in the 20-µg and 30-µg dose groups (Supplemental Table 14.170). By 6 to 8 days after Dose 1, no Grade 2 or Grade 3 decrease in lymphocyte counts were observed.

In the older age group, laboratory abnormalities of transient decreases in lymphocytes (<0.8 × LLN) were also observed in 1 (8.3%) participant each 1 to 3 days after Dose 1 of BNT162b2 across all dose levels, which returned to normal by 6 to 8 days after Dose 1 (Supplemental Table 14.171). A shift from normal to Grade 3 (10-µg dose group) and a Grade 1 to Grade 3 (30-µg dose group) decrease in lymphocyte counts was observed in 1 (8.3%) participant each after Dose 1 (Supplemental Table 14.172). A shift from normal to Grade 2 neutrophil decrease was observed in 2 (16.7%) participants in the 20-µg dose group at 1 to 3 days after Dose 1, and no shifts to Grade 2 were observed by 6 to 8 days after Dose 1. A shift from normal to Grade 2 neutrophil decrease was observed in 1 (8.3%) participant in the 10-µg dose group at 6 to 8 days after Dose 1. By 19 to 23 days after Dose 1, no shifts to Grade 2 neutrophil decrease were observed for any dose group.

Overall, clinical chemistry and other hematology abnormalities reported or shifts of laboratory results were infrequent. The incidence of decreased lymphocyte counts was lower for BNT162b2 recipients compared with BNT162b1 recipients. None of the laboratory abnormalities were associated with clinical findings.

12.1.6. Physical Examination Findings – Phase 1

Overall, there were fewer abnormalities noted during physical examinations after BNT162b2 than after BNT162b1 in both age groups. Abnormalities were generally observed 1 to 3 days after Dose 1 and most were of the extremities, musculoskeletal system, or skin.

BNT162b1

In the younger age group, there were no abnormalities noted during baseline physical examinations (Supplemental Table 14.173). Overall, after randomization, most abnormalities were observed 1 to 3 days after Dose 1 of 10 µg, 20 µg, or 30 µg BNT162b1 (9 [20.0%] participants) and 6 to 8 days after Dose 2 (7 [15.6%] participants) (Supplemental Table 14.174 and Appendix 16.2.5.2.1). In the 30-µg dose group, a maximum of 6 (50.0%) participants had abnormalities 1 to 3 days after Dose 1, and most abnormalities were of the extremities.

In the 100-µg dose group, only 1 (8.3%) participant had an abnormality at baseline (Supplemental Table 14.175 and Appendix 16.2.5.2.1.1). From Dose 1 to 3 weeks after

Dose 1, 9 (75.0%) participants had abnormalities 1 to 3 days after BNT162b1, and most abnormalities were of the extremities (Supplemental Table 14.176 and Appendix 16.2.5.2.1.1).

In the older age group, there were 5 (11.1%) participants with abnormalities noted during baseline physical examinations, with ≤2 participants in any dose group (Supplemental Table 14.177 and Appendix 16.2.5.2.1). Overall, after randomization, most abnormalities were observed 1 to 3 days after Dose 1 of BNT162b1 (15 [33.3%] participants) (Supplemental Table 14.178 and Appendix 16.2.5.2.1). In the 20-µg and 30-µg dose groups, 6 (50.0%) and 4 (33.3%) participants had abnormalities 1 to 3 days after Dose 1, and most abnormalities involved either the musculoskeletal system or extremities.

There were no clinically important findings from physical examinations.

BNT162b2

In the younger age group, there were 5 (11.1%) participants with abnormalities noted during baseline physical examinations, with ≤2 participants in any dose group (Supplemental Table 14.179 and Appendix 16.2.5.2.1). Overall, after randomization, most abnormalities were observed 1 to 3 days after Dose 1 of 10 µg, 20 µg, or 30 µg BNT162b2 (5 [11.1%] participants) and 6 to 8 days after Dose 2 (4 [8.9%] participants), with most being abnormalities of the extremities or skin (Supplemental Table 14.180 and Appendix 16.2.5.2.1).

In the older age group, there was 1 (8.3%) participant in the 30-µg dose group with an abnormality noted during the baseline physical examination (Supplemental Table 14.181 and Appendix 16.2.5.2.1). After randomization, ≤2 participants in any dose group overall had an abnormality in physical examination during any visit window (Supplemental Table 14.182).

There were no clinically important findings from physical examinations at baseline.

12.1.7. Phase 1 Summary of Safety Results Evaluating BNT162b1 and BNT162b2

Overall, reactogenicity events were well tolerated and short-lived (median durations 1.0 to 4.0 days). All participants returned to receive their second dose. All AEs as a result of reactogenicity events resolved without sequelae.

- For local reactions in both age groups, pain at the injection site (58.3% to 100.0%), redness (0% to 16.7%), and swelling (0% to 25.0%) were reported for BNT162b1 recipients, which were more frequent than for BNT162b2 recipients: pain at the injection site (33.3% to 91.7%), redness (0% to 8.3%), and swelling (0% to 16.7%). In general, frequencies of local reactions were observed to be higher with increased dose level.

- The frequency of local reactions was lower in the older age group compared to the younger age group. The frequency of pain at the injection site, the most frequently reported local reaction, was lower in the older age groups after 30 µg BNT162b1 (91.7% and 75.0%) and after 30 µg of BNT162b2 (75.0% and 66.7% for Dose 1 and Dose 2, respectively), compared to the younger age groups after 30 µg of BNT162b1

(100.0% for both Dose 1 and Dose 2) and 30 µg of BNT162b2 (91.7% and 83.3% for Dose 1 and Dose 2, respectively).

- BNT162b2 recipients in the older age group reported lower frequencies of local reactions compared with BNT162b1 recipients in the older age group. In the older 30-µg BNT162b2 group, pain at the injection site was lower after Dose 1 (75.0%) and Dose 2 (66.7%) than in the older 30-µg BNT162b1 group after Dose 1 (91.7%) and Dose 2 (75.0%).

- Common systemic events in both age groups after either Dose 1 or Dose 2 included fatigue (16.7% to 83.3%), headache (25.0% to 100%), chills (8.3% to 66.7%), fever (0% to 75.0%), and muscle pain (8.3% to 75.0%) for BNT162b1 recipients up to 30 µg, which were more frequent than BNT162b2 recipients up to 30 µg: fatigue (8.3% to 75.0%), headache (0% to 66.7%), chills (0% to 58.3%), fever (0% to 16.7%), and muscle pain (0% to 58.3%). In general, frequencies of systemic events were observed to be higher with increased dose level.

- The frequency of systemic events was lower in the older age group compared to the younger age group. The frequency of fatigue was lower in the older age groups after 30 µg of BNT162b1 (50.0% and 66.7%) and after 30 µg of BNT162b2 (25.0% and 41.7% for Dose 1 and Dose 2, respectively), compared to the younger age groups after 30 µg of BNT162b1 (50.0% and 83.3%) and after 30 µg of BNT162b2 (41.7% and 75.0%) for Dose 1 and Dose 2, respectively.

- BNT162b2 recipients in the older age group reported lower frequencies of systemic events compared with BNT162b1 recipients in the older age group. The frequency of fatigue was lower in the older 30-µg BNT162b2 group (25.0% and 41.7% for Dose 1 and Dose 2, respectively) than in the older 30-µg BNT162b1 group (50.0% and 66.7% for Dose 1 and Dose 2, respectively).

Most AEs were mild or moderate in severity. Most related AEs were similar to the solicited reactogenicity events reported in the e-diary. Few severe AE were reported but were considered not related to study intervention.

There were no SAEs reported in the BNT162b1 groups (across all dose levels). There was 1 SAE reported in the BNT162b2 30-µg younger age group (neuritis).

Transient decrease in lymphocytes were observed in all age and dose groups 1 to 3 days after Dose 1, which resolved by 6 to 8 days after Dose 1.

There were no clinically important findings from physical examinations.

BNT162b2 demonstrated a favorable reactogenicity and safety profile compared with BNT162b1, contributing to the selection of BNT162b2 for Phase 2/3 development.

12.1.8. Phase 1 Safety Conclusions

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

- Reactogenicity was generally higher after Dose 2 than Dose 1.

- The frequency of local and systemic reactogenicity was generally lower for BNT162b2 compared to BNT162b1 especially after the second dose.

- Reactogenicity events after each dose for both BNT162b1 and BNT162b2 in older adults were milder and less frequent than those observed in younger adults. The majority of reactogenicity events were mild or moderate in severity.

- Most AEs were mild or moderate. There were no discontinuations because of AEs. There was 1 severe SAE (neuritis; unrelated to vaccination) reported in a younger participant in the BNT162b2 30 µg group.

- Overall, fewer AEs were experienced by participants who received BNT162b2 compared with those who received BNT162b1, with the least number of participants experiencing AEs in the BNT162b2 older age group. Few severe AEs in the older age group after BNT162b2 were observed, and all were considered unrelated to study intervention.

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

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

12.2. Phase 2

Safety data are available up to the data cutoff date (02 September 2020) and are summarized up to the data cutoff date for the 360 participants in Phase 2. All participants in Phase 2 used an e-diary for reporting local reactions and systemic events.

12.2.1. Local Reactions – Phase 2

Local reactions across all age groups by maximum severity within 7 days after each dose are presented in Supplemental Figure 14.25 and Supplemental Table 14.213. After the first and second dose of BNT162b2 and in both age groups, the majority of local reactions were mild or moderate in severity, and no Grade 4 (potentially life-threatening) local reactions were reported.

In the BNT162b2 group, pain at the injection site was reported more frequently in the younger age group (N=88 post Dose 1; N=86 post Dose 2) than in the older age group

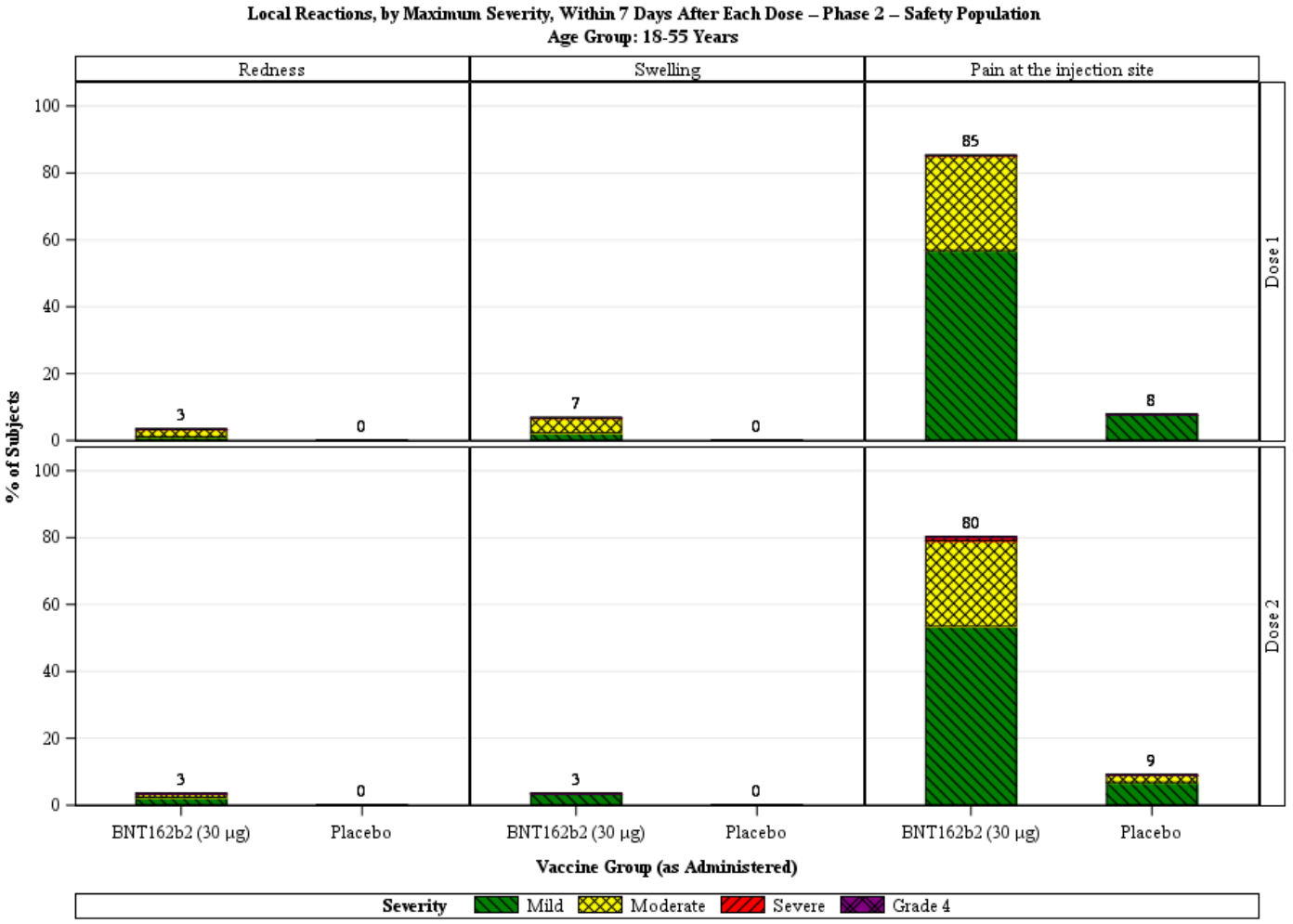
(N=92 post Dose 1; N=91 post Dose 2) , and frequency was similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (85.2% vs. 80.2%, respectively) and in the older age group (70.7% vs. 72.5%, respectively) (Figure 26 and Figure 27, respectively, and Supplemental Table 14.214). In the placebo group, pain at the injection site was reported at similar frequencies (7.8% to 10.2%) in the younger and older age groups after Dose 1 and Dose 2.

In the BNT162b2 group, redness and swelling were similar in the younger and older age group after Dose 1 (Supplemental Table 14.214). After Dose 2, the frequency of redness and swelling was slightly higher in the older age group (7.7% and 12.1%, respectively) than in the younger age group (3.5% and 3.5%, respectively). In the placebo group, only 1 participant in the older age group reported redness after Dose 1, and no swelling was reported.

One participant in the BNT162b2 group (older age group) reported severe injection site pain after Dose 1, and 1 participant in the younger age group reported severe injection site pain after Dose 2 (Appendix 16.2.7.2.2). One participant in the BNT162b2 group (older age group) reported severe redness after Dose 2 (Supplemental Table 14.214 and Appendix 16.2.7.2.2).

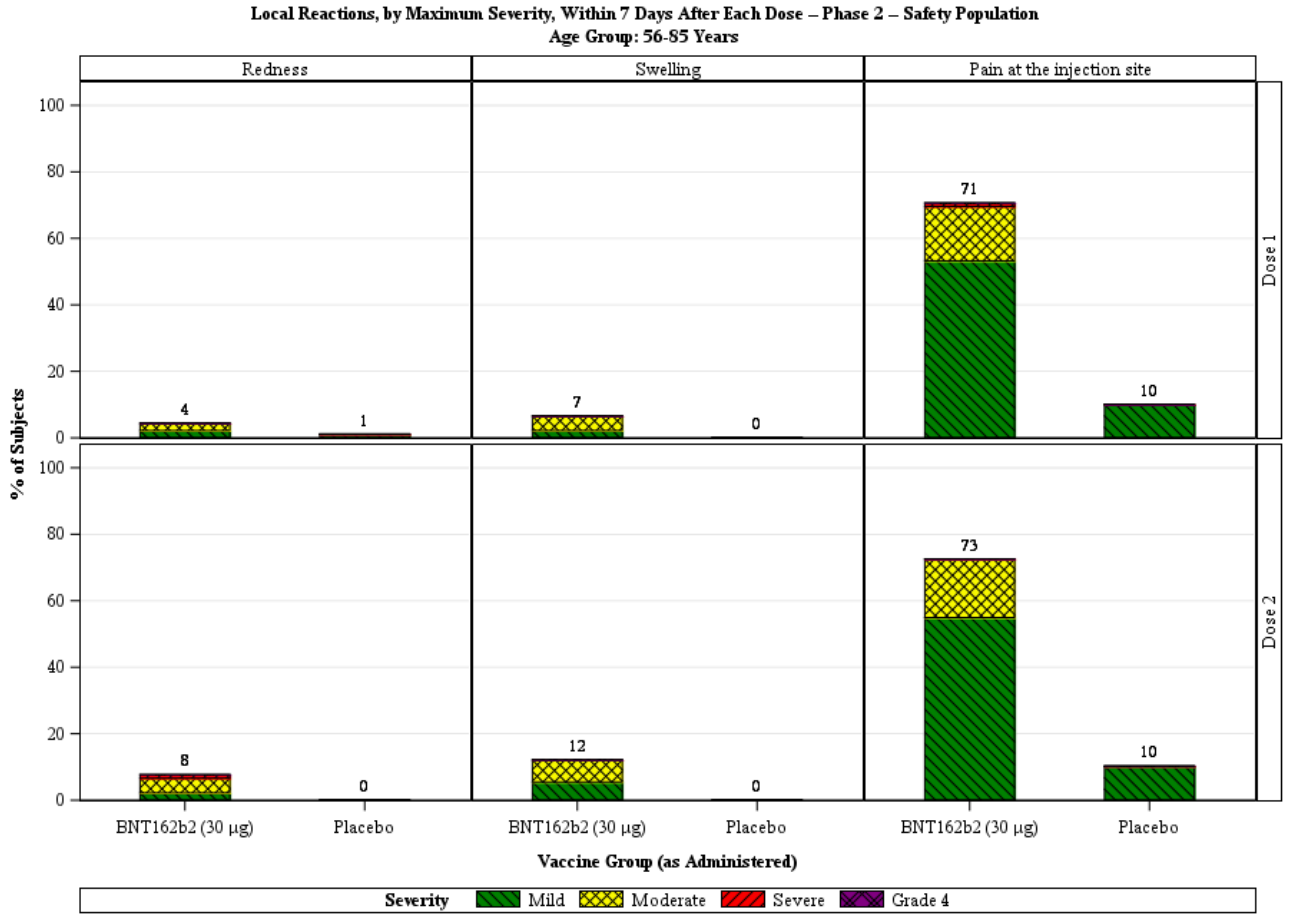
Overall, across age groups, pain at the injection site was the most frequent local reaction and did not increase after Dose 2, and redness and swelling were generally similar in frequency after Dose 1 and Dose 2.

Figure 26. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, Age Group 18-55 Years – Phase 2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_f001_lr_max_age_p2

Figure 27. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, Age Group 56-85 Years – Phase 2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_f001_lr_max_age_p2

Across age groups, local reactions for the BNT162b2 group after either dose had a median onset day between Day 1.0 and Day 3.0 (Day 1.0 was the day of vaccination) (Supplemental Table 14.215), and ranges were generally similar in the younger and older age groups (Supplemental Table 14.216). Across age groups, after either dose of BNT162b2, local reactions resolved after a median duration of 1.0 to 3.0 days (Supplemental Table 14.217), which was generally similar in the younger and older age groups (Supplemental Table 14.218).

12.2.2. Systemic Events – Phase 2

Systemic events across age groups by maximum severity within 7 days after each dose are presented in Supplemental Figure 14.26 and Supplemental Table 14.219.

In the BNT162b2 group, systemic events were generally reported more frequently and were of higher severity in the younger group (N=88 post Dose 1; N=86 post Dose 2) compared with the older group (N=92 post Dose 1; N=91 post Dose 2) (Figure 28 and Figure 29, respectively, and Supplemental Table 14.220), with frequencies and severity increasing with number of doses (Dose 1 vs Dose 2). Vomiting and diarrhea were exceptions with vomiting infrequent and similar in both age groups and vomiting and diarrhea similar after each dose. Frequencies of systemic events in the younger and older BNT162b2 groups (Dose 1 vs Dose 2) are listed below (Supplemental Table 14.220):

- fatigue: younger group (50.0% vs 59.3%) compared to older group (35.9% vs 52.7%)
- headache: younger group (31.8% vs 51.2%) compared to older group (27.2% vs 36.3%)
- muscle pain: younger group (23.9% vs 45.3%) compared to older group (14.1% vs 28.6%)
- chills: younger group (9.1% vs 40.7%) compared to older group (7.6% vs 20.9%)
- joint pain: younger group (9.1% vs 17.4%) compared to older group (4.3% vs 16.5%)
- fever: younger group (3.4% vs 17.4%) compared to older group (0.0% vs 11.0%).
- vomiting: similar in both age groups and after either dose.
- diarrhea: reported less frequently in the older group and was similar after each dose.

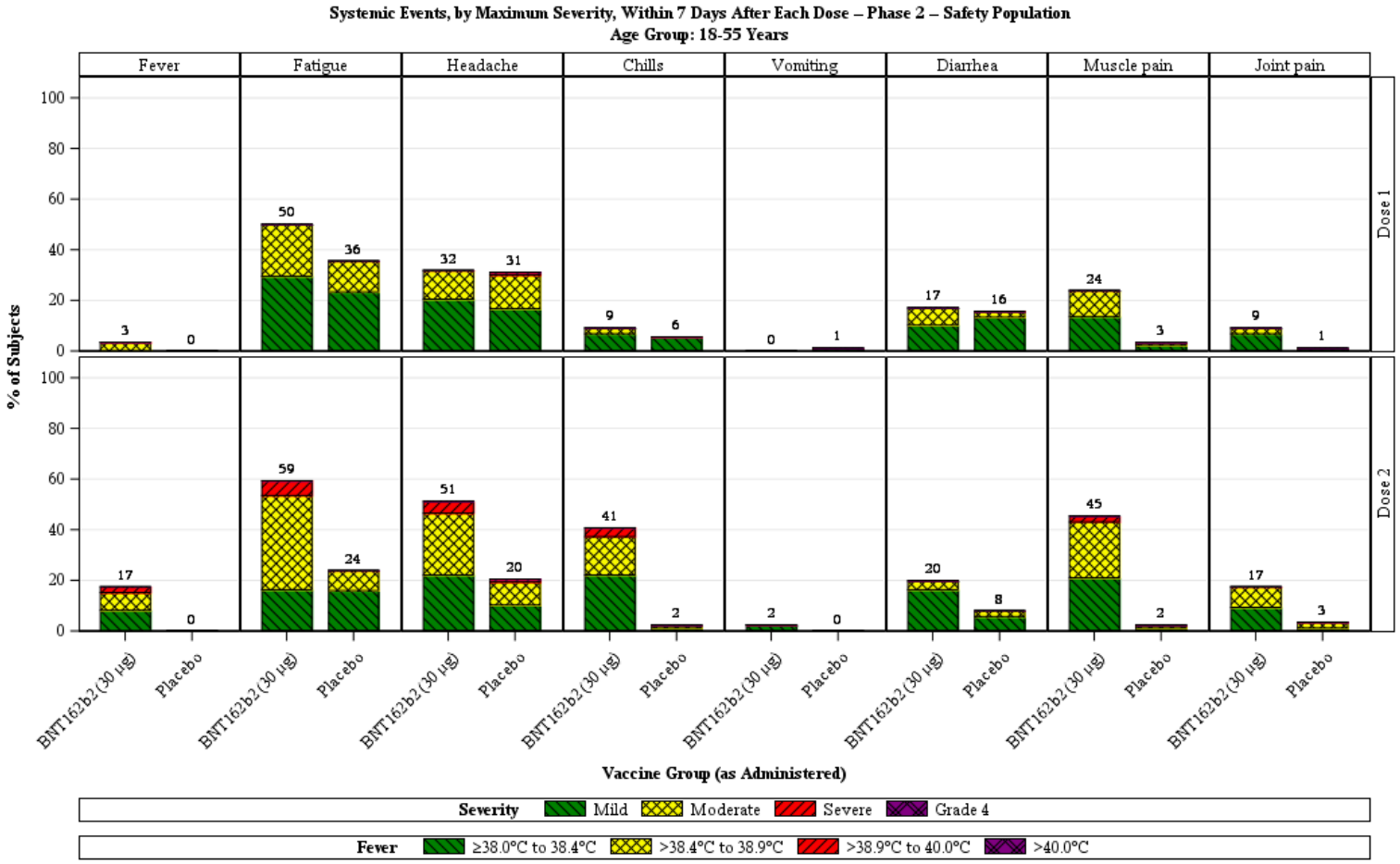
Systemic events were generally reported less frequently in the placebo group than in the BNT162b2 group, for both age groups and doses, with some exceptions. In the younger age group, fever, headache, chills, vomiting, and diarrhea after Dose 1, and vomiting after Dose 2 were reported at similar frequencies in both the placebo and BNT162b2 groups (Figure 28). In the older age group, vomiting, diarrhea, muscle pain, and joint pain after Dose 1, and vomiting and diarrhea after Dose 2 were reported at similar frequencies in the placebo and BNT162b2 groups (Figure 29).

Use of antipyretic/pain medication was slightly less frequent in the older age group after both doses but increased in both age groups overall after Dose 2 as compared with after Dose 1

(Supplemental Table 14.220). Use of antipyretic/pain medication was less frequent in the placebo group than in the BNT162b2 group.

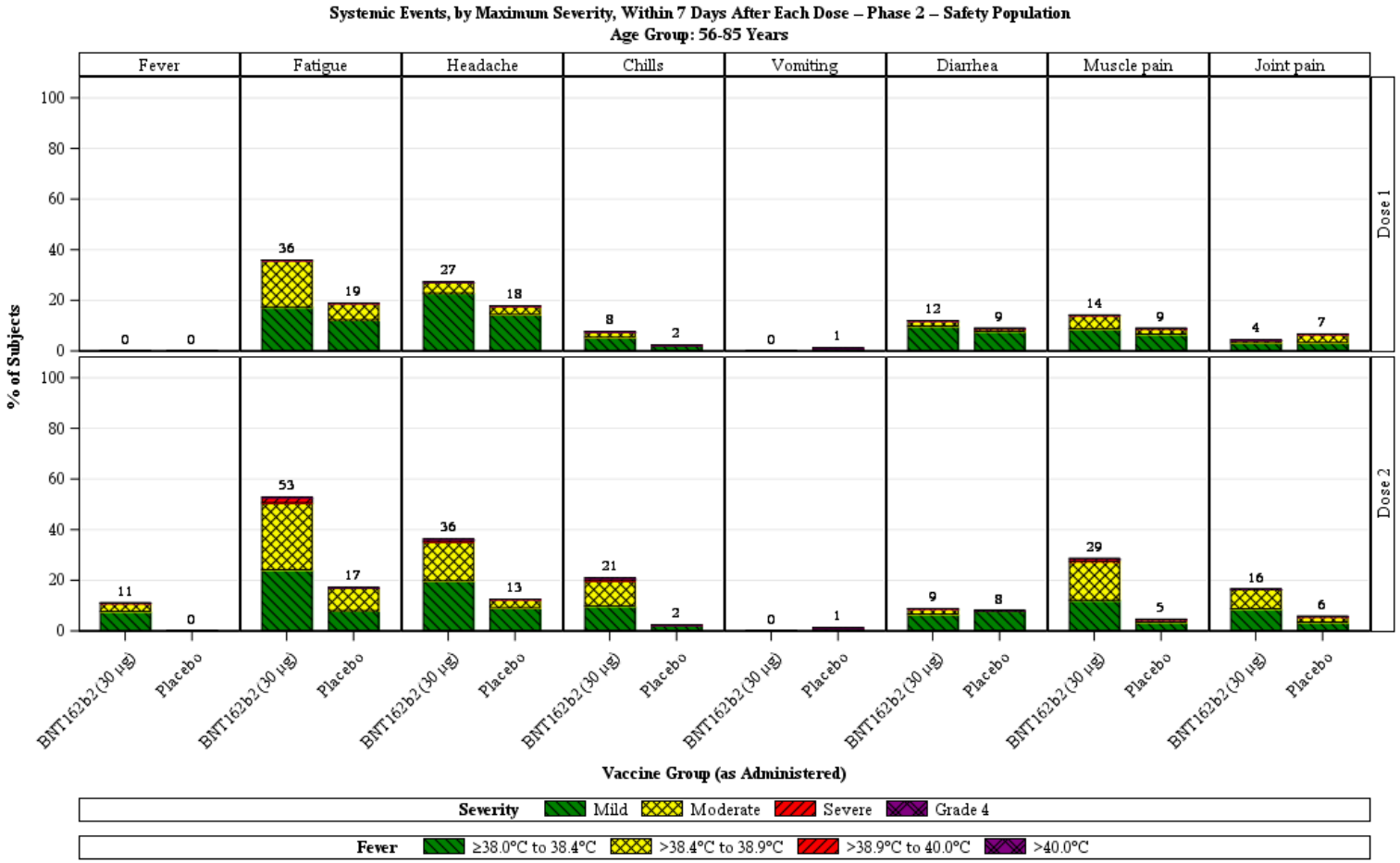
After the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity, and no Grade 4 (potentially life-threatening) systemic events were reported. Across age groups, severe systemic events were only reported after Dose 2 of BNT162b2 overall and included fever (1.1%), fatigue (4.0%), headache (2.8%), chills (2.3%), and muscle pain (1.7%) (Supplemental Table 14.219).

Figure 28. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group 18-55 Years – Phase 2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_f001_se_max_age_p2

Figure 29. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group 56-85 Years – Phase 2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_f001_se_max_age_p2

Across age groups, systemic events after both doses of BNT162b2 had a median onset day between Day 2.0 to Day 3.0 (Day 1.0 was the day of vaccination) (Supplemental Table 14.221), and ranges were similar in the younger and older age groups (Supplemental Table 14.222). The median duration of either fever or chills from first to last day after Dose 1 and Dose 2 was 1.0 day for both younger and older age groups. Across age groups, systemic events for this group after either dose resolved with a median duration of 1.0 day (Supplemental Table 14.223), which was similar in the younger and older age groups (Supplemental Table 14.224). There was no clear difference in the durations of systemic events that occurred after Dose 1 compared to those that occurred after Dose 2.

12.2.3. Adverse Events – Phase 2

12.2.3.1. Summary of Adverse Events – Phase 2

AE reporting for 360 participants evaluated in Phase 2 as of the data cutoff date (14 November 2020) includes at least 2 months of follow-up. AEs reported up to 7 days after Dose 2 are summarized first, followed up by additional safety follow-up up to the data cutoff date.

12.2.3.1.1. Up to 7 Days After Dose 2 - Phase 2

A summary of the overall number of participants reporting at least 1 AE from Dose 1 to 7 days after Dose 2 is presented in Supplemental Table 14.225.

The number of participants who reported at least 1 AE was similar in the BNT162b2 group compared with the placebo group, which was generally similar in the 2 vaccine groups in the younger and older age groups (Table 45 and Table 46, respectively).

Two severe events were reported for 2 participants in the BNT162b2 younger age group: myalgia (AE) and gastric adenocarcinoma (SAE) (Section 12.2.3.2.4 and Section 12.2.4.2, respectively). The SAE of gastric adenocarcinoma occurred 23 days after receiving Dose 1. Both events were assessed by the investigator as not related to study intervention.

Table 45. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=88)	Placebo (N^a=90)
Adverse Event	n^b (%)	n^b (%)
Any event	8 (9.1)	10 (11.1)
Related[c]	3 (3.4)	6 (6.7)
Severe	2 (2.3)	0

Table 45. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)	
Adverse Event	**BNT162b2 (30 µg) (N[a]=88) n[b] (%)**	**Placebo (N[a]=90) n[b] (%)**
Life-threatening	0	0
Any serious adverse event	1 (1.1)	0
Related[c]	0	0
Severe	1 (1.1)	0
Life-threatening	0	0
Any adverse event leading to withdrawal	1 (1.1)	0
Related[c]	0	0
Severe	1 (1.1)	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 adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adae Table Generation: 09OCT2020 (19:15) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2 unblinded/C4591001 IA P2 2/adae s091 pd2 age p2 saf

Table 46. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=92) n[b] (%)	Placebo (N[a]=90) n[b] (%)
Any event	4 (4.3)	8 (8.9)
Related[c]	2 (2.2)	2 (2.2)
Severe	0	0
Life-threatening	0	0
Any serious adverse event	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any 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 adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adae Table Generation: 09OCT2020 (19:15) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adae_s091_pd2_age_p2_saf

12.2.3.1.2. Through the Data Cutoff Date - Phase 2

A summary of the overall number of participants reporting at least 1 AE from Dose 1 through the data cutoff date (14 November 2020) is presented in Supplemental Table 14.226.

The proportions of participants who reported at least 1 AE from Dose 1 to the data cutoff date, inclusive of those that occurred up to 7 days after Dose 2 (Section 12.2.3.1.1), were similar overall between the BNT162b2 and placebo groups and within the age groups for younger (12 [13.6%] vs 16 [17.8%]) and older (10 [10.9%] vs 13 [14.4%]) participants (Supplemental Tables 14.227 and 14.228).

From 7 days after Dose 2 to the data cutoff date, 10 additional participants in the younger age group (4 in the BNT162b2 group and 6 in the placebo group) and 11 additional participants in the older age group (6 in the BNT162b2 group and 5 in the placebo group) reported at least 1 AE.

Based on longer-term follow-up data to at least 2 months after Dose 2, there were no additional related AEs, SAEs, or AEs leading to withdrawal reported from 7 days after Dose 2 up to the data cutoff date in the younger BNT162b2 and placebo groups. There were no related SAEs or related AEs leading to withdrawal reported in older participants in the BNT162b2 or placebo groups. One additional severe AE (muscle spasms [back muscle cramp]) was reported in the younger BNT162b2 group. In the older age group, an additional 2 related AEs (1 in the BNT162b2 [injection site pain] and 1 in the placebo group [hyperhidrosis]) were reported (Appendix 16.2.7.4.4). Three life-threatening SAEs (cardiac arrest, which led to withdrawal, and coronary artery dissection in the BNT162b2 group; and interstitial lung disease in the placebo group) were reported from 7 days after Dose 2 up to the data cutoff date in the older age group (Section 12.2.4.2). There was 1 death in the older BNT162b2 group (cardiac arrest), which was assessed by the investigator as not related to the study intervention (Section 12.2.4.1).

12.2.3.2. Analysis of Adverse Events – Phase 2

12.2.3.2.1. Adverse Events by System Organ Class and Preferred Term – Phase 2

12.2.3.2.1.1. Up to 7 Days After Dose 2 – Phase 2

Table 47 presents the number of participants who reported at least 1 AE from Dose 1 to 7 days after Dose 2 by SOC and PT.

The number of participants who reported at least 1 AE was similar in the BNT162b2 group compared to the placebo group from Dose 1 to 7 days after Dose 2.

In the younger age group, 8 (9.1%) and 10 (11.1%) participants reported at least 1 AE in the BNT162b2 group and the placebo group, respectively (Supplemental Table 14.229). In the older age group, 4 (4.3%) and 8 (8.9%) participants reported at least 1 AE in the BNT162b2 group and the placebo group, respectively (Supplemental Table 14.230).

Overall, most AEs reported up to 7 days after Dose 2 were in the SOCs of gastrointestinal disorders (3 [1.7%] in the BNT162b2 group and 2 [1.1%] in the placebo group), general disorders and administration site conditions (3 [1.7%] in the BNT162b2 group and 7 [3.9%] in the placebo group), and musculoskeletal and connective tissue disorders (3 [1.7%] in the BNT162b2 group and 1 [0.6%] in the placebo group).

The most frequently reported AE by PT was injection site pain (3 [3.4%]) in the younger BNT162b2 group, which all occurred on the day of vaccination with Dose 1 during the reporting period for local reactions. Two events resolved within 3 days, and 1 event resolved 11 days later (Appendix 16.2.7.4.2). All other AEs by PT were reported in ≤2 participants in each vaccine group.

One participant in the older BNT162b2 group had an AE of contusion in the upper left arm deltoid region, which was assessed by the investigator as related to study intervention (Appendix 16.2.7.4.2).

Table 47. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)						Placebo	
	18-55 Years (N^a=88)		56-85 Years (N^a=92)		18-85 Years (N^a=180)		18-85 Years (N^a=180)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Any event	8 (9.1)	(4.0, 17.1)	4 (4.3)	(1.2, 10.8)	12 (6.7)	(3.5, 11.4)	18 (10.0)	(6.0, 15.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Lymphadenopathy	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
GASTROINTESTINAL DISORDERS	1 (1.1)	(0.0, 6.2)	2 (2.2)	(0.3, 7.6)	3 (1.7)	(0.3, 4.8)	2 (1.1)	(0.1, 4.0)
Diarrhoea	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 5.9)	2 (1.1)	(0.1, 4.0)	1 (0.6)	(0.0, 3.1)
Odynophagia	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Tongue discomfort	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (3.4)	(0.7, 9.6)	0	(0.0, 3.9)	3 (1.7)	(0.3, 4.8)	7 (3.9)	(1.6, 7.8)
Injection site erythema	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	2 (1.1)	(0.1, 4.0)
Injection site pain	3 (3.4)	(0.7, 9.6)	0	(0.0, 3.9)	3 (1.7)	(0.3, 4.8)	0	(0.0, 2.0)
Fatigue	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	2 (1.1)	(0.1, 4.0)
Chills	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Injection site discolouration	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Injection site swelling	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
INFECTIONS AND INFESTATIONS	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Vulvovaginal mycotic infection	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	3 (1.7)	(0.3, 4.8)
Contusion	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	1 (0.6)	(0.0, 3.1)
Fall	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Muscle rupture	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Tendon rupture	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
INVESTIGATIONS	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
White blood cell count increased	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (2.3)	(0.3, 8.0)	1 (1.1)	(0.0, 5.9)	3 (1.7)	(0.3, 4.8)	1 (0.6)	(0.0, 3.1)

Table 47. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)						Placebo	
	18-55 Years (N[a]=88)		56-85 Years (N[a]=92)		18-85 Years (N[a]=180)		18-85 Years (N[a]=180)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myalgia	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	1 (0.6)	(0.0, 3.1)
Arthralgia	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Neck pain	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Headache	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	2 (1.1)	(0.1, 4.0)
Oropharyngeal pain	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Productive cough	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Rhinorrhoea	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 5.9)	2 (1.1)	(0.1, 4.0)	1 (0.6)	(0.0, 3.1)
Dermatitis	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Hangnail	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Macule	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Rash macular	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 12SEP2020 (19:59) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2 unblinded/C4591001 IA P2/adae s130 1md2 vax p2 saf

12.2.3.2.1.2. Through the Data Cutoff Date – Phase 2

Supplemental Table 14.231 presents the number of participants who reported at least 1 AE from Dose 1 through the data cutoff date (14 November 2020) by SOC and PT.

The number of participants who reported at least 1 AE was similar in the BNT162b2 group compared to the placebo group from Dose 1 through the data cutoff date (22 [12.2%] and 29 [16.1%], respectively), and from 7 days after Dose 2 through the data cutoff date (10 [5.5%] and 11 [6.1%], respectively) (Supplemental Table 14.231 and Table 47).

Overall, most AEs reported up to the data cutoff date, inclusive of those that occurred up to 7 days after Dose 2 (Section 12.2.3.2.1.1), were in the SOC of general disorders and administration site conditions (5 [2.8%] in the BNT162b2 group and 8 [4.4%] in the placebo group), musculoskeletal and connective tissue disorders (5 [2.8%] in the BNT162b2 group and 4 [2.2%] in the placebo group), and gastrointestinal disorders (4 [2.2%] in the BNT162b2 group and 2 [1.1%] in the placebo group). In the BNT162b2 group, 1 or 2 additional AEs were reported from 7 days after Dose 2 through the data cutoff date in each of the most frequently reported SOCs.

In both the younger and older age groups, the frequencies of AEs by PT from 7 days after Dose 2 to the data cutoff were similar to the those from Dose 1 to 7 days after Dose 2 (Supplemental Tables 14.232 and 14.233, respectively).

12.2.3.2.2. Related Adverse Events by System Organ Class and Preferred Term – Phase 2

The number of participants with AEs assessed by the investigator as related to study intervention from Dose 1 to 7 days after Dose 2 were low in frequency and similar in the BNT162b2 group and placebo group (Supplemental Table 14.234). Within the BNT162b2 group, a similar proportion of participants in the young and old age groups reported related AEs. Most investigator-assessed related AEs were reactogenicity events in the SOC of general disorders and administration site conditions, and they were reported by a similar proportion of participants in the BNT162b2 group overall compared with the placebo group, with injection site pain being the PT reported most frequently and exclusively in the BNT162b2 younger age group.

From 7 days after Dose 2 to the data cutoff date, there was 1 additional related AE reported in each of the BNT162b2 and placebo groups (Supplemental Table 14.226).

12.2.3.2.3. Immediate Adverse Events – Phase 2

There were no immediate AEs after any dose of BNT162b2 30 µg or placebo.

12.2.3.2.4. Severe or Life-Threatening Adverse Events – Phase 2

Two participants (both in the BNT162b2 younger age group) reported severe events of myalgia (AE) and gastric adenocarcinoma (SAE, discussed in Section 12.2.4.2) (Supplemental Table 14.235). The participant who reported myalgia had scapular muscle pain, which began 2 days after Dose 2 which lasted 12 days (Appendix 16.2.7.4.4). Both events were assessed by the investigator as not related to study intervention.

From 7 days after Dose 2 to the data cutoff date, 1 additional severe AE was reported in the BNT162b2 group (Supplemental Table 14.226). This participant, in the younger BNT162b2 group experienced a severe AE of muscle spasms (back muscle cramp) 18 days after Dose 2

which lasted for 3 days. This AE was assessed by the investigator as not related to the study intervention.

From 7 days after Dose 2 to the data cutoff date, life-threatening SAEs were reported in 2 participants in the BNT162b2 group (cardiac arrest and coronary artery dissection) (Section 12.2.4.2). A severe SAE of scleroderma and a life-threatening SAE of interstitial lung disease were reported in 1 participant in the placebo group. These SAEs were assessed by the investigator as not related to study intervention.

12.2.4. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 2

12.2.4.1. Deaths – Phase 2

There was 1 Phase 2 participant in the BNT162b2 group who died through the data cutoff date of 14 November 2020 in this interim CSR (Appendix 16.2.7.7.4). This participant in the older BNT162b2 group experienced a life-threatening SAE of cardiac arrest 60 days after Dose 2 and died 63 days after Dose 2. This death was assessed by the investigator as not related to the study intervention (Appendix 16.2.7.5.4).

12.2.4.2. Serious Adverse Events – Phase 2

One participant had an SAE from Dose 1 to 7 days after Dose 2 (Table 45 and Supplemental Tables 14.236 and 14.237). One participant, who was in the BNT162b2 younger age group, had an SAE of gastric adenocarcinoma 23 days after Dose 1, which was assessed by the investigator as not related to study intervention (Table 48 and Appendix 16.2.7.5.4). The SAE was ongoing at the time of the data cutoff, and the participant was withdrawn from the study because of the SAE (Section 12.2.4.3).

From 7 days after Dose 2 to the data cutoff date (14 November 2020), 2 additional participants in the BNT162b2 older age group and 1 additional participant in the placebo older age group reported at least 1 SAE (Supplemental Tables 14.238, 14.239, and 14.240). None of these SAEs were assessed as related to study intervention by the investigator.

In the BNT162b2 group:

- One participant in the older age group experienced a life-threatening SAE of coronary artery dissection 12 days after Dose 2 and recovered the same day (Appendix 16.2.7.5.4).
- One participant in the older age group experienced a life-threatening SAE of cardiac arrest 60 days after Dose 2 (Appendix 16.2.7.5.4) and died 63 days after Dose 2 (Section 12.2.4.1).

In the placebo group:

One participant in the older age group experienced a life-threatening SAE of interstitial lung disease 59 days after Dose 2 and a Grade 3 SAE of scleroderma 62 days after Dose 2 (Appendix 16.2.7.5.4). The participant was recovering at the time of the data cutoff date.

Table 48. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)						Placebo	
	18-55 Years (N[a]=88)		56-85 Years (N[a]=92)		18-85 Years (N[a]=180)		18-85 Years (N[a]=180)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adae Table Generation: 11SEP2020 (11:02) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adae_s130_1md2_ser_p2_saf

12.2.4.3. Safety-Related Participant Withdrawals – Phase 2

From Dose 1 to 7 days after Dose 2, the participant in the BNT162b2 younger age group who reported an SAE of gastric adenocarcinoma (Section 12.2.4.2) was discontinued from the study on Day 23 after Dose 1 of BNT162b2 (Supplemental Tables 14.241, and Appendix 16.2.7.6.2).

A participant in the BNT162b2 older age group was withdrawn from the study during the period from 7 days after Dose 2 through the data cutoff date (14 November 2020) due to an SAE of cardiac arrest (Section 12.2.4.2), which resulted in death and was assessed by the investigator as not related to the study intervention.

12.2.4.3.1. Narratives of Safety-Related Participant Withdrawals – Phase 2

Narratives for the Phase 2 participants who were withdrawn from the study because of an SAE through the data cutoff date (14 November 2020) are provided in Section 14.

12.2.4.4. Other Significant Adverse Events – Phase 2

AEs of special interest were not defined for Phase 2 of this study; however, targeted medical events were monitored throughout the study.

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

Up to the data cutoff date of 14 November 2020, there were 2 safety-related withdrawals from the study; both were in the BNT162b2 group and both were assessed by the investigator as not related to study intervention. One participant in the younger age group was withdrawn from the study because of an SAE of gastric adenocarcinoma, and 1 participant in the older age group was withdrawn from the study because of a life-threatening SAE of cardiac arrest which resulted in death.

12.2.5. Phase 2 Safety Conclusions

- Across age groups, local reactions were generally similar in frequency after each dose, and systemic events generally increased in frequency and severity after Dose 2 compared to Dose 1. Local and systemic reactogenicity events were well-tolerated and short-lived.

- Reactogenicity events after each dose of BNT162b2 in older adults were generally milder and less frequent than those observed in younger adults. The majority of reactogenicity events were mild or moderate in severity. No Grade 4 events were reported.

- AEs in participants were low in frequency, and most AEs were mild or moderate in severity. There were no SAEs or discontinuations because of AEs that were assessed as related by the investigator. There was 1 death in the BNT162b2 group (cardiac arrest) that was assessed as not related to study intervention.

- The reactogenicity and AE profile after BNT162b2 30 µg evaluated in 360 participants was consistent with the safety profile observed after BNT162b2 30 µg in Phase 1.

- BNT162b2 at 30 µg was safe and well tolerated up to 7 days after Dose 2 and up to at least 2 months of follow-up.

12.3. Phase 2/3

In this interim CSR, as of the time of the safety cutoff date (14 November 2020), the Phase 2/3 reactogenicity subset was comprised of 8183 participants (16 to 55 and >55 years of age), which included the 360 participants in Phase 2. The reactogenicity data were collected by participants' e-diary for reporting prompted local reactions and systemic events for 7 days after each dose.

12.3.1. Local Reactions – Phase 2/3

Local reactions across age groups by maximum severity within 7 days after each dose are presented in Supplemental Table 14.364.

In the BNT162b2 group, pain at the injection site was reported more frequently in the younger age group (N=2291 post Dose 1; N=2098 post Dose 2) than in the older age group (N=1802 post Dose 1; N=1660 post Dose 2), and frequency was similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (83.1% vs 77.8%) and in the older group (71.1% vs 66.1%) (Figure 30 and Figure 31, respectively, and Supplemental Table 14.365). In the placebo group, pain at the injection site after Doses 1 and 2 was reported at slightly higher frequencies in the younger age group (14.0% and 11.7%, respectively) than in the older age group (9.3% and 7.7%, respectively).

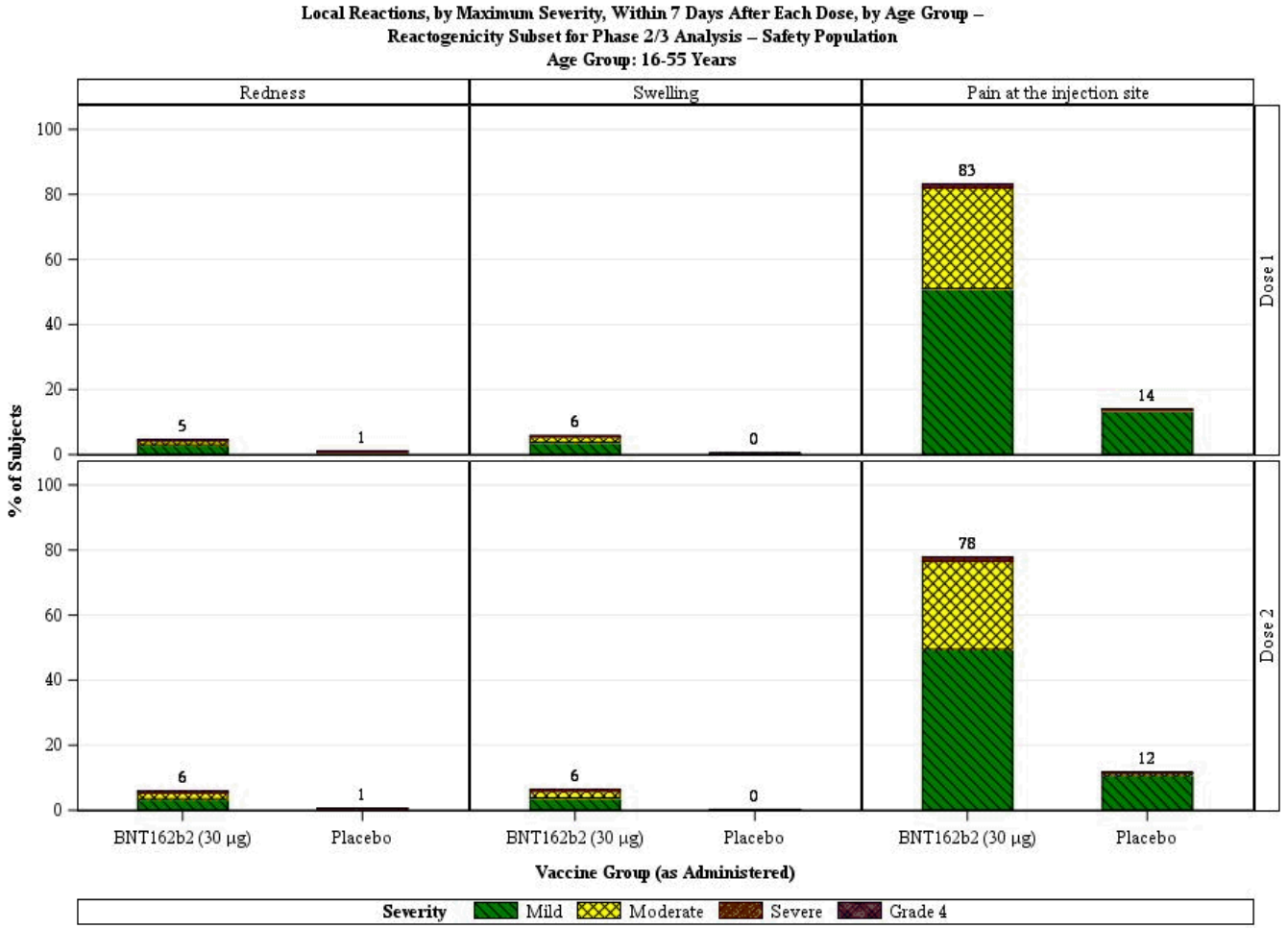
In the BNT162b2 group, frequencies of redness and swelling were similar in the younger and older age group after Doses 1 and 2 (Supplemental Table 14.365). Frequencies of redness were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (4.5% vs 5.9%) and in the older age group (4.7% vs 7.2%). Frequencies of swelling were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (5.8% vs 6.3%, respectively) and in the older age group (6.5% vs 7.5%). In the placebo group, redness and swelling were reported infrequently in the younger (≤1.1%) and older (≤1.2%) groups after Doses 1 and 2.

Overall, across age groups, pain at the injection site did not increase after Dose 2, and redness and swelling were generally similar in frequency after Dose 1 and Dose 2. Severe local reactions (≤0.7%) were reported infrequently in the BNT162b2 group after either dose overall but occurred more frequently in the younger group (Supplemental Tables 14.364 and 14.365, respectively). After the first and second dose and in both age groups, the majority of local reactions were mild or moderate in severity, and no Grade 4 local reactions were reported.

Subgroup Analyses

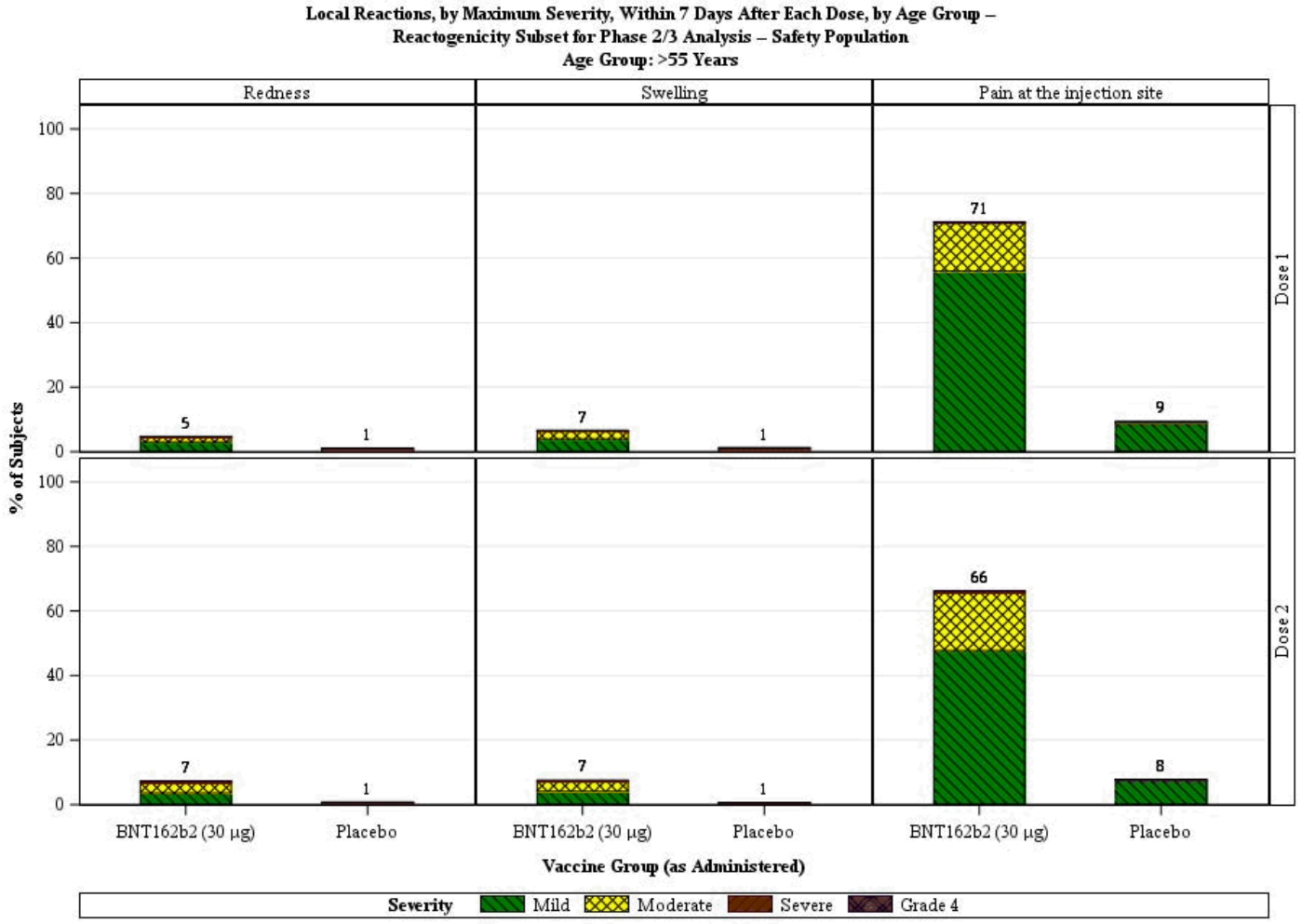
No clinically meaningful differences in local reactions were observed by baseline SARS-CoV-2 status subgroups (Supplemental Tables 14.366 and 14.367). Note that the baseline SARS-CoV-2 positive subgroup included very few participants, so their results should be interpreted with caution.

Figure 30. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, Age Group 16-55 Years – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: /nda2_unblinded/C4591001_IA_P3_2MPD2/adce_f001_lr_max_age_p3

Figure 31. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, Age Group >55 Years – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_f001_lr_max_age_p3

Across age groups, local reactions for the BNT162b2 group after either dose had a median onset day between Day 1.0 and Day 3.0 (Day 1.0 was the day of vaccination) (Supplemental Table 14.368), and ranges were similar in the younger and older age groups (Supplemental Table 14.369). Across age groups, local reactions for this group after either dose resolved with median durations between 1 to 2 days (Supplemental Table 14.370), which were similar in the younger and older age groups (Supplemental Table 14.371).

12.3.2. Systemic Events – Phase 2/3

Systemic events across age groups by maximum severity within 7 days after each dose are presented in Supplemental Table 14.372.

Systemic events were generally increased in frequency and severity in the younger group (Figure 32) compared with the older group (Figure 33), with frequencies and severity increasing with number of doses (Dose 1 vs Dose 2). Vomiting and diarrhea were exceptions, with vomiting reported similarly infrequently in both age groups and diarrhea reported at similar incidences after each dose.

Systemic events in the younger group (N=2291 post Dose 1; N=2098 post Dose 2) compared with the older group (N=1802 post Dose 1; N=1660 post Dose 2), with frequencies increasing with number of doses (Dose 1 vs Dose 2) (Supplemental Table 14.373), were:

- fatigue: younger group (47.4% vs 59.4%) compared to older group (34.1% vs 50.5%)
- headache: younger group (41.9% vs 51.7%) compared to older group (25.2% vs 39.0%)
- muscle pain: younger group (21.3% vs 37.3%) compared to older group (13.9% vs 28.7%)
- chills: younger group (14.0% vs 35.1%) compared to older group (6.3% vs 22.7%)
- joint pain: younger group (11.0% vs 21.9%) compared to older group (8.6% vs 18.9%)
- fever: younger group (3.7% vs 15.8%) compared to older group (1.4% vs 10.9%)
- vomiting: reported less frequently in the older group and was similar after either dose
- diarrhea: reported less frequently in the older group and was similar after each dose.

Systemic events were generally reported less frequently in the placebo group than in the BNT162b2 group, for both age groups and doses, with some exceptions. In the younger age group, vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 32). In the older age group, fever and joint pain (after Dose 1) and vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 33).

Following both Dose 1 and Dose 2, use of antipyretic/pain medication was slightly less frequent in the older age group (19.9% vs 37.7%) than in the younger age group (27.8% vs

45.0%) after both doses, and medication use increased in both age groups after Dose 2 as compared with after Dose 1 (Supplemental Table 14.373). Use of antipyretic/pain medication was less frequent in the placebo group than in the BNT162b2 group and was similar after Dose 1 and Dose 2 in the younger and older placebo groups (ranging from 9.8% to 22.0%).

Systemic events across age groups after Dose 1 of BNT162b2 were generally lower in frequency than after Dose 2: fever (2.7% vs 13.6%), fatigue (41.5% vs 55.5%), headache (34.5% vs 46.1%), chills (10.6% vs 29.6%), muscle pain (18.0% vs 33.5%), and joint pain (9.9% vs 20.5). Diarrhea and vomiting frequencies were generally similar. The frequency of any severe systemic event after Dose 1 was ≤0.9%. After Dose 2, severe systemic events had frequencies of <2% with the exception after Dose 2 of fatigue (3.8%) and headache (2.0%) (Supplemental Table 14.372).

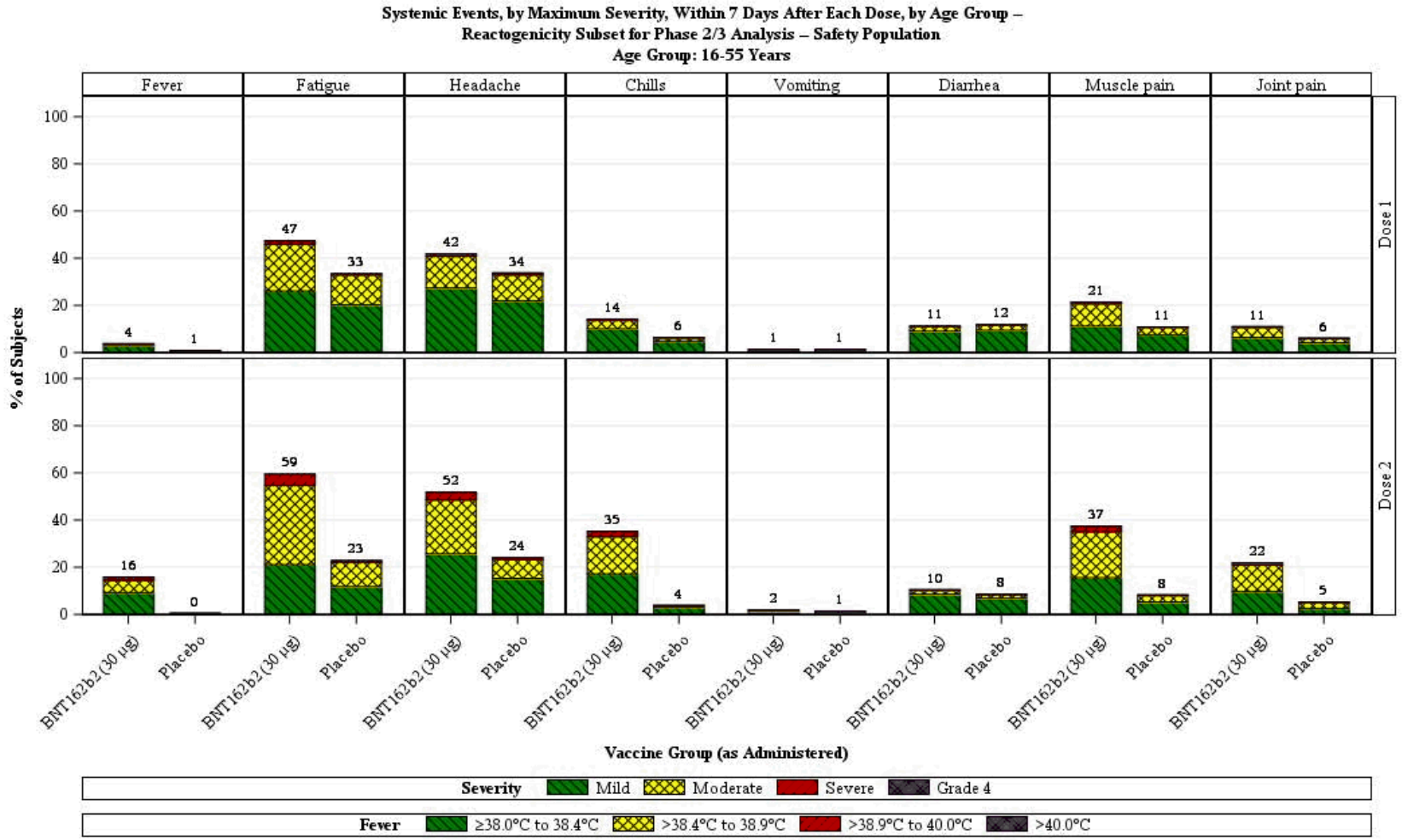
Severe fever (>38.9°C to 40.0°C) was reported in the BNT162b2 group after Dose 1 for 0.2% and after Dose 2 for 0.8% of participants, and in the placebo group after Dose 1 for 0.1% and after Dose 2 for 0.1% of participants. Grade 4 fever (>40.0°C) was reported for 2 participants in each of the BNT162b2 and placebo groups. One participant in the younger BNT162b2 group reported fever of 41.2°C only on Day 2 after Dose 2 and was nonfebrile for all other days of the reporting period. One other participant in the older BNT162b2 group reported fever that reached a high temperature of 40.7°C only on Day 4 after Dose 1 and was nonfebrile for all other days of the reporting period (Supplemental Table 14.373 and Appendix 16.2.7.3.4).

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

Subgroup Analyses

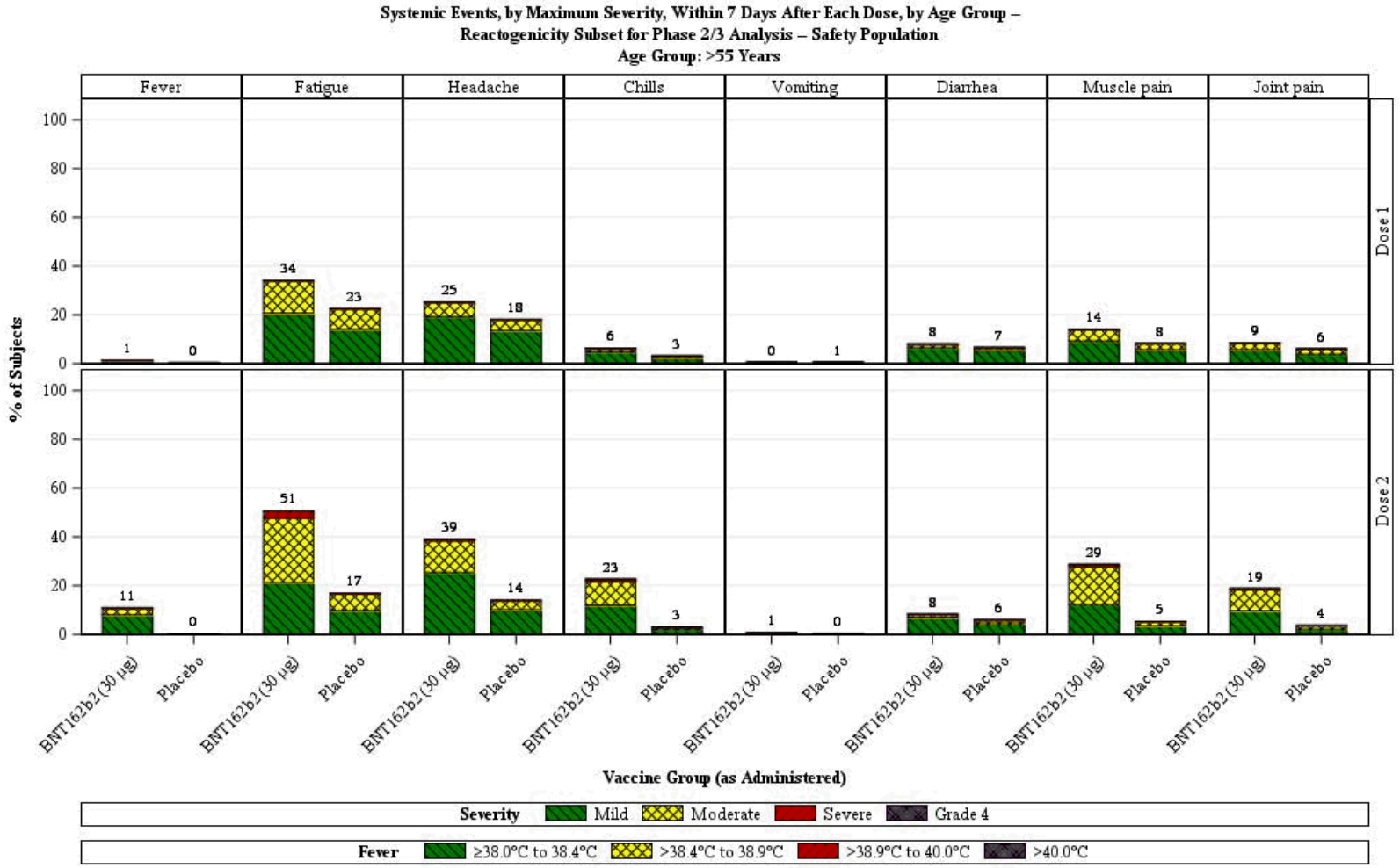
No clinically meaningful differences in systemic events were observed by baseline SARS-CoV-2 status subgroups (Supplemental Tables 14.374 and 14.375). Note that the baseline SARS-CoV-2 positive subgroup included very few participants, so their results should be interpreted with caution.

Figure 32. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group 16-55 Years – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_f001_se_max_age_p3

Figure 33. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group >55 Years – Reactogenicity Subset for Phase 2/3 Analysis– Safety Population



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_f001_se_max_age_p3

Across age groups, median onset day for all systemic events after either dose of BNT162b2 was Day 2.0 to Day 3.0 (Day 1.0 was the day of vaccination) (Supplemental Table 14.376), and ranges were similar in the younger and older age groups (Supplemental Table 14.377). Across age groups, all systemic events resolved with median duration of 1 day (Supplemental Table 14.378), which was similar in the younger and older age groups (Supplemental Table 14.379). The median duration of either fever or chills from first to last day after Dose 1 and Dose 2 was 1 day for both younger and older age groups.

12.3.3. Adverse Events – Phase 2/3

12.3.3.1. Summary of Adverse Events – Phase 2/3

For this study, 37,707 participants who were randomized on or before 9 October 2020 were vaccinated with Dose 1 and included in Table 6 (see Section 10.1.3.1 and Section 10.1.3.2 regarding an additional 4 participants (1 multi-enrolled participant with 2 participant identification numbers) who were vaccinated but not included in the data analyses). Of the 37,707 participants, 1 did not sign an informed consent and is, therefore, not included in any analysis population. The remaining 37,706 participants had a median follow-up time of 2 months after Dose 2. Of these, 19,067 (50.6%) had at least 2 months of follow-up after Dose 2. HIV-positive participants (120 participants) were included for counting purposes in demographic and disposition summaries; however, these participants were not included in the summary of safety or efficacy endpoint results. Therefore, 37,586 participants were included in the AE analyses presented in the sections below.

Results for all enrolled participants (N=43,252 participants) who had variable follow up from Dose 1 to the data cutoff date of 14 November 2020 are also presented below. At the time of the data cutoff date, there was a small percentage (≤0.2%) of participants with at least 1 uncoded term (Section 12.3.3.2.1.2).

12.3.3.1.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Phase 2/3

An overview of AEs from Dose 1 to 1 month after Dose 2 for the 37,586 participants who had a median of at least 2 months of follow-up after Dose 2 (including those analyzed in Phase 2) is presented in Table 49. The numbers of overall participants were higher in the BNT162b2 group as compared with the placebo group who reported at least 1 AE (27.0% vs 12.5%) and at least 1 related AE (20.8% vs 5.1%). This trend continued to be seen through the data cutoff date for all enrolled participants (43,252 participants) and is further described in Section 12.3.3.2.1.2 for that population. Severe AEs, SAEs, and AEs leading to withdrawal were few and reported by ≤1.2%, ≤0.5%, and ≤0.2%, respectively, in both groups. Discontinuations due to related AEs were reported in 14 participants in the BNT162b2 group and 7 participants in the placebo group.

Three Phase 3 participants died: 1 participant in the BNT162b2 group and 2 participants in the placebo group (Section 12.3.4.1). The participant in the BNT162b2 group who died experienced an SAE of arteriosclerosis which was assessed by the investigator as not related to study intervention. In the placebo group, 1 participant who died experienced an unevaluable event (of unknown origin) and 1 participant who died experienced hemorrhagic stroke.

In the younger age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 3177 (29.3%) and 1427 (13.2%) in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.380). In the older age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 1894 (23.8%) and 929 (11.7%) in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.381).

Table 49. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=18801)	Placebo (N[a]=18785)
Adverse Event	n[b] (%)	n[b] (%)
Any event	5071 (27.0)	2356 (12.5)
Related[c]	3915 (20.8)	953 (5.1)
Severe	220 (1.2)	109 (0.6)
Life-threatening	18 (0.1)	20 (0.1)
Any serious adverse event	103 (0.5)	81 (0.4)
Related[c]	3 (0.0)	0
Severe	57 (0.3)	48 (0.3)
Life-threatening	18 (0.1)	19 (0.1)
Any adverse event leading to withdrawal	34 (0.2)	25 (0.1)
Related[c]	14 (0.1)	7 (0.0)
Severe	13 (0.1)	7 (0.0)
Life-threatening	2 (0.0)	4 (0.0)
Death	1 (0.0)	2 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:21)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_pd2_p3_saf

Among the 37,586 participants, no clinically meaningful differences in AEs by category were observed by age group, baseline SARS-CoV-2 status, ethnicity, race, or sex subgroups.

Age Group: 16-55 Years	Supplemental Table 14.380
Age Group: >55 Years	Supplemental Table 14.381

Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.382
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.383
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: 16 to 55 Years	Supplemental Table 14.384
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: >55 Years	Supplemental Table 14.385
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: 16 to 55 Years	Supplemental Table 14.386
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: >55 Years	Supplemental Table 14.387
Ethnicity: Hispanic/Latino	Supplemental Table 14.388
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.389
Ethnicity: Not Reported	Supplemental Table 14.390
Race: White	Supplemental Table 14.391
Race: Black or African American	Supplemental Table 14.392
Race: All Others	Supplemental Table 14.393
Sex: Male	Supplemental Table 14.394
Sex: Female	Supplemental Table 14.395

12.3.3.1.1.1. Participants with At Least 2 Months of Follow-Up After Dose 2

Table 50 presents an AE summary of the subset of 19,067 participants, within the 37,586 group, who had at least 2 months of follow-up after Dose 2. The results regarding the number of overall participants who reported at least 1 AE, related AEs, severe AEs, SAEs, AEs leading to discontinuation, and deaths were consistent with what was seen in the 37,586 participants with 1 month of follow-up after Dose 2. Overall, in the 19,067 participants, from Dose 1 to the data cutoff date, 21.4% and 13.6% of participants in the BNT162b2 group experienced at least 1 AE and 1 related AE, respectively, and 12.6% and 3.6% of participants in the placebo group experienced at least 1 AE and 1 related AE, respectively. Incidences of severe AEs, SAEs, AEs leading to discontinuation, and deaths were ≤1.1%, 0.6%, 0.0%, and 0.0%, respectively, in both the BNT162b2 and placebo groups. The results by age group were also similar (Supplemental Tables 14.396 and 14.397).

Table 50. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020) – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)

Adverse Event	BNT162b2 (30 µg) (N[a]=9531) n[b] (%)	Placebo (N[a]=9536) n[b] (%)	Total (N[a]=19067) n[b] (%)
Any event	2044 (21.4)	1197 (12.6)	3241 (17.0)
Related[c]	1297 (13.6)	343 (3.6)	1640 (8.6)
Severe	105 (1.1)	69 (0.7)	174 (0.9)
Life-threatening	10 (0.1)	11 (0.1)	21 (0.1)
Any serious adverse event	57 (0.6)	53 (0.6)	110 (0.6)
Related[c]	2 (0.0)	0	2 (0.0)
Severe	32 (0.3)	33 (0.3)	65 (0.3)
Life-threatening	10 (0.1)	11 (0.1)	21 (0.1)
Any adverse event leading to withdrawal	1 (0.0)	0	1 (0.0)
Related[c]	0	0	0
Severe	0	0	0
Life-threatening	1 (0.0)	0	1 (0.0)
Death	1 (0.0)	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_2mpd2_p23_saf

12.3.3.1.2. All Participants – Phase 2/3

An overview of AEs reported for all enrolled participants (N=43,252 participants) who had variable follow-up from Dose 1 to the data cutoff date, is presented in Table 51. From Dose 1 to the data cutoff date, the numbers of overall participants who reported at least 1 AE and at least 1 related AE remained higher in the BNT162b2 group as compared with the placebo group. This imbalance in the BNT162b2 and placebo groups is further described in Section 12.3.3.2.1.2. Severe AEs, SAEs, and AEs leading to withdrawal were few and reported by ≤1.1%, ≤0.6%, and ≤0.2%, respectively, in both groups. Discontinuations due to related AEs were reported in 16 participants in the BNT162b2 group and 9 participants in the placebo group.

Six Phase 2/3 participants died: 2 participant in the BNT162b2 group and 4 participants in the placebo group (see Section 12.3.4.1 for details). In the BNT162b2 group, 1 participant died due to an SAE of arteriosclerosis, which was assessed by the investigator as not related to study intervention, and another participant died due to an SAE of cardiac arrest, which was assessed by the investigator as not related to study intervention.

In the younger age group, the number of participants who reported at least 1 AE was 3660 (28.8%) and 1605 (12.6%) in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.398). In the older age group, the number of participants who reported at least 1 AE

was 2110 (23.7%) and 1033 (11.6%) in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.399).

In the 16 to 17 years of age group, 16 participants (11.6%) in the BNT162b2 group and 7 participants (4.8%) in the placebo group experienced at least 1 AE from Dose 1 to the data cutoff date (Table 53).

Table 51. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020) – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N^a=21621) n^b (%)	Placebo (N^a=21631) n^b (%)
Any event	5770 (26.7)	2638 (12.2)
Related[c]	4484 (20.7)	1095 (5.1)
Severe	240 (1.1)	139 (0.6)
Life-threatening	21 (0.1)	24 (0.1)
Any serious adverse event	126 (0.6)	111 (0.5)
Related[c]	4 (0.0)	0
Severe	71 (0.3)	68 (0.3)
Life-threatening	21 (0.1)	23 (0.1)
Any adverse event leading to withdrawal	37 (0.2)	30 (0.1)
Related[c]	16 (0.1)	9 (0.0)
Severe	13 (0.1)	9 (0.0)
Life-threatening	3 (0.0)	6 (0.0)
Death	2 (0.0)	4 (0.0)

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_p23_saf

12.3.3.2. Analysis of Adverse Events – Phase 2/3

12.3.3.2.1. Adverse Events by System Organ Class and Preferred Term – Phase 2/3

12.3.3.2.1.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Phase 2/3

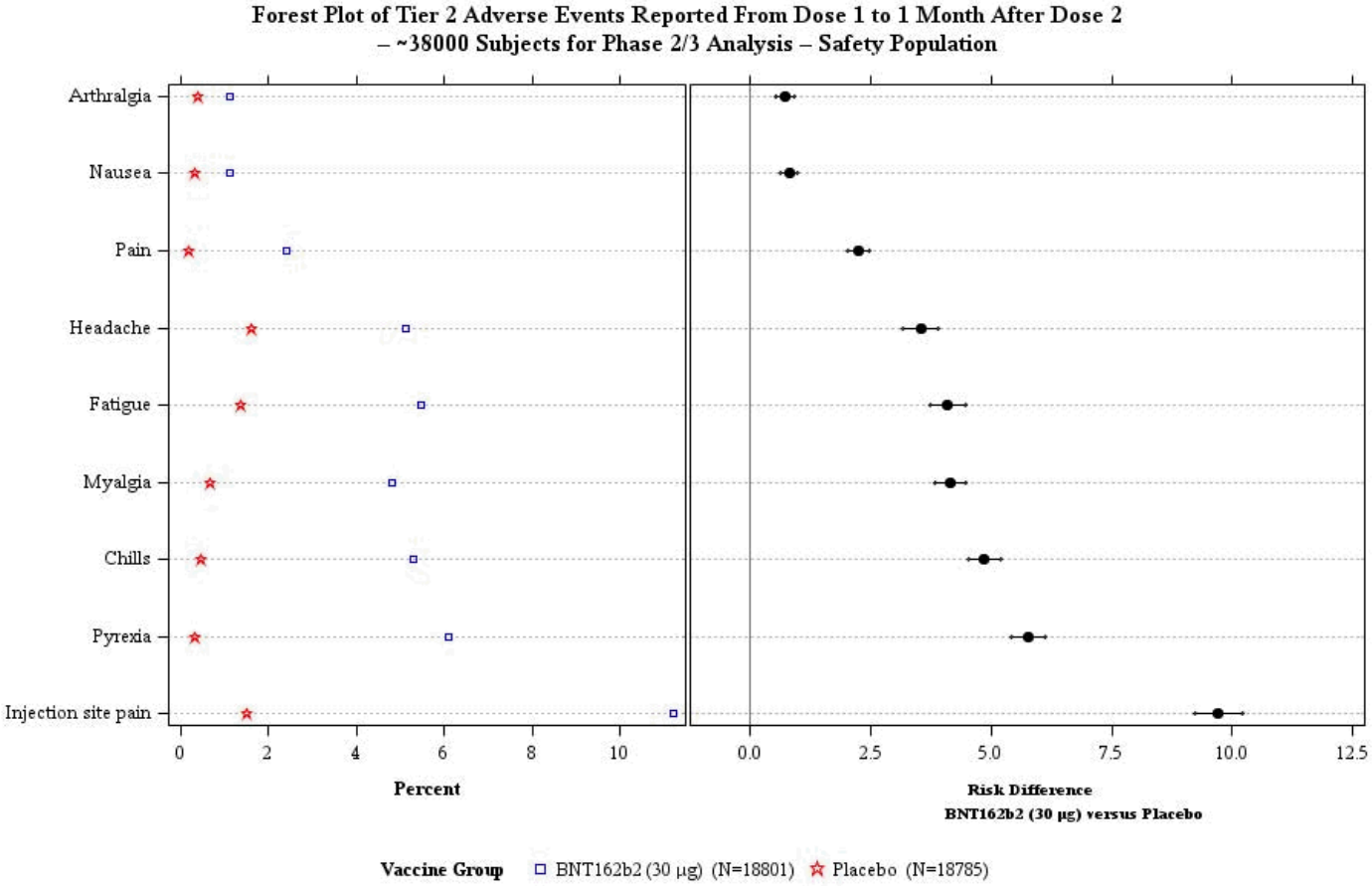
There are no Tier 1 AEs identified for this program.

Tier 2 AEs (defined as an event rate ≥1.0% in any vaccine group [PT level]) reported from Dose 1 to 1 month after Dose 2 are presented in Figure 34 and Supplemental Table 14.400.

Most Tier 2 AEs were reactogenicity events and all were reported in 4 SOCs: general disorders and administration site conditions, musculoskeletal and connective tissue disorders, nervous system disorders, and gastrointestinal disorders. The proportions of participants reporting Tier 2 AEs were generally higher in the BNT162b2 group (N=18801; ranging from 1.1% to 11.2%) than in the placebo group (N=18785; ranging from 0.2% to 1.6%). Most of the PTs were in the SOC of general disorders and administration site conditions:

- injection site pain (2108 [11.2%] BNT162b2 vs 281 [1.5%] placebo)
- pyrexia (1144 [6.1%] BNT162b2 vs 61 [0.3%] placebo)
- fatigue (1026 [5.5%] BNT162b2 vs 258 [1.4%] placebo)
- chills (998 [5.3%] BNT162b2 vs 85 [0.5%] placebo)
- pain (455 [2.4%] BNT162b2 vs 36 [0.2%] placebo).

Figure 34. Forest Plot of Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2 - ~38000 Subjects for Phase 2/3 Analysis - Safety Population



Note: MedDRA (v23.1) coding dictionary applied.
Note: A MedDRA preferred term is defined as a Tier 2 event if there are at least 1% subjects with the AE term in at least 1 vaccine group.
Note: 2-Sided CI based on the Miettinen and Numinen method for the difference in proportions (BNT162b2 (30 µg) - Placebo) expressed as a percentage. They are not adjusted for multiplicity and should be used for screening purposes only.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (03:55)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_f001_t2_p3

Among the 37,586 participants with a median of 2 months of safety follow-up after Dose 2, most AEs reported up to 1 month after Dose 2 (Table 52) were reactogenicity, in SOCs of:

- general disorders and administration site conditions (18.6% BNT162b2 vs 3.9% placebo)
- musculoskeletal and connective tissue disorders (7.3% BNT162b2 vs 2.0% placebo)
- nervous system disorders (6.1% BNT162b2 vs 2.4% placebo)
- infections and infestations (1.5% BNT162b2 vs 1.5% placebo)
- gastrointestinal disorders (2.9% BNT162b2 vs 1.9% placebo).

In the younger versus older BNT162b2 age groups (Supplemental Tables 14.401 and 14.402, respectively), AE incidences in these SOCs were:

- general disorders and administration site conditions (21.1% vs 15.2%)
- musculoskeletal and connective tissue disorders (8.3% vs 5.9%)
- nervous system disorders (6.9% vs 4.9%)
- infections and infestations (1.5% vs 1.6%)
- gastrointestinal disorders (3.0% vs 2.8%).

As shown in Table 52, the most frequently reported AEs in the BNT162b2 group by PT overall were injection site pain (2108 [11.2%]), pyrexia (1144 [6.1%]), chills (998 [5.3%]), fatigue (1026 [5.5%]), headache (966 [5.1%), and myalgia (904 [4.8%]). During this time period from Dose 1 to 1 month after Dose 2, most of these AEs were reported during the e-diary 7-day reporting period (Appendix 16.2.7.4.4). The majority of these PTs were reported in the younger age group: injection site pain (1358 [12.5%]), pyrexia (819 [7.6%]), chills (693 [6.4%]), fatigue (690 [6.4%]), headache (649 [6.0%]), and myalgia (628 [5.8%]).

Among the AEs of lymphadenopathy, the majority (47 of 64) were judged by the investigator as related to study intervention, occurred in the arm and neck region, and were reported within 2 to 4 days after vaccination (Appendix 16.2.7.4.4; further discussed in Section 12.3.4.4).

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	5071 (27.0)	(26.3, 27.6)	2356 (12.5)	(12.1, 13.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
BLOOD AND LYMPHATIC SYSTEM DISORDERS	81 (0.4)	(0.3, 0.5)	13 (0.1)	(0.0, 0.1)
Lymphadenopathy	64 (0.3)	(0.3, 0.4)	6 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anaemia	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	45 (0.2)	(0.2, 0.3)	36 (0.2)	(0.1, 0.3)
Palpitations	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Tachycardia	11 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	55 (0.3)	(0.2, 0.4)	35 (0.2)	(0.1, 0.3)
Vertigo	22 (0.1)	(0.1, 0.2)	16 (0.1)	(0.0, 0.1)
Tinnitus	9 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Ear pain	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vertigo positional	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	11 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypothyroidism	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hypogonadism	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thyroid mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	51 (0.3)	(0.2, 0.4)	40 (0.2)	(0.2, 0.3)
Eye pain	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vision blurred	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cataract	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Eye irritation	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vitreous detachment	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	547 (2.9)	(2.7, 3.2)	358 (1.9)	(1.7, 2.1)
Diarrhoea	187 (1.0)	(0.9, 1.1)	146 (0.8)	(0.7, 0.9)
Nausea	214 (1.1)	(1.0, 1.3)	63 (0.3)	(0.3, 0.4)
Vomiting	44 (0.2)	(0.2, 0.3)	28 (0.1)	(0.1, 0.2)
Toothache	21 (0.1)	(0.1, 0.2)	18 (0.1)	(0.1, 0.2)
Abdominal pain upper	22 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Abdominal pain	14 (0.1)	(0.0, 0.1)	17 (0.1)	(0.1, 0.1)
Dyspepsia	12 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	6 (0.0)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Odynophagia	12 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Constipation	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Dental caries	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Gastritis	2 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Abdominal distension	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Flatulence	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Stomatitis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rectal haemorrhage	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis microscopic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Swollen tongue	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3494 (18.6)	(18.0, 19.1)	725 (3.9)	(3.6, 4.1)
Injection site pain	2108 (11.2)	(10.8, 11.7)	281 (1.5)	(1.3, 1.7)
Fatigue	1026 (5.5)	(5.1, 5.8)	258 (1.4)	(1.2, 1.6)
Pyrexia	1144 (6.1)	(5.7, 6.4)	61 (0.3)	(0.2, 0.4)
Chills	998 (5.3)	(5.0, 5.6)	85 (0.5)	(0.4, 0.6)
Pain	455 (2.4)	(2.2, 2.6)	36 (0.2)	(0.1, 0.3)
Injection site erythema	138 (0.7)	(0.6, 0.9)	20 (0.1)	(0.1, 0.2)
Malaise	96 (0.5)	(0.4, 0.6)	15 (0.1)	(0.0, 0.1)
Injection site swelling	93 (0.5)	(0.4, 0.6)	17 (0.1)	(0.1, 0.1)
Asthenia	64 (0.3)	(0.3, 0.4)	25 (0.1)	(0.1, 0.2)
Injection site pruritus	27 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Influenza like illness	20 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Chest pain	13 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Injection site bruising	10 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Vaccination site pain	13 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Axillary pain	9 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest discomfort	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site induration	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site oedema	8 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Peripheral swelling	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Oedema peripheral	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Injection site haematoma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	11 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Cholelithiasis	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	25 (0.1)	(0.1, 0.2)	20 (0.1)	(0.1, 0.2)
Seasonal allergy	8 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Drug hypersensitivity	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	286 (1.5)	(1.4, 1.7)	289 (1.5)	(1.4, 1.7)
Urinary tract infection	44 (0.2)	(0.2, 0.3)	44 (0.2)	(0.2, 0.3)
Tooth infection	23 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Sinusitis	18 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.2)
Herpes zoster	12 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Cellulitis	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Ear infection	8 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Gastroenteritis	6 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Conjunctivitis	8 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Cystitis	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Diverticulitis	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis media	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Gingivitis	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Oral herpes	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Tooth abscess	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Furuncle	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Periodontitis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Skin infection	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Influenza	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Otitis media acute	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyelonephritis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Folliculitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Herpes simplex	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash pustular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	169 (0.9)	(0.8, 1.0)	204 (1.1)	(0.9, 1.2)
Fall	33 (0.2)	(0.1, 0.2)	35 (0.2)	(0.1, 0.3)
Ligament sprain	13 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.2)
Skin laceration	11 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)
Contusion	11 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Muscle strain	12 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Arthropod bite	10 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Road traffic accident	5 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Skin abrasion	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Exposure during pregnancy	7 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Limb injury	4 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Foot fracture	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth fracture	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Procedural pain	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Meniscus injury	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Facial bones fracture	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Joint dislocation	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint injury	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Rib fracture	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Vaccination complication	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Thermal burn	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Chest injury	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Concussion	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand fracture	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radius fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Head injury	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal compression fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bone contusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	131 (0.7)	(0.6, 0.8)	33 (0.2)	(0.1, 0.2)
Body temperature increased	89 (0.5)	(0.4, 0.6)	8 (0.0)	(0.0, 0.1)
Blood pressure increased	4 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood cholesterol increased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	74 (0.4)	(0.3, 0.5)	54 (0.3)	(0.2, 0.4)
Decreased appetite	29 (0.2)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Dyslipidaemia	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Hypokalaemia	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Gout	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Hyperlipidaemia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Vitamin D deficiency	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dehydration	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hyperglycaemia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Insulin resistance	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1373 (7.3)	(6.9, 7.7)	384 (2.0)	(1.8, 2.3)
Myalgia	904 (4.8)	(4.5, 5.1)	126 (0.7)	(0.6, 0.8)
Arthralgia	210 (1.1)	(1.0, 1.3)	76 (0.4)	(0.3, 0.5)
Pain in extremity	163 (0.9)	(0.7, 1.0)	33 (0.2)	(0.1, 0.2)
Back pain	80 (0.4)	(0.3, 0.5)	71 (0.4)	(0.3, 0.5)
Neck pain	21 (0.1)	(0.1, 0.2)	24 (0.1)	(0.1, 0.2)
Muscle spasms	23 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	12 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Osteoarthritis	7 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Muscle contracture	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tendonitis	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscular weakness	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Musculoskeletal chest pain	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Bursitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Plantar fasciitis	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Arthritis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Flank pain	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Exostosis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Joint stiffness	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Costochondritis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	22 (0.1)	(0.1, 0.2)	30 (0.2)	(0.1, 0.2)
Basal cell carcinoma	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Lipoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1141 (6.1)	(5.7, 6.4)	442 (2.4)	(2.1, 2.6)
Headache	966 (5.1)	(4.8, 5.5)	302 (1.6)	(1.4, 1.8)
Dizziness	56 (0.3)	(0.2, 0.4)	48 (0.3)	(0.2, 0.3)
Paraesthesia	16 (0.1)	(0.0, 0.1)	17 (0.1)	(0.1, 0.1)
Migraine	18 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Lethargy	21 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Syncope	8 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Sciatica	9 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tension headache	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Dysgeusia	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Somnolence	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Presyncope	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tremor	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Burning sensation	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Parosmia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nerve compression	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paralysis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Neuropathy peripheral	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Transient ischaemic attack	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	76 (0.4)	(0.3, 0.5)	54 (0.3)	(0.2, 0.4)
Anxiety	18 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Insomnia	23 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Depression	10 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Irritability	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety disorder	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sleep disorder	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disorientation	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	28 (0.1)	(0.1, 0.2)	22 (0.1)	(0.1, 0.2)
Dysuria	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Haematuria	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pollakiuria	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Acute kidney injury	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	34 (0.2)	(0.1, 0.3)	35 (0.2)	(0.1, 0.3)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ovarian cyst	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pelvic pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	163 (0.9)	(0.7, 1.0)	148 (0.8)	(0.7, 0.9)
Oropharyngeal pain	35 (0.2)	(0.1, 0.3)	32 (0.2)	(0.1, 0.2)
Nasal congestion	21 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Cough	22 (0.1)	(0.1, 0.2)	17 (0.1)	(0.1, 0.1)
Rhinorrhoea	19 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.1)
Rhinitis allergic	10 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Asthma	9 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dyspnoea	7 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Sinus congestion	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bronchospasm	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	(95% CI[c])	Placebo (N[a]=18785) n[b] (%)	(95% CI[c])
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	183 (1.0)	(0.8, 1.1)	127 (0.7)	(0.6, 0.8)
Rash	44 (0.2)	(0.2, 0.3)	36 (0.2)	(0.1, 0.3)
Pruritus	19 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.1)
Hyperhidrosis	24 (0.1)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Dermatitis contact	13 (0.1)	(0.0, 0.1)	17 (0.1)	(0.1, 0.1)
Urticaria	13 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Night sweats	14 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Rash pruritic	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Erythema	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Eczema	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rash maculo-papular	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Skin lesion	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Dermatitis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Angioedema	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dermal cyst	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress at work	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	28 (0.1)	(0.1, 0.2)	18 (0.1)	(0.1, 0.2)
Tooth extraction	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Endodontic procedure	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salpingectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	23 (0.1)	(0.1, 0.2)	16 (0.1)	(0.0, 0.1)
FATIGUE@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	56 (0.3)	(0.2, 0.4)	63 (0.3)	(0.3, 0.4)
Hypertension	26 (0.1)	(0.1, 0.2)	35 (0.2)	(0.1, 0.3)
Hot flush	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Haematoma	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Flushing	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 52. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_soc_p3_saf

Participants reporting at least 1 AE from Dose 1 to 1 month after Dose 2 are presented by subgroup in the following tables:

Age Group: 16 to 55 Years	Supplemental Table 14.401
Age Group: >55 Years	Supplemental Table 14.402
Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.403
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.404
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: 16 to 55 Years	Supplemental Table 14.405
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: >55 Years	Supplemental Table 14.406
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: 16 to 55 Years	Supplemental Table 14.407
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: >55 Years	Supplemental Table 14.408
Ethnicity: Hispanic/Latino	Supplemental Table 14.409

Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.410
Ethnicity: Not Reported	Supplemental Table 14.411
Race: White	Supplemental Table 14.412
Race: Black or African American	Supplemental Table 14.413
Race: All Others	Supplemental Table 14.414
Sex: Male	Supplemental Table 14.415
Sex: Female	Supplemental Table 14.416

12.3.3.2.1.1.1. Participants with At Least 2 Months of Follow-Up After Dose 2

There were 19,067 participants with at least 2 months follow-up time after Dose 2, and similar to the 37,586 participants with a median of 2 months of safety follow up after Dose 2, most AEs reported after Dose 1 up to the safety data cutoff date (Supplemental Table 14.417) were reactogenicity, in SOCs of:

- general disorders and administration site conditions (11.9% BNT162b2 vs 2.9% placebo)
- musculoskeletal and connective tissue disorders (5.5% BNT162b2 vs 2.1% placebo)
- nervous system disorders (4.2% BNT162b2 vs 2.1% placebo)
- infections and infestations (1.9% BNT162b2 vs 1.6% placebo)
- gastrointestinal disorders (2.6% BNT162b2 vs 1.8% placebo).

In the younger versus older BNT162b2 age groups (Supplemental Tables 14.418 and 14.419), AE incidences in these SOCs were:

- general disorders and administration site conditions (13.1% vs 10.4%)
- musculoskeletal and connective tissue disorders (6.0% vs 4.9%)
- nervous system disorders (4.8% vs 3.5%)
- infections and infestations (1.9% vs 1.9%)
- gastrointestinal disorders (2.7% vs 2.5%) .

In the BNT162b2 group, the most frequently reported AEs by PT overall were injection site pain (621 [6.5%]), pyrexia (362 [3.8%]), chills (314 [3.3%]), fatigue (331 [3.5%]), headache (320 [3.4%]), and myalgia (304 [3.2%]) (Supplemental Table 14.417). During this time period from Dose 1 to the safety data cutoff date, most of these AEs were reported during the e-diary 7-day reporting period (Appendix 16.2.7.4.4). The majority of these PTs were reported in the younger age group: injection site pain (373 [7.0%]), pyrexia (256 [4.8%]), chills (211 [3.9%]), fatigue (209 [3.9%]), headache (206 [3.9%]), and myalgia (192 [3.6%]).

12.3.3.2.1.2. All Participants – Phase 2/3

For all 43,448 enrolled participants up to the safety data cutoff date, there were a total of 38 (0.2%) participants in the BNT162b2 group and 23 (0.1%) participants in the placebo group with at least 1 uncoded term. As a result, uncoded terms are also present in other AE tables summarized by SOC and PT.

Similar to the 37,586 participants who had at least a 1-month duration of safety follow-up, most AEs reported after Dose 1 up to the safety data cutoff date for all 43,252 enrolled participants were reactogenicity events (Supplemental Table 14.420).

In the younger versus older BNT162b2 age groups (Supplemental Tables 14.421 and 14.422), AE incidences for all enrolled participants in these reactogenicity SOCs were:

- general disorders and administration site conditions (20.9% vs 15.2%)
- musculoskeletal and connective tissue disorders (7.8% vs 5.8%)
- nervous system disorders (6.6% vs 4.9%)
- infections and infestations (1.4% vs 1.6%)
- gastrointestinal disorders (3.0% vs 2.7%).

Beyond the 8183 participants in the Phase 3 reactogenicity subset, events related to reactogenicity are no longer reported using an e-diary but are instead reported as AEs. Therefore, a post hoc analysis was conducted to evaluate if the imbalance in AEs observed in the overall participants from Dose 1 to the data cutoff date but not observed in the 8183 participants of the reactogenicity subset from Dose 1 to 1 month after Dose 2 was attributed to reactogenicity events (Section 12.3.3.2.1.1). The analysis examined the AEs reported within 7 days after each dose, which represented the reactogenicity reporting period. The time period was chosen because many AEs were reported in the SOCs of general disorders and administration site conditions, musculoskeletal and connective tissue disorders, and nervous system disorders, which includes AEs consistent with reactogenicity events (Section 9.5.2.2), and could only be attributed to reactogenicity if they occurred during this time period as opposed to occurring up to 1 month from each dose.

As shown in Supplemental Table 14.420, incidence of AEs in the BNT162b2 versus placebo groups in the following SOCs consistent with reactogenicity events were reported:

- general disorders and administration site conditions (18.5% vs 3.8%)
- musculoskeletal and connective tissue disorders (7.0% vs 2.0%)
- nervous system disorders (5.9% vs 2.3%)

From Dose 1 to 7 days after Dose 1, incidence of AEs in the BNT162b2 group represented up to approximately half of the total incidence reported in the following SOCs (BNT162b2 versus placebo) (Supplemental Table 14.423):

- general disorders and administration site conditions (10.2% vs 2.3%)
- musculoskeletal and connective tissue disorders (2.2% vs 0.7%)
- nervous system disorders (2.1% vs 1.0%)

Similarly, from Dose 2 to 7 days after Dose 2, incidence of AEs in the BNT162b2 group represented at least half of the total incidence reported in the following SOCs (BNT162b2 versus placebo) (Supplemental Table 14.424):

- general disorders and administration site conditions (13.3% vs 1.6%)

- musculoskeletal and connective tissue disorders (4.8% vs 0.5%)
- nervous system disorders (4.1% vs 0.7%)

PTs reported from Dose 1 to 7 days after Dose 1 and from Dose 2 to 7 days after Dose 2 in the SOCs of general disorders and administration site conditions (injection site pain, pyrexia, chills, and fatigue), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs, and the PTs were reported more frequently in the younger age group (Supplemental Tables 14.425 and 14.427; for the older age group, see Supplemental Tables 14.426 and 14.428).

Overall, AEs reported from Dose 1 to 7 days after Dose 1 and from Dose 2 to 7 days after Dose 2 were largely attributable to reactogenicity events. This observation provides a reasonable explanation for the greater rates of AEs observed overall in the BNT162b2 group compared with the placebo group.

In the 16 to 17-year-old age group, from Dose 1 to the data cutoff date, most AEs were in the general disorders and administration site conditions (15 [10.9%] in the BNT162b2 group and 5 [3.4%] in the placebo group), including the following PTs: pyrexia, injection site pain, chills, pain, fatigue, injection site erythema, and injection site swelling (Table 53).

Table 53. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – 16-17 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=138)		Placebo (N[a]=145)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	16 (11.6)	(6.8, 18.1)	7 (4.8)	(2.0, 9.7)
GASTROINTESTINAL DISORDERS	1 (0.7)	(0.0, 4.0)	3 (2.1)	(0.4, 5.9)
Nausea	1 (0.7)	(0.0, 4.0)	2 (1.4)	(0.2, 4.9)
Diarrhoea	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Vomiting	1 (0.7)	(0.0, 4.0)	1 (0.7)	(0.0, 3.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	15 (10.9)	(6.2, 17.3)	5 (3.4)	(1.1, 7.9)
Pyrexia	10 (7.2)	(3.5, 12.9)	2 (1.4)	(0.2, 4.9)
Injection site pain	8 (5.8)	(2.5, 11.1)	2 (1.4)	(0.2, 4.9)
Chills	4 (2.9)	(0.8, 7.3)	0	(0.0, 2.5)

Table 53. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – 16-17 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=138)		Placebo (N[a]=145)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fatigue	2 (1.4)	(0.2, 5.1)	1 (0.7)	(0.0, 3.8)
Pain	3 (2.2)	(0.5, 6.2)	0	(0.0, 2.5)
Injection site erythema	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Injection site swelling	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Concussion	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Facial bones fracture	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Road traffic accident	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
INVESTIGATIONS	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Body temperature increased	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.7)	(0.0, 4.0)	1 (0.7)	(0.0, 3.8)
Myalgia	1 (0.7)	(0.0, 4.0)	1 (0.7)	(0.0, 3.8)
NERVOUS SYSTEM DISORDERS	4 (2.9)	(0.8, 7.3)	2 (1.4)	(0.2, 4.9)
Headache	4 (2.9)	(0.8, 7.3)	2 (1.4)	(0.2, 4.9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Dyspnoea	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (01:31)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2_LOWAGE/adae_s130_cut_lowage_p23_saf

12.3.3.2.2. Related Adverse Events by System Organ Class and Preferred Term – Phase 2/3

12.3.3.2.2.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Phase 2/3

From Dose 1 to 1 month after Dose 2, among the 37,586 participants with a median of 2 months of follow-up after Dose 2, AEs assessed as related by the investigator were reported by 20.8% of participants in the BNT162b2 group and 5.1% of participants in the placebo group (Table 49). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 3426 (18.2%) BNT162b2 recipients and 628 (3.3%) placebo recipients (Supplemental Table 14.429). Among the participants who had AEs of lymphadenopathy, 47 of 64 participants had events assessed by the investigator as related to study intervention; the majority of lymphadenopathy events occurred in the arm and neck region and were reported within 2 to 4 days after vaccination (Section 12.3.3.2.1.1).

Related AEs from Dose 1 to 1 month after Dose 2 are presented by age group in Supplemental Tables 14.430 and 14.431.

12.3.3.2.2.2. Participants with At Least 2 Months of Follow-Up After Dose 2

For the subset of 19,067 participants within the 37,586 group who had at least 2 months of follow-up after Dose 2, related AEs were reported by 13.6% of participants in the BNT162b2 group and 3.6% participants in the placebo group (Table 50).

12.3.3.2.2.3. All Participants – Phase 2/3

From Dose 1 to the data cutoff date, among all enrolled participants (43,252 participants), AEs assessed as related by the investigator were reported by 20.7% of participants in the BNT162b2 group and 5.1% participants in the placebo group (inclusive of the related AEs for the 37,586 participants discussed in Section 12.3.3.2.2.1) (Table 51). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 3924 (18.1%) BNT162b2 recipients and 720 (3.3%) placebo recipients (Supplemental Table 14.432). Among all enrolled participants who had AEs of lymphadenopathy, 50 of 70 participants had events assessed by the investigator as related to study intervention. At the time of the data cutoff, in the BNT162b2 group:

- Five participants reported immunization reaction (vaccine reaction or systemic vaccine reaction) assessed as related to the study intervention. In most participants, immunization reactions occurred 1 or 2 days after Dose 2, lasted 2 days and were Grade 1 in severity (Appendix 16.2.7.4.4).

- Six participants reported vaccination complication (vaccine adverse reaction, sore arm, post vaccination malaise, range of upward motion decreased) assessed as related to the study intervention. In 4 participants, vaccination complication occurred 1 or 2 days after Dose 1 and in 2 participants, vaccination complication occurred after Dose 2. The duration for most participants was 2 to 3 days and in one participant, duration was 4 days. All but one event of vaccination complication were Grade 1 in severity (one was Grade 2).

- Two participants reported facial paralysis (Bell's palsy) assessed as related to the study intervention. In one participant with facial paralysis that was Grade 1 in severity, the onset was 3 days after Dose 2 and the duration was 3 days. In the other participant, facial paralysis was Grade 2 in severity, with an onset of 9 days after Dose 2 that was continuing at the time of data cutoff.

Related AEs from Dose 1 to the data cutoff date (14 November 2020) for all participants are presented by age group in Supplemental Tables 14.433 and 14.434.

12.3.3.2.3. Immediate Adverse Events – Phase 2/3

12.3.3.2.3.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Phase 2/3

After Dose 1, among the 37,586 participants with a median of 2 months of follow-up after Dose 2 immediate AEs were low in frequency (0.4%). Most immediate AEs after Dose 1 were in the SOC of general disorders and administration site conditions, primarily injection site reactions, in the BNT162b2 versus placebo groups with injection site pain (0.3% vs 0.2%) most frequently reported (Supplemental Table 14.435).

After Dose 2, participants with immediate AEs were low in frequency (≤0.3%). Most immediate AEs after Dose 2 were in the SOC of general disorders and administration site conditions, primarily injection site reactions, in the BNT162b2 versus placebo groups with injection site pain (0.2% vs 0.1%) most frequently reported (Supplemental Table 14.436).

After either BNT162b2 dose, no participant reported an immediate allergic reaction to vaccine.

12.3.3.2.3.2. All Participants – Phase 2/3

After Dose 1, among all enrolled participants analyzed up to the safety data cutoff date, immediate AEs were low in frequency in either group (≤0.5%). Most immediate AEs after Dose 1 were in the SOC of general disorders and administration site conditions, primarily injection site reactions, in the BNT162b2 versus placebo groups, with injection site pain (0.3% vs 0.2%) most frequently reported (Supplemental Table 14.437). One participant had an immediate AE of lymphadenopathy after Dose 1.

After Dose 2, participants with immediate AEs were low in frequency in either group (≤0.3%). Most immediate AEs after Dose 2 were in the SOC of general disorders and administration site conditions, primarily injection site reactions, in the BNT162b2 versus placebo groups, with injection site pain (0.2% vs 0.1%) most frequently reported (Supplemental Table 14.438).

After either dose of BNT162b2, no participant reported an immediate allergic reaction to the vaccine.

12.3.3.2.4. Severe or Life-Threatening Adverse Events – Phase 2/3

12.3.3.2.4.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Phase 2/3

From Dose 1 to 1 month after Dose 2, severe AEs reported by the 37,586 participants who had at least 1 month of follow-up were low in frequency, reported in 1.2% of BNT162b2 recipients and 0.6% of placebo recipients (Supplemental Table 14.439).

There were 18 participants (0.1%) in the BNT162b2 group and 20 participants (0.1%) in the placebo group who had at least 1 life-threatening AE from Dose 1 to 1 month after Dose 2 (Supplemental Table 14.440).

Severe and life-threatening appendicitis events are discussed in (Section 12.3.4.2).

In the BNT162b2 group, 1 participant who was also analyzed in Phase 2 safety had a severe event of gastric adenocarcinoma (SAE), which is discussed in Section 12.2.4.2.

For the subset of 19,067 participants within the 37,586 group who had at least 2 months of follow-up after Dose 2, the numbers of severe or life-threatening AEs were consistent with what was seen in the 37,586 participants with 1 month of follow-up after Dose 2. Overall, in the 19,067 participants, from Dose 1 to the data cutoff date, 1.1% and 0.1% of participants in the BNT162b2 group experienced at least 1 severe AE and 1 life-threatening AE, respectively, and 0.7% and 0.1% of participants in the placebo group experienced at least 1 severe AE and 1 life-threatening AE, respectively (Table 49). The results by age group were also similar (Supplemental Tables 14.396 and 14.397).

Severe and life-threatening AEs are presented by age group in the following tables:

Severe by Age Group: 16-55 Years	Supplemental Table 14.441
Severe by Age Group: >55 Years	Supplemental Table 14.442
Life-Threatening by Age Group: 16-55 Years	Supplemental Table 14.443
Life-Threatening by Age Group: >55 Years	Supplemental Table 14.444

12.3.3.2.4.2. All Participants – Phase 2/3

Severe and life-threatening AEs reported for all enrolled participants (43,252 participants) up to the data cutoff date were consistent with what was seen in the 37,586 participants with median follow-up 2 months after Dose 2 and the 19,067 participants with at least 2 months follow-up after Dose 2. Severe (Supplemental Table 14.445) and life-threatening (Supplemental Table 14.446) AEs were low in frequency in the BNT162b2 group (1.1% and 0.1%, respectively) and placebo group (0.6% and 0.1%, respectively).

In adolescents 16 to 17 years of age, 2 participants in the BNT162b2 group experienced the following 3 severe AEs: facial bones fracture (reported as an SAE), road traffic accident, and headache (Table 54).

Table 54. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – 16-17 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=138) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=145) n[b] (%)	 (95% CI[c])
Any event	2 (1.4)	(0.2, 5.1)	0	(0.0, 2.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Facial bones fracture	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Road traffic accident	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
NERVOUS SYSTEM DISORDERS	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Headache	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (07:42)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2 LOWAGE/adae s130 cut sev all low p3 saf

Severe and life-threatening AEs are presented by age group in the following tables:

Severe by Age Group: 16-55 Years	Supplemental Table 14.447
Severe by Age Group: >55 Years	Supplemental Table 14.448
Life-Threatening by Age Group: 16-55 Years	Supplemental Table 14.449
Life-Threatening by Age Group: >55 Years	Supplemental Table 14.450

12.3.4. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 2/3

12.3.4.1. Deaths – Phase 2/3

There were 6 Phase 2/3 participants (2 in the BNT162b2 group and 4 in the placebo group) who died through the data cutoff date of 14 November 2020 (Table 51 and Appendix 16.2.7.7.4). None of these deaths were assessed by the investigator as related to study intervention (Appendix 16.2.7.4.4).

Details of the 6 reported deaths among all enrolled participants include (Appendix 16.2.7.5.4 and Appendix 16.2.7.7.4):

- One participant in the older BNT162b2 group experienced an SAE of arteriosclerosis and died 3 days after Dose 1.
- One participant in the older BNT162b2 group in Phase 2 experienced an SAE of cardiac arrest 60 days after Dose 2 and died 3 days later (Section 12.2.4).
- One participant in the younger placebo group experienced an SAE of unevaluable event (unknown of unknown origin [no additional information currently available at the time of this report) 8 days after Dose 1 and died the same day.
- One participant in the older placebo group experienced an SAE of hemorrhagic stroke 15 days after Dose 2 and died the next day.
- One participant in the younger placebo group experienced an SAE of death (cause unknown; no additional information currently available at the time of this report) 34 days after Dose 2.
- One participant in the older placebo group experienced an SAE of myocardial infarction 16 days after Dose 1 and died the same day.

12.3.4.1.1. Death Narratives

Narratives for the participants who died through the data cutoff date (14 November 2020) are provided in Section 14.

12.3.4.2. Serious Adverse Events – Phase 2/3

12.3.4.2.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Phase 2/3

Among the 37,586 participants with a median of 2 months of follow-up after Dose 2, from Dose 1 to 1 month after Dose 2 the proportions of participants who reported at least 1 SAE was similar in the BNT162b2 group (0.5%) and in the placebo group (0.4%) (Table 55).

Three of the SAEs in the BNT162b2 group and none in the placebo group were assessed by the investigator as related to study intervention. The most frequently reported SAEs were in the Cardiac Disorders SOC (0.1% in each treatment group), Nervous System Disorders SOC (0.1% in each treatment group), and Infections and Infestations SOC (0.1% in each treatment group).

In the BNT162b2 group, there were 2 participants in the younger age group and 1 participant in the older age group with an SAE each assessed by the investigator as related to study intervention (Appendix 16.2.7.5.4):

- One participant in the younger age group had an SAE of lymphadenopathy (right axilla) 13 days after Dose 1, which was not resolved at the time of the data cutoff. The participant was a 48-year-old woman with a relevant medical history of eczema and

topical crisaborole use who was administered BNT162b2 vaccine in the left deltoid and had right axillary pain and lymphadenopathy. She had no injuries to the right arm, no fever, and no history of a similar incident. Her WBC was normal with a normal lymphocyte count and a right axilla ultrasound showed 4 enlarged lymph nodes (largest 2.5 × 1.1 × 2.4 cm). A biopsy was performed and was reported to be normal and without markers for lymphoma or other cancer. A follow-up visit with oncology (and possible repeat ultrasound) was planned for 3 months' time.

- One participant in the younger age group had an SAE of shoulder injury related to vaccine administration (SIRVA, erroneously administered into or near the shoulder joint capsule) after Dose 2, which was recovering at the time of the data cutoff.

- One participant in the older age group had an SAE of ventricular arrhythmia that occurred 1 day after Dose 2 and lasted for 8 days.

From Dose 1 to 1 month after Dose 2, the number of participants who reported at least 1 SAE in the younger and older age groups was similar (Supplemental Tables 14.451 and 14.452, respectively).

There were a total of 12 participants with SAEs of appendicitis; 8 in the BNT162b2 group (SAEs of appendicitis [7], appendicitis perforated [1]) and 4 in the placebo group (appendicitis [2], appendicitis perforated [1], complicated appendicitis [1]) . Of the 8 total appendicitis cases in the BNT162b2 group, 6 occurred in the younger age group and 2 occurred in the older age group (one of the cases in the older age group was perforated). One of the 6 participants with appendicitis in the younger age group also had a peritoneal abscess. None of the cases were assessed as related to study intervention by the investigators.

Table 55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	103 (0.5)	(0.4, 0.7)	81 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	14 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)

Table 55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	8 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	25 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

Table 55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	7 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	15 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Deep vein thrombosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser p3 saf

Among the 37,586 participants with a median of 2 months of safety follow-up after Dose 2, no clinically meaningful differences in SAEs were observed by age, baseline SARS-CoV-2 status, ethnicity, race or sex subgroups.

SAEs are presented by age group, baseline SARS-CoV-2 status, sex, race, and ethnicity in the following tables:

Age Group: 16-55 Years	Supplemental Table 14.451
Age Group: >55 Years	Supplemental Table 14.452
Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.453
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.454

Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: 16 to 55 Years	Supplemental Table 14.455
Baseline SARS-CoV-2 Status and Age Group: Positive Age Group: >55 Years	Supplemental Table 14.456
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: 16 to 55 Years	Supplemental Table 14.457
Baseline SARS-CoV-2 Status and Age Group: Negative Age Group: >55 Years	Supplemental Table 14.458
Ethnicity: Hispanic/Latino	Supplemental Table 14.459
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.460
Ethnicity: Not Reported	Supplemental Table 14.461
Race: White	Supplemental Table 14.462
Race: Black or African American	Supplemental Table 14.463
Race: All Others	Supplemental Table 14.464
Sex: Male	Supplemental Table 14.465
Sex: Female	Supplemental Table 14.466

With additional follow-up to the data cutoff date of 14 November 2020 for the 37,586 participants with a median of 2 months of follow-up after Dose 2, the number of participants who reported SAEs was similar in the BNT162b2 group (0.7%) and the placebo group (0.5%) (Supplemental Table 14.467). No clinically meaningful differences in SAEs to the data cutoff date were observed by age (Supplemental Table 14.468 and 14.469).

Participants with At Least 2 Months of Follow-Up After Dose 2

Among the 19,067 participants with at 2 months of follow-up after Dose 2, from Dose 1 to the data cutoff date the proportion of participants who reported any SAEs was the same in the BNT162b2 group (0.6%) and in the placebo group (0.6%) (Supplemental Table 14.470). Most PTs for SAEs were reported by only 1 participant (5 participants reported an SAE of appendicitis).

From Dose 1 to the data cutoff date, the number of participants who reported at least 1 SAE in the younger and older age groups was similar (Supplemental Tables 14.471 and 14.472 respectively).

12.3.4.2.2. All Participants – Phase 2/3

Among all 43,448 enrolled participants, from Dose 1 to the data cutoff date, the proportions of participants who reported at least 1 SAE were similar in the BNT162b2 group (0.6%) and in the placebo group (0.5%) (Table 56). An additional 23 participants in the BNT162b2 group and 30 participants in the placebo group had at least 1 SAE compared with the N~38,000 population. There was an equal number of participants (18 [0.1%]) in the BNT162b2 and placebo groups who reported SAEs in the Cardiac Disorders SOC. Results

by age group were similar, consistent with what was seen in the N~38,000 population (Supplemental Tables 14.473 and 14.474).

Four (4) of the SAEs (inclusive of the 3 SAEs that occurred in the participants with a median of 2 months of follow-up) in the BNT162b2 group and none in the placebo group were assessed by the investigator as related to study intervention. The most frequently reported SAEs were the same as those reported in the N~38,000 population.

In participants 16 to 17 years of age, 1 participant in the BNT162b2 group experienced an SAE of facial bones fracture (Table 57).

No clinically significant differences in SAEs were observed by age.

The additional related SAE reported in a participant in the BNT162b2 group was a Grade 2 SAE of lower back pain and bilateral lower extremity pain with radicular paresthesia (uncoded term) that occurred 47 days after Dose 2 and was recovering/resolving at the data cutoff date (Appendix 16.2.7.5.4).

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	126 (0.6)	(0.5, 0.7)	111 (0.5)	(0.4, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	18 (0.1)	(0.0, 0.1)	18 (0.1)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute coronary syndrome	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	10 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Small intestinal obstruction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	27 (0.1)	(0.1, 0.2)	17 (0.1)	(0.0, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diverticulitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	11 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	18 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Cerebrovascular accident	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dizziness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Nephrolithiasis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SHORTNESS OF BREATH@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Deep vein thrombosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 sae all p23 saf

Table 57. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – 16-17 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=138)		Placebo (N[a]=145)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)
Facial bones fracture	1 (0.7)	(0.0, 4.0)	0	(0.0, 2.5)

Table 57. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – 16-17 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=138)		Placebo (N[a]=145)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (01:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2 LOWAGE/adae s130 ser lowage p3 saf

12.3.4.2.3. Serious Adverse Event Narratives – Phase 2/3

Narratives for the Phase 3 participants who reported SAEs assessed as related to study intervention by the investigator who completed their visit at 1 month after Dose 2 and through the data cutoff date (14 November 2020) are provided in Section 14.

12.3.4.3. Safety-Related Participant Withdrawals – Phase 2/3

12.3.4.3.1. Participants with Median 2 Months of Follow-Up After Dose 2 – Phase 2/3

Among the 37,706 participants with a median of 2 months of follow-up after Dose 2, from Dose 1 to 1 month after Dose 2 few participants in the BNT162b2 group (0.2%) and in the placebo group (0.1%) were withdrawn because of AEs (Table 58).

34 participants in the BNT162b2 group and 25 participants in the placebo group had an AE leading to withdrawal, which included:

- 7 participants in the BNT162b2 group and 1 participant in the placebo group withdrew from the study due to AEs in the SOC of General Disorders and Administration Site Conditions (BNT162b2 group: injection site pain [2 participants] and chills, facial pain, fatigue, injection site dermatitis, injection site swelling, pyrexia, and swelling face [1 participant each]; placebo group: 1 unevaluable event).

- 6 participants in the BNT162b2 group and 4 participants in the placebo group withdrew from the study due to AEs in the SOC of Injury, Poisoning and Procedural Complications (BNT162b2 group: exposure during pregnancy [2 participants each] and alcohol poisoning, ankle fracture, and fall [1 participant each]; placebo group: maternal exposure during pregnancy [3 participants] and flail chest [1 participant]

- 5 participants in the BNT162b2 group and no participants in the placebo group withdrew from the study due to AEs in the SOC of Musculoskeletal and Connective Tissue Disorders (BNT162b2 group: muscular weakness [2 participants] and muscle spasm, myalgia, and pain in extremity [1 participant each])

- 5 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Nervous System Disorders (BNT162b2 group: headache [3 participants] and syncope and transient ischemic attack [1 participant each]; placebo group: dizziness [2 participants] and headache, cerebral infarction, hemorrhagic stroke, and Parkinsonism [1 participant each]).

Among the 37,706 participants, no clinically meaningful differences in AEs leading to withdrawal were observed by age subgroups (Supplemental Tables 14.475 and 14.476).

Table 58. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	34 (0.2)	(0.1, 0.3)	25 (0.1)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 58. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chills	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 58. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FATIGUE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 58. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (05:57)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 wd p3 saf

Among 19,067 participants with at least 2 months of follow-up time post Dose 2, 1 participant in the BNT162b2 group and no participants in the placebo group had an AE leading to withdrawal (Table 50). This participant had a life-threatening AE leading to death that was not considered related to study vaccine (Appendix 16.2.7.6.4).

12.3.4.3.2. All Participants – Phase 2/3

Among all 43,448 enrolled participants included in the safety database up to the data cutoff date, few participants in the BNT162b2 group (0.2%) and in the placebo group (0.1%) were withdrawn because of AEs (Supplemental Table 14.477). The results were similar to the AEs leading to withdrawal in the 37,706 population: AEs leading to withdrawal were reported for 3 additional participants in the BNT162b2 group (37 total) and 5 additional participants in the placebo group (30 total).

No participants in the 16 to 17 years of age group experienced an AE leading to withdrawal.

Among all 43.448 participants, no clinically meaningful differences in AEs leading to withdrawal were observed by age subgroups (Supplemental Tables 14.478 and 14.479).

12.3.4.3.3. Narratives of Safety-Related Participant Withdrawals – Phase 2/3

Narratives for the Phase 2/3 participants with any AEs leading to withdrawal from the study through the data cutoff date (14 November 2020) are provided in Section 14.

12.3.4.4. Other Significant Adverse Events – Phase 2/3

AEs of clinical interest, such as the CDC's list of AESIs for COVID-19, which both include terms potentially indicative of severe COVID-19 or serious autoimmune and neuroinflammatory disorders, were considered in the review of reported events. Following review of the AEs, TMEs, and detailed review of the SAEs reported in all participants (N~44,000), there were no adverse events of clinical interest that were identified as safety concerns.

Events of clinical interest identified by the sponsor were reviewed and summarized from the AE analysis among the 37,586 participants. In the BNT162b2 group, there were 64 participants (0.3%) who reported an AE of lymphadenopathy: 54 (0.5%) in the younger age group (Supplemental Table 14.401) and 10 (0.1%) in the older age group (Supplemental Table 14.402), and 6 in the placebo group (Table 52). This included 26 male participants (0.3%) and 38 female participants (0.4%). In cases where location was specified, AEs of lymphadenopathy occurred in the arm and neck region (in axillary [left or right], left para clavicular, left supra clavicular, bilateral cervical, or unspecified lymph nodes). Most lymphadenopathy events were reported within 2 to 4 days after vaccination (15 events were reported ≥8 days after vaccination, including 1 event reported 98 days after). The average duration of these events was approximately 10 days, with 12 events ongoing at the time of the data cutoff (Appendix 16.2.7.4.4).

In the younger age group, an AE of angioedema 13 days after Dose 1 (both eyes) and hypersensitivity (allergy attack; no additional information available at the time of this report, unrelated to study intervention) were reported in 1 participant each (BNT162b2 group), and an AE of drug hypersensitivity (oral penicillin reaction) was reported in 1 participant who received placebo (Table 52); all were assessed by the investigator as unrelated to study intervention (Appendix 16.2.7.4.4).

12.3.4.5. Other Safety Assessments – Phase 2/3

12.3.4.5.1. Severe COVID-19 Illness – Phase 2/3

The protocol had prespecified stopping rules that included monitoring of severe COVID-19 cases, and these stopping criteria were not met. The confinement of the majority of severe cases to the placebo groups suggests no evidence for vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD).

A description of severe COVID-19 cases evaluated for efficacy in Phase 2/3 is presented in Section 11.1.1.3 and Section 11.1.2.3.2 (interim and final analyses).

12.3.4.5.2. Pregnancy – Phase 2/3

At the time of the data cutoff in Study C4591001 (14 November 2020), a total of 23 participants had reported pregnancies in the safety database, including 9 participants who withdrew from the vaccination period of the study due to pregnancies. These participants continue to be followed for pregnancy outcomes.

Narratives for participants who withdrew from the study due to pregnancy are provided in Section 14.

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

Up to the data cutoff date of 14 November 2020, the numbers of SAEs were similar in the BNT162b2 group (0.6%) and in the placebo group (0.5%) (Table 51 and Section 12.3.4.2.2). Four participants in the BNT162b2 group reported SAEs that were assessed by the investigator as related to study intervention.

Few participants in the BNT162b2 group (0.2%) and in the placebo group (0.1%) were withdrawn because of AEs.

There were 6 deaths (2 in the BNT162b2 group and 4 in the placebo group); none of the deaths were assessed by the investigator as related to study intervention (Section 12.3.4.1). All were due to SAEs (see Section 12.3.4.2).

12.3.5. Phase 2/3 Safety Conclusions

- Across age groups, local reactions were generally similar in frequency after each dose, and systemic events generally increased in frequency and severity after Dose 2 compared to Dose 1. Local and systemic reactogenicity events were well-tolerated and short-lived (median durations of 1.0 to 2.0 days).

- Reactogenicity events after each dose of BNT162b2 in older adults were generally milder and less frequent than those observed in younger adults. The majority of reactogenicity events were mild or moderate in severity. No Grade 4 events were reported other than fever in 2 participants: 1 participant in the younger BNT162b2 group that began on Day 2 after Dose 2 and lasted 1 day, and 1 participant in the older BNT162b2 group that began on Day 4 after Dose 1 and lasted for 1 day.

- The reactogenicity profile after BNT162b2 30 µg evaluated in 8183 participants was consistent with the reactogenicity profile observed after BNT162b2 30 µg in Phase 1 and Phase 2.

- In the ~38,000 participants in Phase 2/3 with a median follow-up of at least 2 months after Dose 2, AEs were reported in 27.0% of participants in the BNT162b2 group, and most AEs were mild or moderate in severity. At the time of the data cutoff date, the number of participants with AEs in the BNT162b2 group was greater as compared with the placebo group (12.5%), which upon analysis, was attributed to reactogenicity events reported as AEs within 7 days after each dose.

- Analyses of the data for each population at the data cutoff date of 14 November 2020 (~38,000 with a median follow-up of 2 months after Dose 2, ~19,000 with at least 2 months of follow-up after Dose 2, and ~44,000 enrolled participants with variable length of follow-up) did not identify any new safety signals with longer follow-up or by examining all of the AEs reported in the database.

- At the time of the data cutoff date, there were 4 related SAEs in the BNT162b2 group (lymphadenopathy; shoulder injury related to vaccine administration [SIRVA], erroneously administered into or near the shoulder joint capsule; ventricular arrhythmia; and lower back pain and bilateral lower extremity pain with radicular paresthesia [uncoded term]), and few participants in the BNT162b2 group (0.2%) were withdrawn because of AEs. There were 2 deaths in the BNT162b2 group (arteriosclerosis and cardiac arrest) and 4 deaths in the placebo group that were assessed as not related to study intervention.

- Overall, BNT162b2 at 30 µg was well tolerated with a maximum follow-up time of up to 14 weeks after Dose 2.

13. DISCUSSION AND OVERALL CONCLUSIONS

13.1. Discussion

13.1.1. Phase 1

This is the first study in the US evaluating the BioNTech RNA-based platform for 2 COVID-19 vaccine candidates. In the Phase 1 portion of the study, the number of participants in each vaccine group was small, and the participants were not randomized to receive BNT162b1 or BNT162b2. Discretion was made when interpreting the results for the 2 groups.

Participants who received BNT162b1 or BNT162b2 up to 30-µg dose reported mild to moderate local reactions with a higher frequency of reactions observed after Dose 2. For both candidates a lower frequency of local reactions in the older age group compared to the younger age group was observed. The systemic reactogenicity profiles (particularly in the older age group), however, clearly showed a more favorable reactogenicity profile for the BNT162b2 vaccine candidate compared to each corresponding dose level for BNT162b1. In contrast BNT162b1 at 100 µg was discontinued after the first dose based on reactogenicity.

Overall, fewer AEs were experienced by participants who received BNT162b2 compared with those who received BNT162b1, with the least number of participants experiencing AEs in the BNT162b2 older age group. Few severe AEs in the older age group after BNT162b2 were observed, and all were considered unrelated to study intervention. There were no AEs leading to withdrawal, or deaths reported for either candidate. From additional follow-up from 1 month after to 4 months after Dose 2 to the data cutoff date (14 November 2020), 1 severe SAE (neuritis due to a blood draw in the antecubital fossa) was reported in the younger age group. Since development of a safe and well tolerated COVID-19 vaccine is the highest priority, the overall more favorable reactogenicity profile of BNT162b2 was noteworthy.

Transient decreases in lymphocytes were observed in both candidates (most were Grades 1 through 3). All decreases in lymphocytes returned to normal by 6 to 8 days after any dose. RNA vaccines are known to induce type I interferon,[10] and type I interferons regulate lymphocyte recirculation and are associated with transient migration and/or redistribution of lymphocytes.[11] This rapid rebound of lymphocytes indicates that the lymphocytes are likely

not depleted, but temporarily migrated out of the peripheral blood compartment, and subsequently re-emerged by the time of the next assessment.

Overall, the immunogenicity responses were similar for the 2 candidates. SARS-CoV-2 neutralizing titers for BNT162b1 and BNT162b2 had modest increases in GMTs by Day 21 after the first dose and were substantially increased 7 days after the second dose. Antigen binding IgG levels increased substantially by Day 21 after the first dose and were further increased by 7 days after the second dose. S1-IgG antibody binding concentrations after BNT162b2 favored the selection of the 30-µg dose level. When selecting the dose level for Phase 2/3, the major driver was maximizing SARS-CoV-2 neutralizing antibody responses in the older age group, who are at highest risk of severe disease.

BNT162b1 and BNT162b2 GMTs for neutralizing antibody levels were also compared to those from an HCS panel, composed of 38 human SARS-CoV-2 infection/COVID-19 convalescent sera, drawn from participants 18 to 83 years of age at least 14 days after PCR-confirmed diagnosis, and at a time when participants were asymptomatic.[9] The serum donors predominantly had symptomatic infections (35/38), and one had been hospitalized. In Phase 1, GMTs measured 7 days after Dose 2 (Day 28) of BNT162b1 or BNT162b2 at the 30-µg dose level were 267.1 and 100.8 for younger and older participants who received BNT162b1, and 360.9 and 155.7 for younger and older participants who received BNT162b2. These GMTs were approximately 2.8 to 3.8 times that of the convalescent serum panel GMT for younger participants, and 1.1 to 1.7 times that of the panel for older participants. By 1 month after Dose 2 (Day 52), GMTs were generally stable and were approximately 1.5 to 1.9 times that of the convalescent serum panel GMT for younger participants, and 1.5 to 1.6 times that of the panel for older participants. These comparisons to HCS further support the benefit of both candidates at the 30-µg dose level.

The SARS-CoV-2 neutralizing titers to both candidates showed the benefit of the second dose compared to a panel of HCS with a dose response up to 30 µg. The safety evaluation showed a milder profile of BNT162b2 compared to BNT162b1, especially in the older age population. Overall, the profile is consistent within the spectrum of profiles for other vaccines administered to adults. With these considerations in mind, the risk-benefit for the 2 vaccine candidates was most favorable for BNT162b2 at the 30-µg dose level. Therefore, BNT162b2 at 30 µg was selected to proceed into the Phase 2/3 portion of the study because this dose and construct provided the optimum combination of a favorable reactogenicity profile and a robust immune response, likely to afford protection against COVID-19 in younger and older adults.

13.1.2. Phase 2/3

In the first interim analysis, the first primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 occurring at least 7 days after Dose 2 in participants without evidence of SARS-CoV-2 infection before and during vaccination regimen in the evaluable efficacy population, was met at the planned interim analysis of 94 evaluable cases of COVID-19. There were 4 COVID-19 cases in the BNT162b2 group compared to 90 COVID-19 cases in the placebo group. These data give an observed vaccine efficacy of 95.5% for BNT162b2. The posterior probability of >99.99% met the prespecified interim analysis success criterion

of > 99.5%. The 2-sided 95% credible interval for the vaccine efficacy was 88.8% to 98.4%. Moreover, all the severe cases of COVID-19 were observed in the placebo group, thus giving reassurance in this interim analysis that to date, there is no evidence of enhanced disease with BNT162b2 in the all-available efficacy population.

In the final efficacy analysis, among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%, with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group. The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%.

For the second primary endpoint, observed VE against confirmed COVID-19 occurring at least 7 days after Dose 2 in participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%, indicating that the true VE is at least 89.9% with a 97.5% probability given the available data.

Efficacy analyses counting COVID-19 occurring at least 14 days after Dose 2 resulted in similar efficacy estimates as the 7 day efficacy analyses. Moreover, the analyses of efficacy using CDC-defined symptoms gave similar efficacy estimates as the definition used in other primary and secondary endpoints.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, observed VE of 66.3% against severe COVID-19 occurring at least 7 days after Dose 2 did not meet based the prespecified success criterion of the posterior probability >98.6%, due to the small number of severe cases (1 in the BNT162b2 group, 3 in the placebo group) observed after Dose 2 in the study. Consequently, no further statistical testing of pre-specified secondary endpoints related to severe disease was performed. However, from the total of 10 severe COVID-19 cases observed after Dose 1 (Dose 1 all-available population), only 1 severe case was seen in BNT162b2 recipients compared to 9 severe cases in placebo recipients after Dose 1; these results, as well as case splits between Dose 1 and Dose 2 and after Dose 2, were consistent with overall efficacy seen against COVID-19.

In Phase 2, 360 participants who entered the Phase 2/3 portion of the study were evaluated for safety and immunogenicity after dosing with the selected vaccine candidate, BNT162b2 at 30 µg or placebo through 7 days after Dose 2, which did not reveal new or clinically important safety observations. Phase 2 immunogenicity data demonstrated that BNT162b2 elicited robust SARS-CoV-2 neutralization and S1-binding IgG antibody responses 1 month after Dose 2, similar to those previously observed in Phase 1 of the study. Of note, GMTs for younger and older participants at 1 month after Dose 2 were similar to the GMTs of a comparative panel of HCS (GMT = 319).[12] The HCS is the same panel described in Section 13.1.1 except that 5 sera from the N=38 serum panel had been depleted.. The reactogenicity and AE profile in Phase 2 was confirmatory compared to observations in younger and older groups in the Phase 1 portion of the study, with most events being mild to

moderate in severity and resolving shortly after onset. During the additional safety follow-up of at least 2 months after Dose 2 as of the data cutoff date (14 November 2020) no treatment-related SAEs were reported and the incidence of discontinuations due to AEs was low. As of the data cutoff date, there was 1 death (cardiac arrest) in the BNT162b2 older age group that was not related to study intervention. Phase 2 safety data were concordant with safety data in the Phase 1 portion of the study, both overall and with regard to younger and older participants.

In the Phase 2/3 portion of the study, safety data are available for ~38,000 participants who received BNT162b2 30 µg or placebo (inclusive of the 360 participants from Phase 2) and had a median follow-up of at least 2 months after Dose 2 at the time of the data cutoff date (14 November 2020) . In this larger study population, safety results continued to show similar trends in line with outcomes in earlier phases. The prompted local reactogenicity profile was consistent with results observed in Phase 1. Consistent patterns were observed for the prompted systemic reactogenicity profile compared to earlier phases, with increases in systemic reactogenicity observed after Dose 2 compared with after Dose 1. Older adults generally reported milder and lower frequencies of local and systemic reactogenicity events compared with younger adults. Most prompted local and systemic reactogenicity events were short-lived, and only 2 Grade 4 events of fever each lasting 1 day were reported. Median onset day for most local and systemic reactions occurred within the first 3 days following vaccination and resolved with median durations within 2 days without sequela.

The Phase 2/3 AE profile of BNT162b2 at 30 µg was also consistent with earlier phases. AEs reported by ~38,000 participants in Phase 2/3 with a median follow-up of at least 2 months after Dose 2 were mostly mild or moderate and AE frequencies were higher in the BNT162b2 group than in the placebo group; however, most were reactogenicity events. Few participants had severe AEs, SAEs, or AEs leading to withdrawal. There were 3 SAEs (lymphadenopathy, shoulder injury related to vaccine administration [SIRVA], and ventricular arrhythmia) assessed by the investigator as related to study intervention in the ~38,000 participants who had a median follow-up of at least 2 months after Dose 2. SAEs in the Cardiac Disorders SOC were reported by 0.1% of participants each in the BNT162b2 and the placebo groups. Subgroup analyses by ethnicity, sex, and race did not reveal any clinically meaningful differences in safety results. The numbers of participants in a subset of ~19,000 subjects with at least 2 months of follow-up who reported at least 1 AE, related AEs, severe AEs, SAEs, and AEs leading to discontinuation and deaths were consistent with the results for the larger population of ~38,000.

Overall, AEs reported by all participants in Phase 2/3 to date who received BNT162b2 were also mostly mild or moderate, and AE frequency was higher compared with placebo. Since many AEs were reported in SOCs that contain AEs consistent with reactogenicity events, an ad hoc analyses of AEs reported within 7 days after each dose was performed. This analysis showed that the numbers of participants who reported AEs during this time period represented a large proportion of the total number of participants who reported AEs, supporting that the greater proportion of AEs in the BNT162b2 group was largely attributed to reactogenicity events being reported as AEs.

In the BNT162b2 group, mild and reversible lymphadenopathy was observed in 0.3% of all participants. In non-clinical rodent studies, BNT162b2 elicited B and T cell responses in draining lymph nodes which was associated with a reversible increase in lymph node size in some animals. As lymph nodes are the principal immune educated compartments for proficient B- and T-cell priming, these effects are likely the result of an immune response by the vaccine.[8,13] Given the low frequency and clinically benign nature of this event, the overall risk profile for the vaccine is not impacted.

Among all participants, the frequency of severe AEs was 1.1% in the BNT162b2 group and 0.6% in the placebo group. Severe SAEs were reported for 0.3% of participants in each group. There was 1 additional SAE (lower back pain and bilateral lower extremity pain with radicular paresthesia [uncoded term]) for a total of 4 SAEs assessed by the investigator as related to study intervention in the total enrolled population of 43,252 participants as of the data cutoff date, inclusive of the 3 SAEs assessed as related in the ~38,000 safety population (lymphadenopathy, SIRVA, and ventricular arrhythmia). There was an equal number of participants (18 [0.1%]) in the BNT162b2 and placebo groups who reported SAEs in the Cardiac Disorders SOC. Six deaths (2 in the BNT162b2 group [arteriosclerosis and cardiac arrest], 4 in the placebo group [unevaluable event, hemorrhagic stroke, death [cause unknown], and myocardial infarction]) have been reported among all enrolled participants to date (14 November 2020); none were assessed by the investigator as related to study intervention. Most participants received both doses of vaccine and remained on-study at the time of the data cutoff date (14 November 2020) with 0.2% and 0.1% of discontinuations due to AEs per BNT162b2 and placebo group, respectively, supporting the conclusion that the BNT162b2 is well tolerated.

The available evidence from the Phase 2/3 portion of this study is consistent with outcomes of the Phase 1 part of the study and supports the safety, tolerability, and effectiveness of BNT162b2 at 30 µg administered as a 2-dose regimen (21 days apart) to individuals ≥16 years of age for the prevention of COVID-19.

13.2. Overall Conclusions

- In Phase 1, BNT162b2 at 30 µg induced a robust immune response in both younger and older adults, and the reactogenicity profile was also satisfactory in both younger and older adults. BNT162b2 at 30 µg was selected for further development in the Phase 2/3 part of the study.

- In Phase 2, BNT162b2 at 30 µg elicited robust SARS-CoV-2 neutralization and S1-binding IgG antibody responses, consistent with results observed in Phase 1.

- In Phase 2/3, BNT162b2 at 30 µg provided protection against COVID-19 in participants irrespective of evidence of prior infection with SARS-CoV-2, including across demographic subgroups, with severe cases observed predominantly in the placebo group. The tolerability and safety profile of BNT162b2 30 µg was acceptable, and no clinically significant safety findings other than mild or moderate reactogenicity and mild and reversible lymphadenopathy were identified.

- Overall, the risk-benefit of BNT162b2 30 µg remains favorable.

14. TABLES AND FIGURES

SUPPLEMENTAL TABLES

Phase 1

Conduct of Study

14.1. Disposition of All Subjects – Phase 1, 2 Doses, 21 Days Apart

	Total (N[a]=332) n[b] (%)
Enrolled	332
Screen failures	83 (25.0)
Not assigned	54 (16.3)
Randomized	195 (58.7)

a. N = number of enrolled subjects in the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 01SEP2020 (12:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adds_s002_disp_overall

14.2. Disposition of All Randomized Subjects – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Vaccinated					
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Withdrawn after Dose 1 and before Dose 2	0	0	0	0	0
Withdrawn after Dose 2	0	0	0	0	0

a. N = number of randomized subjects in the specified group, or total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 31AUG2020 (21:00)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adds s002 disp 18 b1 p1

14.3. Disposition of All Randomized Subjects – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg)

	Vaccine Group (as Randomized)		
	100 µg (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)	Total (N^a=15) n^b (%)
Randomized	12 (100.0)	3 (100.0)	15 (100.0)
Not vaccinated	0	0	0
Vaccinated			
Dose 1	12 (100.0)	3 (100.0)	15 (100.0)
Withdrawn after Dose 1 and before Dose 2	0	0	0

a. N = number of randomized subjects in the specified group, or total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 19SEP2020 (08:12)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adds s002 disp 18 b1 100 p1

14.4. Disposition of All Randomized Subjects – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Vaccinated					
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Withdrawn after Dose 1 and before Dose 2	0	0	0	0	0
Withdrawn after Dose 2	0	0	0	0	0

a. N = number of randomized subjects in the specified group, or total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 31AUG2020 (21:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adds s002 disp 65 b1 p1

14.5. Disposition of All Randomized Subjects – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Vaccinated					
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Withdrawn after Dose 1 and before Dose 2	0	0	0	0	0
Withdrawn after Dose 2	0	0	0	0	0

a. N = number of randomized subjects in the specified group, or total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 31AUG2020 (21:07)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adds s002 disp 18 b2 p1

14.6. Disposition of All Randomized Subjects – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Vaccinated					
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Withdrawn after Dose 1 and before Dose 2	0	0	0	0	0
Withdrawn after Dose 2	0	0	0	0	0

a. N = number of randomized subjects in the specified group, or total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 31AUG2020 (21:12)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adds s002 disp 65 b2 p1

14.7. Vaccine as Administered by Vaccine Group – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All Randomized Subjects

Vaccine Group (as Administered)	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Vaccinated	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1					
BNT162b1	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)
Dose 2					
BNT162b1	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:06)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_adm_18_b1_p1

14.8. Vaccine as Administered by Vaccine Group – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All Randomized Subjects

Vaccine (as Administered)	Vaccine Group (as Randomized)		
	100 µg (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)	Total (N^a=15) n^b (%)
Vaccinated	12 (100.0)	3 (100.0)	15 (100.0)
Not vaccinated	0	0	0
Dose 1			
BNT162b1	12 (100.0)	0	12 (80.0)
Placebo	0	3 (100.0)	3 (20.0)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 21SEP2020 (15:18)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/advx_s002_adm_18_b1_100_p1

14.9. Vaccine as Administered by Vaccine Group – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All Randomized Subjects

Vaccine Group (as Administered)	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Vaccinated	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1					
BNT162b1	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)
Dose 2					
BNT162b1	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:13)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_adm_65_b1_p1

14.10. Vaccine Administration Timing – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
< 19 Days	0	0	0	0	0
19 to 23 Days[d]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
> 23 Days	0	0	0	0	0

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. Days calculated since Dose 1.
d. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_time_18_b1_p1

14.11. Vaccine Administration Timing – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
< 19 Days	0	0	0	0	0
19 to 23 Days[d]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
> 23 Days	0	0	0	0	0

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. Days calculated since Dose 1.
d. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:16)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_time_65_b1_p1

14.12. Vaccine as Administered by Vaccine Group – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All Randomized Subjects

Vaccine Group (as Administered)	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Vaccinated	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1					
BNT162b2	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)
Dose 2					
BNT162b2	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:13)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_adm_18_b2_p1

14.13. Vaccine as Administered by Vaccine Group – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All Randomized Subjects

Vaccine Group (as Administered)	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Vaccinated	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1					
BNT162b2	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)
Dose 2					
BNT162b2	12 (100.0)	12 (100.0)	12 (100.0)	0	36 (80.0)
Placebo	0	0	0	9 (100.0)	9 (20.0)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:15)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_adm_65_b2_p1

14.14. Vaccine Administration Timing – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
< 19 Days	0	0	0	0	0
19 to 23 Days[d]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
> 23 Days	0	0	0	0	0

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. Days calculated since Dose 1.
d. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:18)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_time_18_b2_p1

14.15. Vaccine Administration Timing – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
< 19 Days	0	0	0	0	0
19 to 23 Days[d]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
> 23 Days	0	0	0	0	0

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. Days calculated since Dose 1.
d. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 29AUG2020 (09:17)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/advx_s002_time_65_b2_p1

14.16. Safety Population – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1

	Vaccine Group (as Administered)				
	10 µg	20 µg	30 µg	Placebo	Total
	n[a]	n[a]	n[a]	n[a]	n[a] (%)
Randomized[b]					45
Vaccinated	12	12	12	9	45 (100.0)
Safety population	12	12	12	9	45 (100.0)

a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 28AUG2020 (23:58)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adsl s003 saf pop 18 b1 p1

14.17. Safety Population – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg)

	Vaccine Group (as Administered)		
	100 µg	Placebo	Total
	n[a]	n[a]	n[a] (%)
Randomized[b]			15
Vaccinated	12	3	15 (100.0)
Safety population	12	3	15 (100.0)

a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 18SEP2020 (12:30)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adsl_s003_saf_pop_18_b1_100_p1

14.18. Safety Population – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1

	Vaccine Group (as Administered)				
	10 µg	20 µg	30 µg	Placebo	Total
	n[a]	n[a]	n[a]	n[a]	n[a] (%)
Randomized[b]					45
Vaccinated	12	12	12	9	45 (100.0)
Safety population	12	12	12	9	45 (100.0)

a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 28AUG2020 (23:58)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adsl s003 saf pop 65 b1 p1

14.19. Immunogenicity Populations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1

	Vaccine Group (as Randomized)				
	10 µg n[a] (%)	20 µg n[a] (%)	30 µg n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 evaluable immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2 evaluable immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s008_imm_pop_18_b1_p1

14.20. Immunogenicity Populations – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg)

	Vaccine Group (as Randomized)		
	100 µg	Placebo	Total
	n[a] (%)	n[a] (%)	n[a] (%)
Randomized[b]	12 (100.0)	3 (100.0)	15 (100.0)
Dose 1 all-available immunogenicity population	12 (100.0)	3 (100.0)	15 (100.0)
Dose 1 evaluable immunogenicity population	12 (100.0)	3 (100.0)	15 (100.0)

a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adsl Table Generation: 22SEP2020 (00:01) (Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 100/adva s008 imm pop 18 b1 100 p1

14.21. Immunogenicity Populations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1

	Vaccine Group (as Randomized)				
	10 µg n[a] (%)	20 µg n[a] (%)	30 µg n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 evaluable immunogenicity population	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Subjects excluded from Dose 1 evaluable immunogenicity population	1 (8.3)	0	0	0	1 (2.2)
Reason for exclusion[c]					
Had major protocol deviation(s) as determined by the clinician	1 (8.3)	0	0	0	1 (2.2)
Dose 2 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2 evaluable immunogenicity population	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Subjects excluded from Dose 2 evaluable immunogenicity population	1 (8.3)	0	0	0	1 (2.2)
Reason for exclusion[c]					
Had major protocol deviation(s) as determined by the clinician	1 (8.3)	0	0	0	1 (2.2)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s008_imm_pop_65_b1_p1

14.22. Safety Population – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2

	Vaccine Group (as Administered)				
	10 µg	20 µg	30 µg	Placebo	Total
	n[a]	n[a]	n[a]	n[a]	n[a] (%)
Randomized[b]					45
Vaccinated	12	12	12	9	45 (100.0)
Safety population	12	12	12	9	45 (100.0)

a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 28AUG2020 (23:58)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adsl s003 saf pop 18 b2 p1

14.23. Safety Population – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2

	Vaccine Group (as Administered)				
	10 µg	20 µg	30 µg	Placebo	Total
	n[a]	n[a]	n[a]	n[a]	n[a] (%)
Randomized[b]					45
Vaccinated	12	12	12	9	45 (100.0)
Safety population	12	12	12	9	45 (100.0)

a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (20:06) Source Data: adsl Table Generation: 28AUG2020 (23:59)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adsl_s003_saf_pop_65_b2_p1

14.24. Immunogenicity Populations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2

	Vaccine Group (as Randomized)				
	10 µg n[a] (%)	20 µg n[a] (%)	30 µg n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 evaluable immunogenicity population	11 (91.7)	12 (100.0)	12 (100.0)	7 (77.8)	42 (93.3)
Subjects excluded from Dose 1 evaluable immunogenicity population	1 (8.3)	0	0	2 (22.2)	3 (6.7)
Reason for exclusion[c]					
Had major protocol deviation(s) as determined by the clinician	1 (8.3)	0	0	2 (22.2)	3 (6.7)
Dose 2 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2 evaluable immunogenicity population	11 (91.7)	12 (100.0)	11 (91.7)	7 (77.8)	41 (91.1)
Subjects excluded from Dose 2 evaluable immunogenicity population	1 (8.3)	0	1 (8.3)	2 (22.2)	4 (8.9)
Reason for exclusion[c]					
Did not have blood collection within 6-8 days after Dose 2	0	0	1 (8.3)	0	1 (2.2)
Had major protocol deviation(s) as determined by the clinician	1 (8.3)	0	0	2 (22.2)	3 (6.7)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.

PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adva s008 imm pop 18 b2 p1

14.25. Immunogenicity Populations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2

	Vaccine Group (as Randomized)				
	10 µg n[a] (%)	20 µg n[a] (%)	30 µg n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 1 evaluable immunogenicity population	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Subjects excluded from Dose 1 evaluable immunogenicity population	0	0	1 (8.3)	0	1 (2.2)
Reason for exclusion[c]					
Had major protocol deviation(s) as determined by the clinician	0	0	1 (8.3)	0	1 (2.2)
Dose 2 all-available immunogenicity population	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Dose 2 evaluable immunogenicity population	12 (100.0)	11 (91.7)	11 (91.7)	9 (100.0)	43 (95.6)
Subjects excluded from Dose 2 evaluable immunogenicity population	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Reason for exclusion[c]					
Did not have blood collection within 6-8 days after Dose 2	0	1 (8.3)	0	0	1 (2.2)
Had major protocol deviation(s) as determined by the clinician	0	0	1 (8.3)	0	1 (2.2)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.

PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adva s008 imm pop 65 b2 p1

14.26. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Sex					
Male	7 (58.3)	9 (75.0)	6 (50.0)	6 (66.7)	28 (62.2)
Female	5 (41.7)	3 (25.0)	6 (50.0)	3 (33.3)	17 (37.8)
Race					
White	8 (66.7)	11 (91.7)	10 (83.3)	8 (88.9)	37 (82.2)
Black or African American	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Asian	3 (25.0)	0	2 (16.7)	1 (11.1)	6 (13.3)
Ethnicity					
Hispanic/Latino	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	12 (100.0)	10 (83.3)	9 (100.0)	42 (93.3)
Not reported	0	0	1 (8.3)	0	1 (2.2)
Age at vaccination (years)					
Mean (SD)	29.4 (6.39)	44.8 (8.33)	35.8 (9.96)	37.7 (10.93)	36.9 (10.34)
Median	26.5	49.0	33.5	37.0	35.0
Min, max	(24, 42)	(30, 54)	(23, 52)	(22, 54)	(22, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 28AUG2020 (20:18)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adsl s005 demo 18 b1 p1

14.27. Demographic Characteristics – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

	Vaccine Group (as Administered)		
	100 µg (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)	Total (N^a=15) n^b (%)
Sex			
Male	5 (41.7)	1 (33.3)	6 (40.0)
Female	7 (58.3)	2 (66.7)	9 (60.0)
Race			
White	11 (91.7)	3 (100.0)	14 (93.3)
Asian	1 (8.3)	0	1 (6.7)
Ethnicity			
Non-Hispanic/non-Latino	12 (100.0)	3 (100.0)	15 (100.0)
Age at vaccination (years)			
Mean (SD)	38.3 (9.34)	32.0 (13.53)	37.1 (10.07)
Median	38.0	31.0	35.0
Min, max	(25, 53)	(19, 46)	(19, 53)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 19SEP2020 (08:06)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
./nda3/C4591001 IA P1 100/adsl demo 18 b1 100 p1

14.28. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	4 (33.3)	4 (33.3)	4 (33.3)	1 (11.1)	13 (28.9)
Female	8 (66.7)	8 (66.7)	8 (66.7)	8 (88.9)	32 (71.1)
Race					
White	12 (100.0)	11 (91.7)	10 (83.3)	9 (100.0)	42 (93.3)
Black or African American	0	1 (8.3)	0	0	1 (2.2)
Asian	0	0	2 (16.7)	0	2 (4.4)
Ethnicity					
Hispanic/Latino	0	0	0	1 (11.1)	1 (2.2)
Non-Hispanic/non-Latino	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Age at vaccination (years)					
Mean (SD)	69.7 (5.40)	70.6 (4.94)	69.9 (3.55)	68.2 (2.95)	69.7 (4.34)
Median	68.5	69.0	69.0	68.0	69.0
Min, max	(65, 82)	(65, 81)	(65, 77)	(65, 73)	(65, 82)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 28AUG2020 (20:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adsl s005 demo 65 b1 p1

14.29. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Dose 1 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Sex					
Male	7 (58.3)	9 (75.0)	6 (50.0)	6 (66.7)	28 (62.2)
Female	5 (41.7)	3 (25.0)	6 (50.0)	3 (33.3)	17 (37.8)
Race					
White	8 (66.7)	11 (91.7)	10 (83.3)	8 (88.9)	37 (82.2)
Black or African American	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Asian	3 (25.0)	0	2 (16.7)	1 (11.1)	6 (13.3)
Ethnicity					
Hispanic/Latino	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	12 (100.0)	10 (83.3)	9 (100.0)	42 (93.3)
Not reported	0	0	1 (8.3)	0	1 (2.2)
Age at vaccination (years)					
Mean (SD)	29.4 (6.39)	44.8 (8.33)	35.8 (9.96)	37.7 (10.93)	36.9 (10.34)
Median	26.5	49.0	33.5	37.0	35.0
Min, max	(24, 42)	(30, 54)	(23, 52)	(22, 54)	(22, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:17)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adsl s005 demo d1aav 18 b1 p1

14.30. Demographic Characteristics – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Dose 1 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)		
	100 µg (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)	Total (N^a=15) n^b (%)
Sex			
Male	5 (41.7)	1 (33.3)	6 (40.0)
Female	7 (58.3)	2 (66.7)	9 (60.0)
Race			
White	11 (91.7)	3 (100.0)	14 (93.3)
Asian	1 (8.3)	0	1 (6.7)
Ethnicity			
Non-Hispanic/non-Latino	12 (100.0)	3 (100.0)	15 (100.0)
Age at vaccination (years)			
Mean (SD)	38.3 (9.34)	32.0 (13.53)	37.1 (10.07)
Median	38.0	31.0	35.0
Min, max	(25, 53)	(19, 46)	(19, 53)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 19SEP2020 (08:06)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adsl_s005_dem_d1aa_18_b1_100_p1

14.31. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Dose 1 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	4 (33.3)	4 (33.3)	4 (33.3)	1 (11.1)	13 (28.9)
Female	8 (66.7)	8 (66.7)	8 (66.7)	8 (88.9)	32 (71.1)
Race					
White	12 (100.0)	11 (91.7)	10 (83.3)	9 (100.0)	42 (93.3)
Black or African American	0	1 (8.3)	0	0	1 (2.2)
Asian	0	0	2 (16.7)	0	2 (4.4)
Ethnicity					
Hispanic/Latino	0	0	0	1 (11.1)	1 (2.2)
Non-Hispanic/non-Latino	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Age at vaccination (years)					
Mean (SD)	69.7 (5.40)	70.6 (4.94)	69.9 (3.55)	68.2 (2.95)	69.7 (4.34)
Median	68.5	69.0	69.0	68.0	69.0
Min, max	(65, 82)	(65, 81)	(65, 77)	(65, 73)	(65, 82)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:17)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d1aav 65 b1 p1

14.32. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Dose 1 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	7 (58.3)	9 (75.0)	6 (50.0)	6 (66.7)	28 (62.2)
Female	5 (41.7)	3 (25.0)	6 (50.0)	3 (33.3)	17 (37.8)
Race					
White	8 (66.7)	11 (91.7)	10 (83.3)	8 (88.9)	37 (82.2)
Black or African American	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Asian	3 (25.0)	0	2 (16.7)	1 (11.1)	6 (13.3)
Ethnicity					
Hispanic/Latino	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	12 (100.0)	10 (83.3)	9 (100.0)	42 (93.3)
Not reported	0	0	1 (8.3)	0	1 (2.2)
Age at vaccination (years)					
Mean (SD)	29.4 (6.39)	44.8 (8.33)	35.8 (9.96)	37.7 (10.93)	36.9 (10.34)
Median	26.5	49.0	33.5	37.0	35.0
Min, max	(24, 42)	(30, 54)	(23, 52)	(22, 54)	(22, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:16)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d1eva 18 b1 p1

14.33. Demographic Characteristics – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Dose 1 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)		
	100 µg (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)	Total (N^a=15) n^b (%)
Sex			
Male	5 (41.7)	1 (33.3)	6 (40.0)
Female	7 (58.3)	2 (66.7)	9 (60.0)
Race			
White	11 (91.7)	3 (100.0)	14 (93.3)
Asian	1 (8.3)	0	1 (6.7)
Ethnicity			
Non-Hispanic/non-Latino	12 (100.0)	3 (100.0)	15 (100.0)
Age at vaccination (years)			
Mean (SD)	38.3 (9.34)	32.0 (13.53)	37.1 (10.07)
Median	38.0	31.0	35.0
Min, max	(25, 53)	(19, 46)	(19, 53)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 19SEP2020 (08:06)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adsl s005 dem d1ev 18 b1 100 p1

14.34. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Dose 1 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=11) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=44) n[b] (%)
Sex					
Male	4 (36.4)	4 (33.3)	4 (33.3)	1 (11.1)	13 (29.5)
Female	7 (63.6)	8 (66.7)	8 (66.7)	8 (88.9)	31 (70.5)
Race					
White	11 (100.0)	11 (91.7)	10 (83.3)	9 (100.0)	41 (93.2)
Black or African American	0	1 (8.3)	0	0	1 (2.3)
Asian	0	0	2 (16.7)	0	2 (4.5)
Ethnicity					
Hispanic/Latino	0	0	0	1 (11.1)	1 (2.3)
Non-Hispanic/non-Latino	11 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	43 (97.7)
Age at vaccination (years)					
Mean (SD)	69.6 (5.66)	70.6 (4.94)	69.9 (3.55)	68.2 (2.95)	69.7 (4.39)
Median	68.0	69.0	69.0	68.0	68.5
Min, max	(65, 82)	(65, 81)	(65, 77)	(65, 73)	(65, 82)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:16)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d1eva 65 b1 p1

14.35. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Dose 2 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Sex					
Male	7 (58.3)	9 (75.0)	6 (50.0)	6 (66.7)	28 (62.2)
Female	5 (41.7)	3 (25.0)	6 (50.0)	3 (33.3)	17 (37.8)
Race					
White	8 (66.7)	11 (91.7)	10 (83.3)	8 (88.9)	37 (82.2)
Black or African American	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Asian	3 (25.0)	0	2 (16.7)	1 (11.1)	6 (13.3)
Ethnicity					
Hispanic/Latino	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	12 (100.0)	10 (83.3)	9 (100.0)	42 (93.3)
Not reported	0	0	1 (8.3)	0	1 (2.2)
Age at vaccination (years)					
Mean (SD)	29.4 (6.39)	44.8 (8.33)	35.8 (9.96)	37.7 (10.93)	36.9 (10.34)
Median	26.5	49.0	33.5	37.0	35.0
Min, max	(24, 42)	(30, 54)	(23, 52)	(22, 54)	(22, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d2aav 18 b1 p1

14.36. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Dose 2 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	4 (33.3)	4 (33.3)	4 (33.3)	1 (11.1)	13 (28.9)
Female	8 (66.7)	8 (66.7)	8 (66.7)	8 (88.9)	32 (71.1)
Race					
White	12 (100.0)	11 (91.7)	10 (83.3)	9 (100.0)	42 (93.3)
Black or African American	0	1 (8.3)	0	0	1 (2.2)
Asian	0	0	2 (16.7)	0	2 (4.4)
Ethnicity					
Hispanic/Latino	0	0	0	1 (11.1)	1 (2.2)
Non-Hispanic/non-Latino	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Age at vaccination (years)					
Mean (SD)	69.7 (5.40)	70.6 (4.94)	69.9 (3.55)	68.2 (2.95)	69.7 (4.34)
Median	68.5	69.0	69.0	68.0	69.0
Min, max	(65, 82)	(65, 81)	(65, 77)	(65, 73)	(65, 82)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d2aav 65 b1 p1

14.37. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	7 (58.3)	9 (75.0)	6 (50.0)	6 (66.7)	28 (62.2)
Female	5 (41.7)	3 (25.0)	6 (50.0)	3 (33.3)	17 (37.8)
Race					
White	8 (66.7)	11 (91.7)	10 (83.3)	8 (88.9)	37 (82.2)
Black or African American	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Asian	3 (25.0)	0	2 (16.7)	1 (11.1)	6 (13.3)
Ethnicity					
Hispanic/Latino	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	12 (100.0)	10 (83.3)	9 (100.0)	42 (93.3)
Not reported	0	0	1 (8.3)	0	1 (2.2)
Age at vaccination (years)					
Mean (SD)	29.4 (6.39)	44.8 (8.33)	35.8 (9.96)	37.7 (10.93)	36.9 (10.34)
Median	26.5	49.0	33.5	37.0	35.0
Min, max	(24, 42)	(30, 54)	(23, 52)	(22, 54)	(22, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:22)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adsl s005 demo d2eva 18 b1 p1

14.38. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=11) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=44) n[b] (%)
Sex					
Male	4 (36.4)	4 (33.3)	4 (33.3)	1 (11.1)	13 (29.5)
Female	7 (63.6)	8 (66.7)	8 (66.7)	8 (88.9)	31 (70.5)
Race					
White	11 (100.0)	11 (91.7)	10 (83.3)	9 (100.0)	41 (93.2)
Black or African American	0	1 (8.3)	0	0	1 (2.3)
Asian	0	0	2 (16.7)	0	2 (4.5)
Ethnicity					
Hispanic/Latino	0	0	0	1 (11.1)	1 (2.3)
Non-Hispanic/non-Latino	11 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	43 (97.7)
Age at vaccination (years)					
Mean (SD)	69.6 (5.66)	70.6 (4.94)	69.9 (3.55)	68.2 (2.95)	69.7 (4.39)
Median	68.0	69.0	69.0	68.0	68.5
Min, max	(65, 82)	(65, 81)	(65, 77)	(65, 73)	(65, 82)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:22)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d2eva 65 b1 p1

14.39. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Any medical history	10 (83.3)	11 (91.7)	11 (91.7)	8 (88.9)	40 (88.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0	0	1 (11.1)	1 (2.2)
Iron deficiency anaemia	0	0	0	1 (11.1)	1 (2.2)
CARDIAC DISORDERS	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Bradycardia	0	0	0	1 (11.1)	1 (2.2)
Bundle branch block left	0	1 (8.3)	0	0	1 (2.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0	1 (8.3)	0	1 (2.2)
Congenital hypothyroidism	0	0	1 (8.3)	0	1 (2.2)
EAR AND LABYRINTH DISORDERS	0	1 (8.3)	0	0	1 (2.2)
Excessive cerumen production	0	1 (8.3)	0	0	1 (2.2)
ENDOCRINE DISORDERS	0	1 (8.3)	0	0	1 (2.2)
Hypothyroidism	0	1 (8.3)	0	0	1 (2.2)
EYE DISORDERS	5 (41.7)	2 (16.7)	3 (25.0)	2 (22.2)	12 (26.7)
Astigmatism	0	1 (8.3)	0	0	1 (2.2)
Dacryostenosis acquired	1 (8.3)	0	0	0	1 (2.2)
Hypermetropia	0	0	1 (8.3)	0	1 (2.2)
Myopia	5 (41.7)	1 (8.3)	3 (25.0)	2 (22.2)	11 (24.4)
GASTROINTESTINAL DISORDERS	1 (8.3)	2 (16.7)	1 (8.3)	2 (22.2)	6 (13.3)
Aphthous ulcer	1 (8.3)	0	0	0	1 (2.2)
Diarrhoea	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Dyspepsia	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Gastrooesophageal reflux disease	0	1 (8.3)	0	0	1 (2.2)
Haemorrhoids	0	0	0	2 (22.2)	2 (4.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	0	1 (8.3)	0	1 (2.2)
Swelling face	0	0	1 (8.3)	0	1 (2.2)

14.39. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
HEPATOBILIARY DISORDERS	0	0	0	1 (11.1)	1 (2.2)
Hepatic cyst	0	0	0	1 (11.1)	1 (2.2)
IMMUNE SYSTEM DISORDERS	8 (66.7)	7 (58.3)	3 (25.0)	4 (44.4)	22 (48.9)
Allergy to animal	2 (16.7)	0	0	2 (22.2)	4 (8.9)
Cockroach allergy	0	0	0	1 (11.1)	1 (2.2)
Drug hypersensitivity	1 (8.3)	1 (8.3)	1 (8.3)	1 (11.1)	4 (8.9)
Food allergy	3 (25.0)	2 (16.7)	0	0	5 (11.1)
Hypersensitivity	0	0	0	1 (11.1)	1 (2.2)
Milk allergy	0	2 (16.7)	0	0	2 (4.4)
Perfume sensitivity	0	0	0	1 (11.1)	1 (2.2)
Reaction to colouring	0	0	0	1 (11.1)	1 (2.2)
Rubber sensitivity	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Seasonal allergy	8 (66.7)	7 (58.3)	2 (16.7)	2 (22.2)	19 (42.2)
INFECTIONS AND INFESTATIONS	3 (25.0)	4 (33.3)	2 (16.7)	2 (22.2)	11 (24.4)
Appendicitis	0	0	1 (8.3)	0	1 (2.2)
Chlamydial infection	0	0	0	1 (11.1)	1 (2.2)
Genital herpes	0	1 (8.3)	0	0	1 (2.2)
Hepatitis A	0	0	1 (8.3)	0	1 (2.2)
Herpes simplex	1 (8.3)	0	0	0	1 (2.2)
Onychomycosis	0	0	1 (8.3)	0	1 (2.2)
Papilloma viral infection	0	1 (8.3)	0	0	1 (2.2)
Pilonidal cyst	0	1 (8.3)	0	0	1 (2.2)
Sinusitis	0	1 (8.3)	0	0	1 (2.2)
Tooth abscess	0	0	0	1 (11.1)	1 (2.2)
Upper respiratory tract infection	1 (8.3)	0	0	0	1 (2.2)
Urinary tract infection	1 (8.3)	0	0	0	1 (2.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (16.7)	3 (25.0)	2 (16.7)	2 (22.2)	9 (20.0)
Cartilage injury	1 (8.3)	2 (16.7)	0	0	3 (6.7)
Concussion	0	0	0	1 (11.1)	1 (2.2)
Facial bones fracture	0	0	1 (8.3)	0	1 (2.2)
Joint injury	0	0	1 (8.3)	0	1 (2.2)
Meniscus injury	0	1 (8.3)	0	0	1 (2.2)
Muscle strain	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Skeletal injury	0	1 (8.3)	0	0	1 (2.2)
Upper limb fracture	1 (8.3)	0	0	1 (11.1)	2 (4.4)

14.39. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
INVESTIGATIONS	1 (8.3)	1 (8.3)	1 (8.3)	3 (33.3)	6 (13.3)
Biopsy colon	0	0	1 (8.3)	0	1 (2.2)
Blood cholesterol increased	0	0	0	1 (11.1)	1 (2.2)
Colonoscopy	0	0	1 (8.3)	0	1 (2.2)
Human papilloma virus test positive	1 (8.3)	0	0	0	1 (2.2)
Smear cervix abnormal	0	1 (8.3)	0	2 (22.2)	3 (6.7)
METABOLISM AND NUTRITION DISORDERS	0	1 (8.3)	0	0	1 (2.2)
Hypercholesterolaemia	0	1 (8.3)	0	0	1 (2.2)
Vitamin D deficiency	0	1 (8.3)	0	0	1 (2.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	1 (8.3)	1 (8.3)	2 (22.2)	4 (8.9)
Arthralgia	0	0	0	1 (11.1)	1 (2.2)
Back pain	0	0	1 (8.3)	0	1 (2.2)
Myalgia	0	1 (8.3)	0	0	1 (2.2)
Scoliosis	0	0	0	1 (11.1)	1 (2.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (8.3)	2 (16.7)	0	0	3 (6.7)
Basal cell carcinoma	0	1 (8.3)	0	0	1 (2.2)
Hair follicle tumour benign	0	1 (8.3)	0	0	1 (2.2)
Squamous cell carcinoma of skin	1 (8.3)	0	0	0	1 (2.2)
NERVOUS SYSTEM DISORDERS	2 (16.7)	2 (16.7)	1 (8.3)	1 (11.1)	6 (13.3)
Headache	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Migraine	0	1 (8.3)	0	0	1 (2.2)
Piriformis syndrome	0	0	1 (8.3)	0	1 (2.2)
Tension headache	1 (8.3)	0	0	1 (11.1)	2 (4.4)
PSYCHIATRIC DISORDERS	3 (25.0)	4 (33.3)	3 (25.0)	2 (22.2)	12 (26.7)
Anxiety	3 (25.0)	3 (25.0)	3 (25.0)	1 (11.1)	10 (22.2)
Attention deficit hyperactivity disorder	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Depression	1 (8.3)	1 (8.3)	1 (8.3)	2 (22.2)	5 (11.1)
Insomnia	0	1 (8.3)	0	1 (11.1)	2 (4.4)
RENAL AND URINARY DISORDERS	0	1 (8.3)	1 (8.3)	0	2 (4.4)

14.39. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Nephrolithiasis	0	1 (8.3)	1 (8.3)	0	2 (4.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (8.3)	1 (8.3)	1 (8.3)	2 (22.2)	5 (11.1)
Dysmenorrhoea	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Oligospermia	0	1 (8.3)	0	0	1 (2.2)
Polycystic ovaries	0	0	1 (8.3)	0	1 (2.2)
Uterine haemorrhage	0	0	0	1 (11.1)	1 (2.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	2 (16.7)	0	0	2 (4.4)
Nasal septum deviation	0	1 (8.3)	0	0	1 (2.2)
Upper respiratory tract congestion	0	1 (8.3)	0	0	1 (2.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (25.0)	4 (33.3)	3 (25.0)	3 (33.3)	13 (28.9)
Acne	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Androgenetic alopecia	0	1 (8.3)	0	0	1 (2.2)
Dermal cyst	0	0	0	1 (11.1)	1 (2.2)
Dry skin	0	0	1 (8.3)	1 (11.1)	2 (4.4)
Eczema	1 (8.3)	1 (8.3)	0	1 (11.1)	3 (6.7)
Keratosis pilaris	0	1 (8.3)	0	0	1 (2.2)
Perioral dermatitis	1 (8.3)	0	0	0	1 (2.2)
Rash	0	1 (8.3)	0	0	1 (2.2)
Rosacea	0	0	1 (8.3)	0	1 (2.2)
Transient acantholytic dermatosis	0	0	1 (8.3)	0	1 (2.2)
SOCIAL CIRCUMSTANCES	0	0	1 (8.3)	0	1 (2.2)
Menopause	0	0	1 (8.3)	0	1 (2.2)
SURGICAL AND MEDICAL PROCEDURES	2 (16.7)	8 (66.7)	2 (16.7)	4 (44.4)	16 (35.6)
Appendicectomy	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Cardiac pacemaker insertion	0	0	0	1 (11.1)	1 (2.2)
Chondroplasty	1 (8.3)	0	0	0	1 (2.2)
Cyst removal	0	0	1 (8.3)	0	1 (2.2)
Female sterilisation	0	1 (8.3)	0	0	1 (2.2)
Fracture treatment	0	1 (8.3)	0	0	1 (2.2)
Hernia repair	0	1 (8.3)	0	0	1 (2.2)
Keratomileusis	0	1 (8.3)	0	0	1 (2.2)
Lacrimal duct procedure	1 (8.3)	0	0	0	1 (2.2)

14.39. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
Lithotripsy	0	1 (8.3)	0	0	1 (2.2)
Nasal septal operation	0	1 (8.3)	0	0	1 (2.2)
Shoulder operation	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Spinal fusion surgery	0	0	0	1 (11.1)	1 (2.2)
Tonsillectomy	0	1 (8.3)	0	0	1 (2.2)
Varicose vein operation	0	1 (8.3)	1 (8.3)	1 (11.1)	3 (6.7)
Vasectomy	0	1 (8.3)	0	0	1 (2.2)
VASCULAR DISORDERS	0	2 (16.7)	0	1 (11.1)	3 (6.7)
Deep vein thrombosis	0	1 (8.3)	0	0	1 (2.2)
Varicose vein	0	1 (8.3)	0	1 (11.1)	2 (4.4)

Note: MedDRA (MedDRA v23.0) coding dictionary applied.
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. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: admh Table Generation: 01SEP2020 (17:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/admh s002 18 b1 p1

14.40. Medical History – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 100 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=3) n[b] (%)	 Total (N[a]=15) n[b] (%)
Any medical history	12 (100.0)	2 (66.7)	14 (93.3)
ENDOCRINE DISORDERS	1 (8.3)	0	1 (6.7)
Hypothyroidism	1 (8.3)	0	1 (6.7)
EYE DISORDERS	3 (25.0)	0	3 (20.0)
Hypermetropia	1 (8.3)	0	1 (6.7)
Myopia	2 (16.7)	0	2 (13.3)
GASTROINTESTINAL DISORDERS	1 (8.3)	0	1 (6.7)
Irritable bowel syndrome	1 (8.3)	0	1 (6.7)
IMMUNE SYSTEM DISORDERS	8 (66.7)	2 (66.7)	10 (66.7)
Allergy to animal	1 (8.3)	1 (33.3)	2 (13.3)
Drug hypersensitivity	2 (16.7)	0	2 (13.3)
Dust allergy	1 (8.3)	0	1 (6.7)
Mycotic allergy	1 (8.3)	0	1 (6.7)
Rubber sensitivity	1 (8.3)	0	1 (6.7)
Seasonal allergy	6 (50.0)	2 (66.7)	8 (53.3)
INFECTIONS AND INFESTATIONS	0	1 (33.3)	1 (6.7)
Osteomyelitis	0	1 (33.3)	1 (6.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (16.7)	0	2 (13.3)
Ankle fracture	1 (8.3)	0	1 (6.7)
Ligament rupture	1 (8.3)	0	1 (6.7)
Road traffic accident	1 (8.3)	0	1 (6.7)
INVESTIGATIONS	1 (8.3)	0	1 (6.7)
Arthroscopy	1 (8.3)	0	1 (6.7)
Endoscopy upper gastrointestinal tract	1 (8.3)	0	1 (6.7)
Vitamin D decreased	1 (8.3)	0	1 (6.7)
METABOLISM AND NUTRITION DISORDERS	1 (8.3)	0	1 (6.7)
Hypercholesterolaemia	1 (8.3)	0	1 (6.7)

14.40. Medical History – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 100 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=3) n[b] (%)	 Total (N[a]=15) n[b] (%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (8.3)	0	1 (6.7)
Osteoarthritis	1 (8.3)	0	1 (6.7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (8.3)	0	1 (6.7)
Benign neoplasm of thyroid gland	1 (8.3)	0	1 (6.7)
NERVOUS SYSTEM DISORDERS	1 (8.3)	0	1 (6.7)
Sciatica	1 (8.3)	0	1 (6.7)
PSYCHIATRIC DISORDERS	3 (25.0)	0	3 (20.0)
Anxiety	2 (16.7)	0	2 (13.3)
Depression	1 (8.3)	0	1 (6.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (16.7)	0	2 (13.3)
Asthma	1 (8.3)	0	1 (6.7)
Asthma exercise induced	1 (8.3)	0	1 (6.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (25.0)	1 (33.3)	4 (26.7)
Acne	1 (8.3)	1 (33.3)	2 (13.3)
Dermatitis allergic	1 (8.3)	0	1 (6.7)
Eczema	0	1 (33.3)	1 (6.7)
Urticaria	1 (8.3)	0	1 (6.7)
SURGICAL AND MEDICAL PROCEDURES	7 (58.3)	1 (33.3)	8 (53.3)
Appendicectomy	1 (8.3)	0	1 (6.7)
Caesarean section	2 (16.7)	0	2 (13.3)
Female sterilisation	1 (8.3)	0	1 (6.7)
Intervertebral disc operation	1 (8.3)	0	1 (6.7)
Knee arthroplasty	1 (8.3)	0	1 (6.7)
Large intestinal polypectomy	1 (8.3)	0	1 (6.7)
Ligament operation	1 (8.3)	0	1 (6.7)
Sinuplasty	0	1 (33.3)	1 (6.7)
Tendon operation	1 (8.3)	0	1 (6.7)
Vasectomy	1 (8.3)	0	1 (6.7)
Wound closure	1 (8.3)	0	1 (6.7)

14.40. Medical History – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 100 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=3) n[b] (%)	 Total (N[a]=15) n[b] (%)
VASCULAR DISORDERS	1 (8.3)	0	1 (6.7)
Hypertension	1 (8.3)	0	1 (6.7)

Note: MedDRA (v23.0) coding dictionary applied.
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. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: admh Table Generation: 21SEP2020 (14:48)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
./nda3/C4591001 IA P1 100/admh s002 18 b1 100 p1

14.41. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Any medical history	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
CARDIAC DISORDERS	1 (8.3)	2 (16.7)	2 (16.7)	0	5 (11.1)
Atrial fibrillation	0	0	1 (8.3)	0	1 (2.2)
Bundle branch block left	0	1 (8.3)	0	0	1 (2.2)
Bundle branch block right	0	1 (8.3)	0	0	1 (2.2)
Sinus node dysfunction	0	0	1 (8.3)	0	1 (2.2)
Supraventricular tachycardia	0	0	1 (8.3)	0	1 (2.2)
Ventricular extrasystoles	1 (8.3)	0	0	0	1 (2.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (16.7)	1 (8.3)	0	0	3 (6.7)
Developmental hip dysplasia	0	1 (8.3)	0	0	1 (2.2)
Heart disease congenital	1 (8.3)	0	0	0	1 (2.2)
Tourette's disorder	1 (8.3)	0	0	0	1 (2.2)
EAR AND LABYRINTH DISORDERS	3 (25.0)	2 (16.7)	2 (16.7)	2 (22.2)	9 (20.0)
Deafness	1 (8.3)	1 (8.3)	1 (8.3)	0	3 (6.7)
Deafness unilateral	0	0	0	1 (11.1)	1 (2.2)
Hypoacusis	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Tinnitus	2 (16.7)	0	0	1 (11.1)	3 (6.7)
Vertigo	0	0	1 (8.3)	0	1 (2.2)
ENDOCRINE DISORDERS	0	1 (8.3)	2 (16.7)	2 (22.2)	5 (11.1)
Goitre	0	0	1 (8.3)	0	1 (2.2)
Hypothyroidism	0	1 (8.3)	1 (8.3)	2 (22.2)	4 (8.9)
EYE DISORDERS	5 (41.7)	4 (33.3)	3 (25.0)	2 (22.2)	14 (31.1)
Cataract	1 (8.3)	1 (8.3)	1 (8.3)	0	3 (6.7)
Dry eye	3 (25.0)	0	0	0	3 (6.7)
Eyelid ptosis	1 (8.3)	0	0	0	1 (2.2)
Glaucoma	1 (8.3)	1 (8.3)	1 (8.3)	1 (11.1)	4 (8.9)
Hypermetropia	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Macular fibrosis	0	1 (8.3)	0	0	1 (2.2)
Myopia	3 (25.0)	2 (16.7)	0	1 (11.1)	6 (13.3)
Uveitis	0	0	1 (8.3)	0	1 (2.2)

14.41. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
GASTROINTESTINAL DISORDERS	2 (16.7)	3 (25.0)	5 (41.7)	2 (22.2)	12 (26.7)
Abdominal hernia	0	0	1 (8.3)	0	1 (2.2)
Constipation	1 (8.3)	0	0	0	1 (2.2)
Diarrhoea	0	1 (8.3)	0	0	1 (2.2)
Dyspepsia	0	0	2 (16.7)	0	2 (4.4)
Gastrooesophageal reflux disease	1 (8.3)	1 (8.3)	2 (16.7)	2 (22.2)	6 (13.3)
Hyperchlorhydria	0	0	1 (8.3)	0	1 (2.2)
Irritable bowel syndrome	0	0	1 (8.3)	0	1 (2.2)
Reflux gastritis	0	1 (8.3)	0	0	1 (2.2)
Volvulus	1 (8.3)	0	0	0	1 (2.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Adhesion	0	1 (8.3)	0	0	1 (2.2)
Hernia	1 (8.3)	0	0	0	1 (2.2)
HEPATOBILIARY DISORDERS	0	0	0	1 (11.1)	1 (2.2)
Nonalcoholic fatty liver disease	0	0	0	1 (11.1)	1 (2.2)
IMMUNE SYSTEM DISORDERS	7 (58.3)	5 (41.7)	6 (50.0)	7 (77.8)	25 (55.6)
Allergy to animal	0	1 (8.3)	0	0	1 (2.2)
Drug hypersensitivity	2 (16.7)	2 (16.7)	4 (33.3)	1 (11.1)	9 (20.0)
Food allergy	1 (8.3)	0	0	0	1 (2.2)
Hypersensitivity	0	0	0	2 (22.2)	2 (4.4)
Mycotic allergy	0	1 (8.3)	0	0	1 (2.2)
Seasonal allergy	5 (41.7)	4 (33.3)	4 (33.3)	4 (44.4)	17 (37.8)
INFECTIONS AND INFESTATIONS	2 (16.7)	3 (25.0)	4 (33.3)	2 (22.2)	11 (24.4)
Appendicitis	0	0	1 (8.3)	0	1 (2.2)
Bronchitis	0	1 (8.3)	0	0	1 (2.2)
Chronic sinusitis	1 (8.3)	1 (8.3)	0	1 (11.1)	3 (6.7)
Cystitis	0	0	1 (8.3)	0	1 (2.2)
Gingivitis	0	0	1 (8.3)	0	1 (2.2)
Gonorrhoea	0	0	1 (8.3)	0	1 (2.2)
Helicobacter gastritis	0	1 (8.3)	0	0	1 (2.2)
Hepatitis B	0	0	1 (8.3)	0	1 (2.2)
Herpes simplex	0	1 (8.3)	0	0	1 (2.2)

14.41. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
Lyme disease	0	0	1 (8.3)	0	1 (2.2)
Oral herpes	0	0	0	1 (11.1)	1 (2.2)
Osteomyelitis	0	0	1 (8.3)	0	1 (2.2)
Tonsillitis	0	0	2 (16.7)	0	2 (4.4)
Urinary tract infection	1 (8.3)	0	0	1 (11.1)	2 (4.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (33.3)	5 (41.7)	1 (8.3)	0	10 (22.2)
Chillblains	1 (8.3)	0	0	0	1 (2.2)
Clavicle fracture	1 (8.3)	0	0	0	1 (2.2)
Concussion	1 (8.3)	0	0	0	1 (2.2)
Hand fracture	0	1 (8.3)	0	0	1 (2.2)
Hip fracture	0	1 (8.3)	0	0	1 (2.2)
Joint dislocation	1 (8.3)	0	0	0	1 (2.2)
Joint injury	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Ligament rupture	1 (8.3)	0	0	0	1 (2.2)
Limb injury	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Lower limb fracture	1 (8.3)	0	0	0	1 (2.2)
Meniscus injury	0	1 (8.3)	0	0	1 (2.2)
Sciatic nerve injury	0	1 (8.3)	0	0	1 (2.2)
Skin laceration	2 (16.7)	0	0	0	2 (4.4)
INVESTIGATIONS	0	2 (16.7)	1 (8.3)	2 (22.2)	5 (11.1)
Arthroscopy	0	1 (8.3)	0	0	1 (2.2)
Blood cholesterol increased	0	1 (8.3)	1 (8.3)	2 (22.2)	4 (8.9)
Hysteroscopy	0	2 (16.7)	0	0	2 (4.4)
METABOLISM AND NUTRITION DISORDERS	5 (41.7)	5 (41.7)	2 (16.7)	4 (44.4)	16 (35.6)
Alcohol intolerance	0	0	0	1 (11.1)	1 (2.2)
Hypercholesterolaemia	0	2 (16.7)	2 (16.7)	2 (22.2)	6 (13.3)
Hyperlipidaemia	2 (16.7)	1 (8.3)	0	1 (11.1)	4 (8.9)
Vitamin D deficiency	3 (25.0)	2 (16.7)	0	0	5 (11.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (58.3)	9 (75.0)	6 (50.0)	7 (77.8)	29 (64.4)
Arthralgia	1 (8.3)	0	2 (16.7)	0	3 (6.7)
Arthritis	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Dupuytren's contracture	0	0	1 (8.3)	0	1 (2.2)

14.41. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
Foot deformity	0	1 (8.3)	0	0	1 (2.2)
Intervertebral disc protrusion	0	0	1 (8.3)	1 (11.1)	2 (4.4)
Muscle spasms	1 (8.3)	0	0	0	1 (2.2)
Muscular weakness	0	1 (8.3)	0	0	1 (2.2)
Osteoarthritis	3 (25.0)	3 (25.0)	0	4 (44.4)	10 (22.2)
Osteopenia	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Osteoporosis	0	3 (25.0)	3 (25.0)	2 (22.2)	8 (17.8)
Periarthritis	1 (8.3)	0	0	0	1 (2.2)
Rotator cuff syndrome	1 (8.3)	0	0	0	1 (2.2)
Spinal instability	0	1 (8.3)	0	0	1 (2.2)
Synovial cyst	0	0	1 (8.3)	0	1 (2.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (25.0)	3 (25.0)	7 (58.3)	1 (11.1)	14 (31.1)
Acoustic neuroma	0	0	1 (8.3)	0	1 (2.2)
Basal cell carcinoma	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Benign neoplasm of thyroid gland	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Bowen's disease	0	1 (8.3)	0	0	1 (2.2)
Lymphoma	0	0	1 (8.3)	0	1 (2.2)
Malignant melanoma	1 (8.3)	1 (8.3)	1 (8.3)	0	3 (6.7)
Malignant melanoma in situ	0	0	1 (8.3)	0	1 (2.2)
Prostate cancer	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Squamous cell carcinoma	0	1 (8.3)	0	0	1 (2.2)
Thyroid cancer	0	0	1 (8.3)	0	1 (2.2)
Uterine leiomyoma	0	0	2 (16.7)	0	2 (4.4)
NERVOUS SYSTEM DISORDERS	4 (33.3)	3 (25.0)	2 (16.7)	2 (22.2)	11 (24.4)
Carpal tunnel syndrome	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Migraine	2 (16.7)	0	2 (16.7)	2 (22.2)	6 (13.3)
Nerve compression	0	1 (8.3)	0	0	1 (2.2)
Radiculopathy	0	1 (8.3)	0	0	1 (2.2)
Restless legs syndrome	1 (8.3)	0	0	0	1 (2.2)
Spinal cord disorder	1 (8.3)	0	0	0	1 (2.2)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0	0	1 (11.1)	1 (2.2)
Delivery	0	0	0	1 (11.1)	1 (2.2)

14.41. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
PSYCHIATRIC DISORDERS	2 (16.7)	2 (16.7)	4 (33.3)	2 (22.2)	10 (22.2)
Anxiety	1 (8.3)	1 (8.3)	2 (16.7)	1 (11.1)	5 (11.1)
Depression	1 (8.3)	1 (8.3)	0	1 (11.1)	3 (6.7)
Insomnia	0	0	0	2 (22.2)	2 (4.4)
Sleep disorder	0	0	3 (25.0)	0	3 (6.7)
RENAL AND URINARY DISORDERS	1 (8.3)	3 (25.0)	0	0	4 (8.9)
Atonic urinary bladder	1 (8.3)	0	0	0	1 (2.2)
Haematuria	0	1 (8.3)	0	0	1 (2.2)
Nocturia	0	1 (8.3)	0	0	1 (2.2)
Urinary incontinence	0	1 (8.3)	0	0	1 (2.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (16.7)	4 (33.3)	3 (25.0)	0	9 (20.0)
Benign prostatic hyperplasia	0	0	1 (8.3)	0	1 (2.2)
Breast mass	0	0	1 (8.3)	0	1 (2.2)
Fibrocystic breast disease	0	1 (8.3)	0	0	1 (2.2)
Menopausal symptoms	0	0	1 (8.3)	0	1 (2.2)
Ovarian cyst	1 (8.3)	1 (8.3)	1 (8.3)	0	3 (6.7)
Pelvic discomfort	0	1 (8.3)	0	0	1 (2.2)
Prostatomegaly	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Vulvovaginal dryness	0	1 (8.3)	0	0	1 (2.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (8.3)	3 (25.0)	1 (8.3)	0	5 (11.1)
Diaphragmatic paralysis	0	0	1 (8.3)	0	1 (2.2)
Nasal disorder	0	1 (8.3)	0	0	1 (2.2)
Nasal septum deviation	0	1 (8.3)	0	0	1 (2.2)
Pulmonary embolism	0	1 (8.3)	0	0	1 (2.2)
Rhinitis allergic	1 (8.3)	0	0	0	1 (2.2)
Sleep apnoea syndrome	0	1 (8.3)	0	0	1 (2.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (25.0)	0	3 (25.0)	0	6 (13.3)
Dermatitis	1 (8.3)	0	0	0	1 (2.2)
Drug eruption	0	0	1 (8.3)	0	1 (2.2)
Eczema	1 (8.3)	0	2 (16.7)	0	3 (6.7)
Rash	1 (8.3)	0	0	0	1 (2.2)
Urticaria	0	0	1 (8.3)	0	1 (2.2)

14.41. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
SURGICAL AND MEDICAL PROCEDURES	10 (83.3)	8 (66.7)	7 (58.3)	4 (44.4)	29 (64.4)
Ankle arthroplasty	0	1 (8.3)	0	0	1 (2.2)
Ankle operation	0	1 (8.3)	0	0	1 (2.2)
Arthrodesis	0	1 (8.3)	0	0	1 (2.2)
Bunion operation	0	2 (16.7)	0	0	2 (4.4)
Caesarean section	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Cardiac ablation	0	0	1 (8.3)	0	1 (2.2)
Carpal tunnel decompression	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Cataract operation	2 (16.7)	2 (16.7)	0	1 (11.1)	5 (11.1)
Eye laser surgery	1 (8.3)	0	0	0	1 (2.2)
Face lift	1 (8.3)	0	0	0	1 (2.2)
Female sterilisation	1 (8.3)	0	0	0	1 (2.2)
Foraminotomy	0	0	1 (8.3)	0	1 (2.2)
Hernia repair	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Hip arthroplasty	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Hip surgery	0	1 (8.3)	0	0	1 (2.2)
Hysterectomy	0	0	1 (8.3)	1 (11.1)	2 (4.4)
Inguinal hernia repair	0	0	1 (8.3)	0	1 (2.2)
Intervertebral disc operation	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Joint arthroplasty	0	1 (8.3)	0	0	1 (2.2)
Joint injection	0	0	1 (8.3)	0	1 (2.2)
Keratomileusis	0	0	0	1 (11.1)	1 (2.2)
Knee arthroplasty	1 (8.3)	0	0	0	1 (2.2)
Laparotomy	0	0	1 (8.3)	0	1 (2.2)
Ligament operation	1 (8.3)	0	0	0	1 (2.2)
Limb operation	1 (8.3)	0	0	0	1 (2.2)
Lipoma excision	1 (8.3)	0	0	0	1 (2.2)
Lymphoma operation	0	0	1 (8.3)	0	1 (2.2)
Mammoplasty	0	0	1 (8.3)	0	1 (2.2)
Meniscus operation	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Nasal operation	1 (8.3)	0	0	0	1 (2.2)
Oophorectomy	1 (8.3)	0	0	0	1 (2.2)
Ovarian cystectomy	0	0	0	1 (11.1)	1 (2.2)
Peripheral nerve operation	0	1 (8.3)	0	0	1 (2.2)
Prostatectomy	1 (8.3)	0	0	0	1 (2.2)
Ptosis repair	1 (8.3)	0	0	0	1 (2.2)
Rotator cuff repair	0	0	1 (8.3)	0	1 (2.2)
Salpingo-oophorectomy	0	0	1 (8.3)	0	1 (2.2)

14.41. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
Sclerotherapy	1 (8.3)	0	0	0	1 (2.2)
Shoulder arthroplasty	0	0	0	1 (11.1)	1 (2.2)
Sinus operation	0	1 (8.3)	0	0	1 (2.2)
Skin neoplasm excision	0	0	2 (16.7)	1 (11.1)	3 (6.7)
Spinal fusion surgery	0	1 (8.3)	0	0	1 (2.2)
Spinal laminectomy	0	0	2 (16.7)	0	2 (4.4)
Thyroidectomy	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Tonsillectomy	2 (16.7)	0	2 (16.7)	0	4 (8.9)
Varicose vein operation	1 (8.3)	0	0	0	1 (2.2)
Vasectomy	0	1 (8.3)	0	0	1 (2.2)

Note: MedDRA (MedDRA v23.0) coding dictionary applied.
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. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: admh Table Generation: 01SEP2020 (18:03)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/admh s002 65 b1 p1

14.42. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Sex					
Male	5 (41.7)	6 (50.0)	3 (25.0)	5 (55.6)	19 (42.2)
Female	7 (58.3)	6 (50.0)	9 (75.0)	4 (44.4)	26 (57.8)
Race					
White	11 (91.7)	10 (83.3)	9 (75.0)	9 (100.0)	39 (86.7)
Black or African American	0	2 (16.7)	1 (8.3)	0	3 (6.7)
Asian	1 (8.3)	0	2 (16.7)	0	3 (6.7)
Ethnicity					
Hispanic/Latino	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	11 (91.7)	12 (100.0)	9 (100.0)	43 (95.6)
Age at vaccination (years)					
Mean (SD)	36.8 (12.20)	37.6 (10.07)	37.3 (9.85)	34.4 (13.22)	36.7 (10.95)
Median	37.0	38.0	36.5	30.0	37.0
Min, max	(21, 53)	(23, 53)	(23, 54)	(19, 53)	(19, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 28AUG2020 (20:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adsl s005 demo 18 b2 p1

14.43. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	2 (16.7)	5 (41.7)	6 (50.0)	4 (44.4)	17 (37.8)
Female	10 (83.3)	7 (58.3)	6 (50.0)	5 (55.6)	28 (62.2)
Race					
White	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Ethnicity					
Non-Hispanic/non-Latino	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Age at vaccination (years)					
Mean (SD)	68.0 (2.89)	71.0 (5.82)	68.5 (2.81)	70.0 (3.84)	69.3 (4.09)
Median	67.0	68.5	68.0	69.0	68.0
Min, max	(65, 73)	(65, 81)	(65, 74)	(65, 77)	(65, 81)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 28AUG2020 (20:20)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adsl s005 demo 65 b2 p1

14.44. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Dose 1 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	5 (41.7)	6 (50.0)	3 (25.0)	5 (55.6)	19 (42.2)
Female	7 (58.3)	6 (50.0)	9 (75.0)	4 (44.4)	26 (57.8)
Race					
White	11 (91.7)	10 (83.3)	9 (75.0)	9 (100.0)	39 (86.7)
Black or African American	0	2 (16.7)	1 (8.3)	0	3 (6.7)
Asian	1 (8.3)	0	2 (16.7)	0	3 (6.7)
Ethnicity					
Hispanic/Latino	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	11 (91.7)	12 (100.0)	9 (100.0)	43 (95.6)
Age at vaccination (years)					
Mean (SD)	36.8 (12.20)	37.6 (10.07)	37.3 (9.85)	34.4 (13.22)	36.7 (10.95)
Median	37.0	38.0	36.5	30.0	37.0
Min, max	(21, 53)	(23, 53)	(23, 54)	(19, 53)	(19, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:17)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d1aav 18 b2 p1

14.45. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Dose 1 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Sex					
Male	2 (16.7)	5 (41.7)	6 (50.0)	4 (44.4)	17 (37.8)
Female	10 (83.3)	7 (58.3)	6 (50.0)	5 (55.6)	28 (62.2)
Race					
White	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Ethnicity					
Non-Hispanic/non-Latino	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Age at vaccination (years)					
Mean (SD)	68.0 (2.89)	71.0 (5.82)	68.5 (2.81)	70.0 (3.84)	69.3 (4.09)
Median	67.0	68.5	68.0	69.0	68.0
Min, max	(65, 73)	(65, 81)	(65, 74)	(65, 77)	(65, 81)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:17)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d1aav 65 b2 p1

14.46. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Dose 1 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N^a=11) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=7) n^b (%)	Total (N^a=42) n^b (%)
Sex					
Male	4 (36.4)	6 (50.0)	3 (25.0)	3 (42.9)	16 (38.1)
Female	7 (63.6)	6 (50.0)	9 (75.0)	4 (57.1)	26 (61.9)
Race					
White	10 (90.9)	10 (83.3)	9 (75.0)	7 (100.0)	36 (85.7)
Black or African American	0	2 (16.7)	1 (8.3)	0	3 (7.1)
Asian	1 (9.1)	0	2 (16.7)	0	3 (7.1)
Ethnicity					
Hispanic/Latino	0	1 (8.3)	0	0	1 (2.4)
Non-Hispanic/non-Latino	11 (100.0)	11 (91.7)	12 (100.0)	7 (100.0)	41 (97.6)
Age at vaccination (years)					
Mean (SD)	38.0 (12.07)	37.6 (10.07)	37.3 (9.85)	29.3 (9.66)	36.2 (10.60)
Median	39.0	38.0	36.5	25.0	36.0
Min, max	(21, 53)	(23, 53)	(23, 54)	(19, 44)	(19, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:16)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d1eva 18 b2 p1

14.47. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Dose 1 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=11) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=44) n^b (%)
Sex					
Male	2 (16.7)	5 (41.7)	6 (54.5)	4 (44.4)	17 (38.6)
Female	10 (83.3)	7 (58.3)	5 (45.5)	5 (55.6)	27 (61.4)
Race					
White	12 (100.0)	12 (100.0)	11 (100.0)	9 (100.0)	44 (100.0)
Ethnicity					
Non-Hispanic/non-Latino	12 (100.0)	12 (100.0)	11 (100.0)	9 (100.0)	44 (100.0)
Age at vaccination (years)					
Mean (SD)	68.0 (2.89)	71.0 (5.82)	68.5 (2.94)	70.0 (3.84)	69.3 (4.14)
Median	67.0	68.5	68.0	69.0	68.0
Min, max	(65, 73)	(65, 81)	(65, 74)	(65, 77)	(65, 81)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:16)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d1eva 65 b2 p1

14.48. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Dose 2 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Sex					
Male	5 (41.7)	6 (50.0)	3 (25.0)	5 (55.6)	19 (42.2)
Female	7 (58.3)	6 (50.0)	9 (75.0)	4 (44.4)	26 (57.8)
Race					
White	11 (91.7)	10 (83.3)	9 (75.0)	9 (100.0)	39 (86.7)
Black or African American	0	2 (16.7)	1 (8.3)	0	3 (6.7)
Asian	1 (8.3)	0	2 (16.7)	0	3 (6.7)
Ethnicity					
Hispanic/Latino	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Non-Hispanic/non-Latino	11 (91.7)	11 (91.7)	12 (100.0)	9 (100.0)	43 (95.6)
Age at vaccination (years)					
Mean (SD)	36.8 (12.20)	37.6 (10.07)	37.3 (9.85)	34.4 (13.22)	36.7 (10.95)
Median	37.0	38.0	36.5	30.0	37.0
Min, max	(21, 53)	(23, 53)	(23, 54)	(19, 53)	(19, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d2aav 18 b2 p1

14.49. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Dose 2 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=12) n^b (%)	30 µg (N^a=12) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=45) n^b (%)
Sex					
Male	2 (16.7)	5 (41.7)	6 (50.0)	4 (44.4)	17 (37.8)
Female	10 (83.3)	7 (58.3)	6 (50.0)	5 (55.6)	28 (62.2)
Race					
White	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Ethnicity					
Non-Hispanic/non-Latino	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Age at vaccination (years)					
Mean (SD)	68.0 (2.89)	71.0 (5.82)	68.5 (2.81)	70.0 (3.84)	69.3 (4.09)
Median	67.0	68.5	68.0	69.0	68.0
Min, max	(65, 73)	(65, 81)	(65, 74)	(65, 77)	(65, 81)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d2aav 65 b2 p1

14.50. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N[a]=11) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=11) n[b] (%)	Placebo (N[a]=7) n[b] (%)	Total (N[a]=41) n[b] (%)
Sex					
Male	4 (36.4)	6 (50.0)	3 (27.3)	3 (42.9)	16 (39.0)
Female	7 (63.6)	6 (50.0)	8 (72.7)	4 (57.1)	25 (61.0)
Race					
White	10 (90.9)	10 (83.3)	9 (81.8)	7 (100.0)	36 (87.8)
Black or African American	0	2 (16.7)	1 (9.1)	0	3 (7.3)
Asian	1 (9.1)	0	1 (9.1)	0	2 (4.9)
Ethnicity					
Hispanic/Latino	0	1 (8.3)	0	0	1 (2.4)
Non-Hispanic/non-Latino	11 (100.0)	11 (91.7)	11 (100.0)	7 (100.0)	40 (97.6)
Age at vaccination (years)					
Mean (SD)	38.0 (12.07)	37.6 (10.07)	37.2 (10.33)	29.3 (9.66)	36.2 (10.73)
Median	39.0	38.0	35.0	25.0	35.0
Min, max	(21, 53)	(23, 53)	(23, 54)	(19, 44)	(19, 54)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:22)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d2eva 18 b2 p1

14.51. Demographic Characteristics – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	10 µg (N^a=12) n^b (%)	20 µg (N^a=11) n^b (%)	30 µg (N^a=11) n^b (%)	Placebo (N^a=9) n^b (%)	Total (N^a=43) n^b (%)
Sex					
Male	2 (16.7)	5 (45.5)	6 (54.5)	4 (44.4)	17 (39.5)
Female	10 (83.3)	6 (54.5)	5 (45.5)	5 (55.6)	26 (60.5)
Race					
White	12 (100.0)	11 (100.0)	11 (100.0)	9 (100.0)	43 (100.0)
Ethnicity					
Non-Hispanic/non-Latino	12 (100.0)	11 (100.0)	11 (100.0)	9 (100.0)	43 (100.0)
Age at vaccination (years)					
Mean (SD)	68.0 (2.89)	71.4 (5.95)	68.5 (2.94)	70.0 (3.84)	69.4 (4.17)
Median	67.0	69.0	68.0	69.0	68.0
Min, max	(65, 73)	(65, 81)	(65, 74)	(65, 77)	(65, 81)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:22)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl s005 demo d2eva 65 b2 p1

14.52. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Any medical history	11 (91.7)	12 (100.0)	10 (83.3)	9 (100.0)	42 (93.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0	1 (8.3)	1 (11.1)	2 (4.4)
Anaemia	0	0	1 (8.3)	1 (11.1)	2 (4.4)
EAR AND LABYRINTH DISORDERS	1 (8.3)	0	0	0	1 (2.2)
Otosclerosis	1 (8.3)	0	0	0	1 (2.2)
ENDOCRINE DISORDERS	0	0	1 (8.3)	0	1 (2.2)
Hypothyroidism	0	0	1 (8.3)	0	1 (2.2)
GASTROINTESTINAL DISORDERS	0	1 (8.3)	0	2 (22.2)	3 (6.7)
Gastrooesophageal reflux disease	0	1 (8.3)	0	0	1 (2.2)
Irritable bowel syndrome	0	0	0	2 (22.2)	2 (4.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	2 (16.7)	1 (8.3)	0	3 (6.7)
Hernia	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Pain	0	1 (8.3)	0	0	1 (2.2)
HEPATOBILIARY DISORDERS	1 (8.3)	0	0	0	1 (2.2)
Cholelithiasis	1 (8.3)	0	0	0	1 (2.2)
IMMUNE SYSTEM DISORDERS	5 (41.7)	10 (83.3)	6 (50.0)	5 (55.6)	26 (57.8)
Allergy to animal	2 (16.7)	0	1 (8.3)	0	3 (6.7)
Drug hypersensitivity	0	3 (25.0)	2 (16.7)	1 (11.1)	6 (13.3)
Food allergy	1 (8.3)	0	0	0	1 (2.2)
Hypersensitivity	0	1 (8.3)	0	0	1 (2.2)
Seasonal allergy	3 (25.0)	8 (66.7)	5 (41.7)	4 (44.4)	20 (44.4)
INFECTIONS AND INFESTATIONS	0	0	3 (25.0)	3 (33.3)	6 (13.3)
Appendicitis	0	0	2 (16.7)	1 (11.1)	3 (6.7)
Helicobacter infection	0	0	1 (8.3)	0	1 (2.2)
Herpes simplex	0	0	0	1 (11.1)	1 (2.2)
Paronychia	0	0	0	1 (11.1)	1 (2.2)

14.52. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (8.3)	1 (8.3)	1 (8.3)	1 (11.1)	4 (8.9)
Arthropod bite	0	1 (8.3)	0	0	1 (2.2)
Concussion	0	0	0	1 (11.1)	1 (2.2)
Contusion	0	0	0	1 (11.1)	1 (2.2)
Ligament rupture	1 (8.3)	0	0	0	1 (2.2)
Upper limb fracture	0	0	1 (8.3)	0	1 (2.2)
INVESTIGATIONS	0	2 (16.7)	1 (8.3)	0	3 (6.7)
Arthroscopy	0	0	1 (8.3)	0	1 (2.2)
Blood cholesterol increased	0	1 (8.3)	0	0	1 (2.2)
False positive tuberculosis test	0	1 (8.3)	0	0	1 (2.2)
METABOLISM AND NUTRITION DISORDERS	1 (8.3)	0	0	0	1 (2.2)
Hypercholesterolaemia	1 (8.3)	0	0	0	1 (2.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (16.7)	3 (25.0)	4 (33.3)	1 (11.1)	10 (22.2)
Arthralgia	0	0	1 (8.3)	0	1 (2.2)
Arthritis	1 (8.3)	0	0	0	1 (2.2)
Back pain	0	1 (8.3)	0	0	1 (2.2)
Bursitis	0	0	1 (8.3)	0	1 (2.2)
Groin pain	0	1 (8.3)	0	0	1 (2.2)
Intervertebral disc protrusion	0	0	1 (8.3)	0	1 (2.2)
Muscle spasms	1 (8.3)	0	0	0	1 (2.2)
Musculoskeletal pain	0	0	0	1 (11.1)	1 (2.2)
Pain in extremity	0	0	1 (8.3)	0	1 (2.2)
Rotator cuff syndrome	1 (8.3)	0	0	0	1 (2.2)
Scoliosis	0	2 (16.7)	0	0	2 (4.4)
Tendonitis	1 (8.3)	0	0	0	1 (2.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (8.3)	1 (8.3)	1 (8.3)	0	3 (6.7)
Basal cell carcinoma	0	1 (8.3)	0	0	1 (2.2)
Malignant melanoma in situ	1 (8.3)	0	0	0	1 (2.2)
Uterine leiomyoma	0	0	1 (8.3)	0	1 (2.2)

14.52. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
NERVOUS SYSTEM DISORDERS	1 (8.3)	3 (25.0)	4 (33.3)	1 (11.1)	9 (20.0)
Headache	0	1 (8.3)	0	0	1 (2.2)
Migraine	0	0	3 (25.0)	0	3 (6.7)
Nystagmus	0	0	1 (8.3)	0	1 (2.2)
Seizure	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Sinus headache	1 (8.3)	0	0	0	1 (2.2)
Syncope	0	1 (8.3)	0	0	1 (2.2)
PSYCHIATRIC DISORDERS	3 (25.0)	0	1 (8.3)	2 (22.2)	6 (13.3)
Anxiety	3 (25.0)	0	0	2 (22.2)	5 (11.1)
Depression	1 (8.3)	0	0	0	1 (2.2)
Seasonal affective disorder	0	0	1 (8.3)	0	1 (2.2)
RENAL AND URINARY DISORDERS	0	0	1 (8.3)	0	1 (2.2)
Nephrolithiasis	0	0	1 (8.3)	0	1 (2.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	1 (8.3)	0	0	1 (2.2)
Uterine polyp	0	1 (8.3)	0	0	1 (2.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (8.3)	3 (25.0)	2 (16.7)	3 (33.3)	9 (20.0)
Acne	0	0	0	2 (22.2)	2 (4.4)
Dermatitis contact	1 (8.3)	1 (8.3)	1 (8.3)	1 (11.1)	4 (8.9)
Eczema	0	1 (8.3)	0	0	1 (2.2)
Miliaria	0	1 (8.3)	0	0	1 (2.2)
Rosacea	0	0	1 (8.3)	0	1 (2.2)
SOCIAL CIRCUMSTANCES	2 (16.7)	3 (25.0)	1 (8.3)	2 (22.2)	8 (17.8)
Corrective lens user	0	3 (25.0)	1 (8.3)	2 (22.2)	6 (13.3)
Hearing aid user	1 (8.3)	0	0	0	1 (2.2)
Postmenopause	1 (8.3)	0	0	0	1 (2.2)
SURGICAL AND MEDICAL PROCEDURES	5 (41.7)	3 (25.0)	6 (50.0)	1 (11.1)	15 (33.3)
Appendicectomy	0	0	2 (16.7)	1 (11.1)	3 (6.7)
Cholecystectomy	1 (8.3)	0	0	0	1 (2.2)
Hernia repair	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Hysterectomy	0	1 (8.3)	0	0	1 (2.2)
Ligament operation	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Mastectomy	0	0	1 (8.3)	0	1 (2.2)

14.52. Medical History – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
Nasal septal operation	0	0	1 (8.3)	0	1 (2.2)
Rotator cuff repair	1 (8.3)	0	0	0	1 (2.2)
Stapedectomy	1 (8.3)	0	0	0	1 (2.2)
Turbinectomy	1 (8.3)	0	0	0	1 (2.2)
Uterine operation	0	0	1 (8.3)	0	1 (2.2)

Note: MedDRA (MedDRA v23.0) coding dictionary applied.
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. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: admh Table Generation: 01SEP2020 (18:18)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/admh_s002_18_b2_p1

14.53. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Any medical history	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (8.3)	0	0	0	1 (2.2)
Anaemia	1 (8.3)	0	0	0	1 (2.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	3 (25.0)	0	0	0	3 (6.7)
Duchenne muscular dystrophy gene carrier	1 (8.3)	0	0	0	1 (2.2)
Spine malformation	1 (8.3)	0	0	0	1 (2.2)
Von Willebrand's disease	1 (8.3)	0	0	0	1 (2.2)
EAR AND LABYRINTH DISORDERS	0	2 (16.7)	2 (16.7)	1 (11.1)	5 (11.1)
Aural polyp	0	1 (8.3)	0	0	1 (2.2)
Deafness	0	0	1 (8.3)	0	1 (2.2)
Deafness bilateral	0	0	0	1 (11.1)	1 (2.2)
Deafness unilateral	0	0	1 (8.3)	0	1 (2.2)
Tinnitus	0	1 (8.3)	0	0	1 (2.2)
ENDOCRINE DISORDERS	0	1 (8.3)	0	2 (22.2)	3 (6.7)
Hypothyroidism	0	1 (8.3)	0	2 (22.2)	3 (6.7)
EYE DISORDERS	0	3 (25.0)	0	3 (33.3)	6 (13.3)
Cataract	0	2 (16.7)	0	1 (11.1)	3 (6.7)
Corneal erosion	0	1 (8.3)	0	0	1 (2.2)
Dry eye	0	0	0	1 (11.1)	1 (2.2)
Retinal tear	0	0	0	1 (11.1)	1 (2.2)
GASTROINTESTINAL DISORDERS	2 (16.7)	2 (16.7)	1 (8.3)	1 (11.1)	6 (13.3)
Anal incontinence	1 (8.3)	0	0	0	1 (2.2)
Gastrooesophageal reflux disease	0	2 (16.7)	1 (8.3)	1 (11.1)	4 (8.9)
Hiatus hernia	1 (8.3)	0	0	0	1 (2.2)
Inguinal hernia	0	1 (8.3)	0	0	1 (2.2)
Irritable bowel syndrome	1 (8.3)	0	0	0	1 (2.2)
HEPATOBILIARY DISORDERS	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Cholecystitis	0	0	1 (8.3)	0	1 (2.2)

14.53. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	20 µg (N[a]=12) n[b] (%)	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=9) n[b] (%)	Total (N[a]=45) n[b] (%)
Cholelithiasis	1 (8.3)	0	0	0	1 (2.2)
IMMUNE SYSTEM DISORDERS	6 (50.0)	8 (66.7)	6 (50.0)	4 (44.4)	24 (53.3)
Allergy to arthropod sting	0	0	1 (8.3)	0	1 (2.2)
Contrast media allergy	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Drug hypersensitivity	3 (25.0)	5 (41.7)	2 (16.7)	2 (22.2)	12 (26.7)
Perfume sensitivity	0	1 (8.3)	0	0	1 (2.2)
Rubber sensitivity	1 (8.3)	0	0	0	1 (2.2)
Seasonal allergy	4 (33.3)	4 (33.3)	4 (33.3)	2 (22.2)	14 (31.1)
INFECTIONS AND INFESTATIONS	1 (8.3)	1 (8.3)	0	2 (22.2)	4 (8.9)
Diverticulitis	0	1 (8.3)	0	0	1 (2.2)
Epididymitis	1 (8.3)	0	0	0	1 (2.2)
Oral herpes	0	0	0	1 (11.1)	1 (2.2)
Rhinitis	0	0	0	1 (11.1)	1 (2.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (16.7)	1 (8.3)	2 (16.7)	1 (11.1)	6 (13.3)
Exposure to communicable disease	0	0	1 (8.3)	0	1 (2.2)
Hand fracture	0	1 (8.3)	0	0	1 (2.2)
Ligament rupture	1 (8.3)	0	0	0	1 (2.2)
Limb injury	0	0	1 (8.3)	0	1 (2.2)
Lumbar vertebral fracture	1 (8.3)	0	0	0	1 (2.2)
Meniscus injury	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Tendon rupture	0	0	0	1 (11.1)	1 (2.2)
Tooth fracture	0	0	0	1 (11.1)	1 (2.2)
INVESTIGATIONS	2 (16.7)	1 (8.3)	2 (16.7)	2 (22.2)	7 (15.6)
Arthroscopy	1 (8.3)	0	0	0	1 (2.2)
Blood cholesterol increased	1 (8.3)	1 (8.3)	2 (16.7)	1 (11.1)	5 (11.1)
White blood cell count decreased	0	0	0	1 (11.1)	1 (2.2)
METABOLISM AND NUTRITION DISORDERS	2 (16.7)	3 (25.0)	0	1 (11.1)	6 (13.3)
Hypercholesterolaemia	1 (8.3)	2 (16.7)	0	0	3 (6.7)
Hyperlipidaemia	0	1 (8.3)	0	0	1 (2.2)
Lactose intolerance	1 (8.3)	0	0	1 (11.1)	2 (4.4)

14.53. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5 (41.7)	6 (50.0)	6 (50.0)	7 (77.8)	24 (53.3)
Arthritis	2 (16.7)	0	1 (8.3)	3 (33.3)	6 (13.3)
Back pain	0	0	1 (8.3)	0	1 (2.2)
Chondrocalcinosis pyrophosphate	0	0	1 (8.3)	0	1 (2.2)
Foot deformity	0	1 (8.3)	0	0	1 (2.2)
Intervertebral disc degeneration	0	1 (8.3)	0	0	1 (2.2)
Intervertebral disc disorder	0	0	1 (8.3)	0	1 (2.2)
Intervertebral disc protrusion	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Muscle spasms	0	0	1 (8.3)	0	1 (2.2)
Musculoskeletal pain	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Neck pain	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Osteoarthritis	1 (8.3)	0	1 (8.3)	2 (22.2)	4 (8.9)
Osteopenia	0	1 (8.3)	1 (8.3)	1 (11.1)	3 (6.7)
Osteoporosis	2 (16.7)	0	1 (8.3)	0	3 (6.7)
Plantar fasciitis	0	0	0	1 (11.1)	1 (2.2)
Spinal osteoarthritis	0	0	1 (8.3)	0	1 (2.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	1 (8.3)	2 (16.7)	0	3 (6.7)
Basal cell carcinoma	0	1 (8.3)	0	0	1 (2.2)
Malignant melanoma	0	0	1 (8.3)	0	1 (2.2)
Prostate cancer	0	0	1 (8.3)	0	1 (2.2)
NERVOUS SYSTEM DISORDERS	2 (16.7)	3 (25.0)	4 (33.3)	1 (11.1)	10 (22.2)
Anosmia	0	1 (8.3)	0	0	1 (2.2)
Arachnoiditis	0	0	1 (8.3)	0	1 (2.2)
Headache	1 (8.3)	1 (8.3)	1 (8.3)	0	3 (6.7)
Migraine	1 (8.3)	1 (8.3)	2 (16.7)	1 (11.1)	5 (11.1)
Radiculopathy	0	0	0	1 (11.1)	1 (2.2)
Sciatica	0	0	1 (8.3)	0	1 (2.2)
PSYCHIATRIC DISORDERS	1 (8.3)	1 (8.3)	2 (16.7)	2 (22.2)	6 (13.3)
Anxiety	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Depression	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Insomnia	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Rapid eye movement sleep behaviour disorder	0	0	0	1 (11.1)	1 (2.2)
Sleep disorder	0	0	1 (8.3)	0	1 (2.2)

14.53. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
RENAL AND URINARY DISORDERS	2 (16.7)	2 (16.7)	1 (8.3)	0	5 (11.1)
Nephrolithiasis	0	1 (8.3)	0	0	1 (2.2)
Stress urinary incontinence	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Urinary incontinence	1 (8.3)	0	1 (8.3)	0	2 (4.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (16.7)	4 (33.3)	2 (16.7)	4 (44.4)	12 (26.7)
Atrophic vulvovaginitis	0	1 (8.3)	0	0	1 (2.2)
Benign prostatic hyperplasia	0	1 (8.3)	1 (8.3)	0	2 (4.4)
Breast cyst	1 (8.3)	0	0	0	1 (2.2)
Erectile dysfunction	0	1 (8.3)	0	2 (22.2)	3 (6.7)
Menorrhagia	0	1 (8.3)	0	0	1 (2.2)
Ovarian cyst	0	0	0	1 (11.1)	1 (2.2)
Uterine cyst	1 (8.3)	0	0	0	1 (2.2)
Uterine polyp	0	0	1 (8.3)	0	1 (2.2)
Vulvovaginal dryness	1 (8.3)	0	0	1 (11.1)	2 (4.4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Epistaxis	1 (8.3)	0	0	0	1 (2.2)
Sleep apnoea syndrome	0	0	1 (8.3)	0	1 (2.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0	1 (8.3)	1 (11.1)	2 (4.4)
Acne	0	0	1 (8.3)	0	1 (2.2)
Dermatitis contact	0	0	0	1 (11.1)	1 (2.2)
Seborrhoeic dermatitis	0	0	0	1 (11.1)	1 (2.2)
SOCIAL CIRCUMSTANCES	5 (41.7)	5 (41.7)	3 (25.0)	2 (22.2)	15 (33.3)
Corrective lens user	3 (25.0)	2 (16.7)	2 (16.7)	1 (11.1)	8 (17.8)
Familial risk factor	0	1 (8.3)	0	0	1 (2.2)
Hearing aid user	0	1 (8.3)	0	0	1 (2.2)
Postmenopause	2 (16.7)	1 (8.3)	1 (8.3)	1 (11.1)	5 (11.1)
SURGICAL AND MEDICAL PROCEDURES	7 (58.3)	8 (66.7)	6 (50.0)	4 (44.4)	25 (55.6)
Breast cyst excision	1 (8.3)	0	0	0	1 (2.2)
Bunion operation	0	1 (8.3)	0	0	1 (2.2)
Cataract operation	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Cholecystectomy	1 (8.3)	0	1 (8.3)	0	2 (4.4)

14.53. Medical History – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) 10 µg (N[a]=12) n[b] (%)	 20 µg (N[a]=12) n[b] (%)	 30 µg (N[a]=12) n[b] (%)	 Placebo (N[a]=9) n[b] (%)	 Total (N[a]=45) n[b] (%)
Corneal transplant	0	1 (8.3)	0	0	1 (2.2)
Epididymectomy	1 (8.3)	0	0	0	1 (2.2)
Hernia repair	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Hysterectomy	1 (8.3)	1 (8.3)	0	0	2 (4.4)
Intraocular lens implant	0	1 (8.3)	0	0	1 (2.2)
Keratomileusis	0	1 (8.3)	0	0	1 (2.2)
Knee operation	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Ligament operation	1 (8.3)	0	0	0	1 (2.2)
Mole excision	0	0	1 (8.3)	0	1 (2.2)
Nasal septal operation	0	0	0	1 (11.1)	1 (2.2)
Oophorectomy	0	1 (8.3)	0	0	1 (2.2)
Ovarian cystectomy	0	0	0	1 (11.1)	1 (2.2)
Prostatectomy	0	0	1 (8.3)	0	1 (2.2)
Shoulder operation	0	0	1 (8.3)	0	1 (2.2)
Skin lesion removal	0	0	1 (8.3)	0	1 (2.2)
Skin neoplasm excision	0	1 (8.3)	1 (8.3)	1 (11.1)	3 (6.7)
Spinal fusion surgery	1 (8.3)	0	0	0	1 (2.2)
Spinal laminectomy	1 (8.3)	0	0	0	1 (2.2)
Tenoplasty	0	0	0	1 (11.1)	1 (2.2)
Transurethral prostatectomy	0	1 (8.3)	0	0	1 (2.2)
Uterine polypectomy	0	0	1 (8.3)	0	1 (2.2)
Varicose vein operation	0	1 (8.3)	0	0	1 (2.2)
Vertebroplasty	1 (8.3)	0	0	0	1 (2.2)
VASCULAR DISORDERS	0	1 (8.3)	0	0	1 (2.2)
Deep vein thrombosis	0	1 (8.3)	0	0	1 (2.2)

Note: MedDRA (MedDRA v23.0) coding dictionary applied.
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. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: admh Table Generation: 01SEP2020 (18:19)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/admh_s002_65_b2_p1

14.54. Immunogenicity Blood Samples Drawn – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Blood sample drawn	0	0	0	0	0
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn before Dose 1[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 1[c]					
6 to 8 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 21 days after Dose 1 (before Dose 2)[c]					
19 to 23 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 2[c]					
6 to 8 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 14 days after Dose 2[c]					
12 to 16 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 1 month after Dose 2[c]					
28 to 35 Days	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
>35 Days	1 (8.3)	0	0	0	1 (2.2)

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. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 02SEP2020 (11:11)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adsl s001 imm bld 18 b1 p1

14.55. Immunogenicity Blood Samples Drawn – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All Randomized Subjects

	Vaccine Group (as Randomized)		
	100 µg (N^a=12)	Placebo (N^a=3)	Total (N^a=15)
	n^b (%)	n^b (%)	n^b (%)
Randomized	12 (100.0)	3 (100.0)	15 (100.0)
Not vaccinated	0	0	0
Blood sample drawn	0	0	0
Vaccinated at Dose 1	12 (100.0)	3 (100.0)	15 (100.0)
Blood sample drawn before Dose 1[c]	12 (100.0)	3 (100.0)	15 (100.0)
Blood sample drawn after Dose 1[c]			
1-Week follow-up visit	12 (100.0)	3 (100.0)	15 (100.0)
3-Week follow-up visit	12 (100.0)	3 (100.0)	15 (100.0)
4-Week follow-up visit	12 (100.0)	3 (100.0)	15 (100.0)
5-Week follow-up visit	12 (100.0)	3 (100.0)	15 (100.0)
7-Week follow-up visit	12 (100.0)	3 (100.0)	15 (100.0)

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. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 18SEP2020 (12:30)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adsl_s001_imm_bld_18_b1_100_p1

14.56. Immunogenicity Blood Samples Drawn – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Blood sample drawn	0	0	0	0	0
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn before Dose 1[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 1[c]					
6 to 8 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 21 days after Dose 1 (before Dose 2)[c]					
19 to 23 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 2[c]					
6 to 8 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 14 days after Dose 2[c]					
12 to 16 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 1 month after Dose 2[c]					
28 to 35 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)

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. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 02SEP2020 (11:11)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adsl s001 imm bld 65 b1 p1

14.57. Immunogenicity Blood Samples Drawn – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Blood sample drawn	0	0	0	0	0
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn before Dose 1[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 1[c]					
6 to 8 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 21 days after Dose 1 (before Dose 2)[c]					
19 to 23 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 2[c]					
<6 Days	0	0	1 (8.3)	0	1 (2.2)
6 to 8 Days	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Blood sample drawn 14 days after Dose 2[c]					
12 to 16 Days	12 (100.0)	12 (100.0)	10 (83.3)	9 (100.0)	43 (95.6)
Not obtained	0	0	2 (16.7)	0	2 (4.4)
Blood sample drawn 1 month after Dose 2[c]					
<28 Days	0	0	1 (8.3)	0	1 (2.2)
28 to 35 Days	12 (100.0)	11 (91.7)	11 (91.7)	9 (100.0)	43 (95.6)
Not obtained	0	1 (8.3)	0	0	1 (2.2)

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. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 02SEP2020 (11:11)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adsl s001 imm bld 18 b2 p1

14.58. Immunogenicity Blood Samples Drawn – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Randomized	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Not vaccinated	0	0	0	0	0
Blood sample drawn	0	0	0	0	0
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn before Dose 1[c]	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 1[c]					
6 to 8 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 21 days after Dose 1 (before Dose 2)[c]					
19 to 23 Days	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Blood sample drawn 7 days after Dose 2[c]					
6 to 8 Days	12 (100.0)	11 (91.7)	12 (100.0)	9 (100.0)	44 (97.8)
>8 Days	0	1 (8.3)	0	0	1 (2.2)
Blood sample drawn 14 days after Dose 2[c]					
12 to 16 Days	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Not obtained	1 (8.3)	0	0	0	1 (2.2)
Blood sample drawn 1 month after Dose 2[c]					
28 to 35 Days	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Not obtained	0	0	0	1 (11.1)	1 (2.2)

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. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 02SEP2020 (11:11)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adsl s001 imm bld 65 b2 p1

14.59. E-Diary Transmission – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 2	10 (83.3)	11 (91.7)	12 (100.0)	9 (100.0)	42 (93.3)
Day 3	12 (100.0)	12 (100.0)	12 (100.0)	7 (77.8)	43 (95.6)
Day 4	11 (91.7)	11 (91.7)	11 (91.7)	9 (100.0)	42 (93.3)
Day 5	12 (100.0)	11 (91.7)	11 (91.7)	8 (88.9)	42 (93.3)
Day 6	12 (100.0)	11 (91.7)	12 (100.0)	9 (100.0)	44 (97.8)
Day 7	12 (100.0)	11 (91.7)	10 (83.3)	9 (100.0)	42 (93.3)
All 7 days[e]	9 (75.0)	7 (58.3)	8 (66.7)	7 (77.8)	31 (68.9)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	11 (91.7)	12 (100.0)	12 (100.0)	8 (88.9)	43 (95.6)
Day 2	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Day 3	10 (83.3)	10 (83.3)	12 (100.0)	8 (88.9)	40 (88.9)
Day 4	10 (83.3)	9 (75.0)	12 (100.0)	9 (100.0)	40 (88.9)
Day 5	12 (100.0)	11 (91.7)	11 (91.7)	9 (100.0)	43 (95.6)
Day 6	12 (100.0)	11 (91.7)	12 (100.0)	8 (88.9)	43 (95.6)
Day 7	11 (91.7)	10 (83.3)	12 (100.0)	7 (77.8)	40 (88.9)
All 7 days[e]	9 (75.0)	5 (41.7)	10 (83.3)	4 (44.4)	28 (62.2)

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. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 to Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 to Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s200 trns 18 b1 p1

14.60. E-Diary Transmission – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

	Vaccine Group (as Administered)		
	100 µg (N^a=12)	Placebo (N^a=3)	Total (N^a=15)
	n^b (%)	n^b (%)	n^b (%)
Vaccinated at Dose 1	12 (100.0)	3 (100.0)	15 (100.0)
E-diary			
Not transmitted[c]	0	0	0
Transmitted[d]			
Day 1	12 (100.0)	3 (100.0)	15 (100.0)
Day 2	12 (100.0)	3 (100.0)	15 (100.0)
Day 3	12 (100.0)	3 (100.0)	15 (100.0)
Day 4	11 (91.7)	3 (100.0)	14 (93.3)
Day 5	11 (91.7)	3 (100.0)	14 (93.3)
Day 6	12 (100.0)	3 (100.0)	15 (100.0)
Day 7	11 (91.7)	3 (100.0)	14 (93.3)
All 7 days[e]	9 (75.0)	3 (100.0)	12 (80.0)

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. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 to Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 to Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 18SEP2020 (12:30)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adce s200 trns 18 b1 100 p1

14.61. E-Diary Transmission – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Day 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 3	11 (91.7)	11 (91.7)	12 (100.0)	9 (100.0)	43 (95.6)
Day 4	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Day 5	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Day 6	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 7	11 (91.7)	12 (100.0)	11 (91.7)	9 (100.0)	43 (95.6)
All 7 days[e]	9 (75.0)	11 (91.7)	10 (83.3)	8 (88.9)	38 (84.4)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 2	11 (91.7)	12 (100.0)	11 (91.7)	9 (100.0)	43 (95.6)
Day 3	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 4	12 (100.0)	10 (83.3)	12 (100.0)	8 (88.9)	42 (93.3)
Day 5	12 (100.0)	11 (91.7)	11 (91.7)	9 (100.0)	43 (95.6)
Day 6	12 (100.0)	11 (91.7)	11 (91.7)	9 (100.0)	43 (95.6)
Day 7	11 (91.7)	10 (83.3)	12 (100.0)	7 (77.8)	40 (88.9)
All 7 days[e]	10 (83.3)	10 (83.3)	9 (75.0)	6 (66.7)	35 (77.8)

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. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 to Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 to Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s200 trns 65 b1 p1

14.62. E-Diary Transmission – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Day 2	12 (100.0)	12 (100.0)	12 (100.0)	7 (77.8)	43 (95.6)
Day 3	11 (91.7)	10 (83.3)	12 (100.0)	9 (100.0)	42 (93.3)
Day 4	11 (91.7)	9 (75.0)	11 (91.7)	8 (88.9)	39 (86.7)
Day 5	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Day 6	12 (100.0)	9 (75.0)	11 (91.7)	8 (88.9)	40 (88.9)
Day 7	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
All 7 days[e]	9 (75.0)	6 (50.0)	10 (83.3)	5 (55.6)	30 (66.7)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Day 2	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Day 3	12 (100.0)	10 (83.3)	12 (100.0)	9 (100.0)	43 (95.6)
Day 4	11 (91.7)	12 (100.0)	11 (91.7)	7 (77.8)	41 (91.1)
Day 5	11 (91.7)	10 (83.3)	11 (91.7)	8 (88.9)	40 (88.9)
Day 6	11 (91.7)	12 (100.0)	11 (91.7)	9 (100.0)	43 (95.6)
Day 7	11 (91.7)	11 (91.7)	9 (75.0)	8 (88.9)	39 (86.7)
All 7 days[e]	8 (66.7)	8 (66.7)	8 (66.7)	5 (55.6)	29 (64.4)

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. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 to Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 to Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s200 trns 18 b2 p1

14.63. E-Diary Transmission – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Vaccinated at Dose 1	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	12 (100.0)	11 (91.7)	12 (100.0)	8 (88.9)	43 (95.6)
Day 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 3	11 (91.7)	10 (83.3)	11 (91.7)	9 (100.0)	41 (91.1)
Day 4	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 5	12 (100.0)	12 (100.0)	12 (100.0)	8 (88.9)	44 (97.8)
Day 6	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 7	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
All 7 days[e]	11 (91.7)	10 (83.3)	10 (83.3)	7 (77.8)	38 (84.4)
Vaccinated at Dose 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
E-diary					
Not transmitted[c]	0	0	0	0	0
Transmitted[d]					
Day 1	11 (91.7)	11 (91.7)	12 (100.0)	9 (100.0)	43 (95.6)
Day 2	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 3	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 4	12 (100.0)	12 (100.0)	11 (91.7)	8 (88.9)	43 (95.6)
Day 5	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Day 6	11 (91.7)	12 (100.0)	11 (91.7)	9 (100.0)	43 (95.6)
Day 7	12 (100.0)	12 (100.0)	10 (83.3)	9 (100.0)	43 (95.6)
All 7 days[e]	10 (83.3)	11 (91.7)	9 (75.0)	8 (88.9)	38 (84.4)

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. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 to Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 to Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s200 trns 65 b2 p1

14.64. Concomitant Vaccines Received From Dose 1 to 1 Month After Dose 2 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Vaccine[b]	Vaccine Group (as Administered)				
	10 µg (N[a]=12) n[c] (%)	20 µg (N[a]=12) n[c] (%)	30 µg (N[a]=12) n[c] (%)	Placebo (N[a]=9) n[c] (%)	Total (N[a]=45) n[c] (%)
Any concomitant vaccine	0	0	1 (8.3)	0	1 (2.2)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT; TETANUS VACCINE TOXOID	0	0	1 (8.3)	0	1 (2.2)

Note: WHO DDE v202003 coding dictionary applied.
a. N = number of subjects in the specified group, or the total sample. 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: 28AUG2020 (16:27) Source Data: adcm Table Generation: 01SEP2020 (22:10)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adcm_s001_vax_1m2_65_b1_p1

Immunogenicity

14.65. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 7	12	10.0 (10.0, 10.0)	0	NE (NE, NE)	12	10.0 (10.0, 10.0)	6	10.0 (10.0, 10.0)
	1/Day 21	12	12.7 (9.6, 16.8)	12	12.5 (9.0, 17.5)	12	28.6 (17.1, 47.9)	9	10.0 (10.0, 10.0)
	2/Day 7	12	167.9 (111.2, 253.5)	12	160.3 (80.1, 320.9)	12	267.1 (172.9, 412.7)	9	10.0 (10.0, 10.0)
	2/Day 14	12	180.1 (107.2, 302.5)	12	202.9 (123.4, 333.4)	12	437.0 (302.6, 631.1)	9	10.0 (10.0, 10.0)
	2/1 Month	12	68.5 (41.8, 112.0)	12	161.2 (102.5, 253.4)	12	180.5 (108.4, 300.7)	9	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 7	12	10.0 (10.0, 10.0)	0	NE (NE, NE)	12	10.0 (10.0, 10.0)	6	10.0 (10.0, 10.0)
	1/Day 21	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	11.9 (9.1, 15.6)	9	10.0 (10.0, 10.0)
	2/Day 7	12	56.8 (35.2, 91.4)	11	67.0 (40.3, 111.3)	12	121.6 (78.8, 187.6)	9	10.0 (10.0, 10.0)
	2/Day 14	12	76.5 (44.4, 131.6)	12	110.4 (71.4, 170.5)	12	188.1 (126.4, 279.8)	9	10.0 (10.0, 10.0)
	2/1 Month	12	37.0 (24.6, 55.5)	11	40.1 (25.0, 64.3)	11	62.0 (35.5, 108.3)	9	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.8 (0.5, 1.1)	12	0.8 (0.6, 1.0)	12	0.8 (0.6, 1.1)	9	1.0 (0.5, 2.0)
	1/Day 7	12	0.8 (0.5, 1.1)	0	NE (NE, NE)	12	0.9 (0.5, 1.4)	6	1.0 (0.5, 2.2)
	1/Day 21	12	294.2 (126.8, 682.8)	12	204.1 (57.5, 723.9)	12	852.7 (479.5, 1516.4)	9	0.8 (0.4, 1.6)
	2/Day 7	12	3868.2 (2052.5, 7290.0)	12	3243.1 (689.9, 15244.1)	12	23516.5 (16552.7, 33409.8)	9	1.2 (0.5, 2.7)

14.65. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Day 14	12	5120.2 (3529.2, 7428.5)	12	7480.5 (4670.8, 11980.2)	12	13940.1 (9746.7, 19937.5)	9	0.9 (0.5, 1.9)
	2/1 Month	12	2530.8 (1684.3, 3802.5)	12	5329.2 (3789.4, 7494.7)	12	8095.2 (5563.4, 11779.1)	9	0.9 (0.5, 1.7)
RBD-binding IgG level assay (U/mL)	1/Prevax	12	0.8 (0.5, 1.3)	12	1.2 (0.6, 2.6)	12	0.9 (0.5, 1.6)	9	0.8 (0.4, 1.5)
	1/Day 7	12	0.9 (0.5, 1.6)	0	NE (NE, NE)	12	0.8 (0.5, 1.5)	6	0.9 (0.4, 2.1)
	1/Day 21	12	534.4 (244.1, 1169.6)	12	362.5 (89.5, 1468.4)	12	1535.9 (938.1, 2514.6)	9	0.8 (0.5, 1.6)
	2/Day 7	12	4813.1 (2479.5, 9343.1)	12	4033.8 (832.8, 19538.0)	12	27871.8 (19430.0, 39981.4)	9	0.9 (0.5, 1.5)
	2/Day 14	12	5880.4 (4249.8, 8136.8)	12	6376.7 (4314.0, 9425.7)	12	16165.9 (11013.3, 23729.2)	9	0.7 (0.5, 1.0)
	2/1 Month	12	3674.2 (2595.4, 5201.4)	12	6215.2 (4312.8, 8956.8)	12	9489.6 (6258.7, 14388.4)	9	0.7 (0.4, 1.3)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NE = not estimable; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s001 gm 18 b1 eval p1

14.66. Summary of Geometric Mean Titers/Concentrations – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

Assay	Dose/ Sampling Time Point[a]	Vaccine Group (as Randomized) 100 µg n[b]	100 µg GMT/GMC[c] (95% CI[c])	Placebo n[b]	Placebo GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/1 Week	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/3 Weeks	12	32.5 (17.0, 62.4)	3	10.0 (10.0, 10.0)
	1/5 Weeks	12	13.1 (8.7, 19.9)	3	10.0 (10.0, 10.0)
	1/7 Weeks	12	11.9 (9.1, 15.4)	3	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/1 Week	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/3 Weeks	12	15.0 (9.3, 24.4)	3	10.0 (10.0, 10.0)
	1/5 Weeks	12	11.7 (9.2, 14.9)	3	10.0 (10.0, 10.0)
	1/7 Weeks	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.8 (0.5, 1.2)	3	0.6 (0.6, 0.6)
	1/1 Week	12	0.9 (0.4, 1.9)	3	0.6 (0.6, 0.6)
	1/3 Weeks	12	1074.4 (702.2, 1643.9)	3	0.6 (0.6, 0.6)
	1/4 Weeks	12	976.1 (609.3, 1563.7)	3	0.6 (0.6, 0.6)
	1/5 Weeks	12	660.5 (485.3, 899.1)	3	0.6 (0.6, 0.6)
	1/7 Weeks	12	410.0 (283.9, 592.1)	3	0.6 (0.6, 0.6)
RBD-binding IgG level assay (U/mL)	1/Prevax	12	0.9 (0.5, 1.6)	3	0.6 (0.6, 0.6)
	1/1 Week	12	1.2 (0.6, 2.6)	3	0.8 (0.2, 3.2)
	1/3 Weeks	12	1778.3 (1218.9, 2594.7)	3	0.9 (0.1, 5.0)
	1/4 Weeks	12	1259.8 (793.4, 2000.3)	3	0.8 (0.2, 3.8)

14.66. Summary of Geometric Mean Titers/Concentrations – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	1/5 Weeks	12	919.4 (662.3, 1276.3)	3	0.6 (0.6, 0.6)
	1/7 Weeks	12	548.2 (387.5, 775.5)	3	0.6 (0.6, 0.6)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 100/adva s001 gm 18 b1 eval 100 p1

14.67. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	11	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	11	11.2 (8.7, 14.4)	12	10.0 (10.0, 10.0)	12	12.5 (9.0, 17.4)	9	10.0 (10.0, 10.0)
	2/Day 7	11	19.9 (11.7, 33.9)	12	178.7 (94.5, 337.7)	12	100.8 (45.7, 222.3)	9	10.0 (10.0, 10.0)
	2/Day 14	11	28.5 (13.7, 59.2)	12	104.7 (43.7, 250.5)	12	105.5 (50.0, 222.6)	9	10.0 (10.0, 10.0)
	2/1 Month	11	22.7 (11.3, 45.3)	12	125.3 (74.7, 210.0)	12	144.7 (70.3, 298.1)	9	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	11	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	11	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	2/Day 7	11	12.1 (9.0, 16.3)	12	73.7 (34.6, 157.1)	12	47.6 (22.1, 102.3)	9	10.0 (10.0, 10.0)
	2/Day 14	11	16.5 (9.6, 28.1)	12	49.0 (25.0, 95.9)	11	50.3 (25.4, 99.5)	9	10.0 (10.0, 10.0)
	2/1 Month	11	14.2 (9.0, 22.4)	12	48.4 (26.0, 90.2)	12	59.9 (30.4, 118.0)	9	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	11	1.0 (0.5, 1.9)	12	0.8 (0.6, 1.0)	12	0.7 (0.6, 0.8)	9	1.1 (0.6, 2.2)
	1/Day 21	11	34.1 (9.7, 120.2)	12	125.1 (56.2, 278.4)	12	86.3 (27.7, 269.2)	9	1.1 (0.6, 2.3)
	2/Day 7	11	860.7 (372.4, 1989.3)	12	10622.7 (5607.8, 20122.3)	12	6579.6 (2827.6, 15310.2)	9	1.3 (0.5, 3.2)
	2/Day 14	11	1436.6 (760.1, 2715.0)	12	6399.4 (3481.6, 11762.3)	12	4798.4 (2209.3, 10421.9)	9	0.9 (0.5, 1.7)
	2/1 Month	11	1089.8 (556.7, 2133.4)	12	5138.2 (2788.0, 9469.5)	12	4151.0 (1872.9, 9200.2)	9	1.2 (0.6, 2.6)
RBD-binding IgG level assay (U/mL)	1/Prevax	11	1.4 (0.4, 4.4)	12	0.6 (0.6, 0.6)	12	0.6 (0.5, 0.7)	9	1.2 (0.4, 4.0)
	1/Day 21	11	61.2 (17.1, 218.9)	12	234.4 (102.9, 533.9)	12	99.2 (30.3, 324.3)	9	1.2 (0.4, 3.6)
	2/Day 7	11	1283.5 (535.2, 3078.4)	12	12932.8 (7091.0, 23587.3)	12	7527.5 (3564.2, 15897.7)	9	1.4 (0.4, 5.0)

14.67. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Day 14	11	1771.9 (947.6, 3313.3)	12	6983.1 (3878.5, 12573.1)	12	6006.5 (2821.3, 12787.6)	9	1.4 (0.4, 4.2)
	2/1 Month	11	1495.4 (825.3, 2709.5)	12	5641.9 (3114.1, 10221.3)	12	4488.5 (2131.3, 9452.6)	9	1.2 (0.4, 4.0)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s001_gm_65_b1_eval_p1

14.68. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 7	12	10.0 (10.0, 10.0)	0	NE (NE, NE)	12	10.0 (10.0, 10.0)	6	10.0 (10.0, 10.0)
	1/Day 21	12	12.7 (9.6, 16.8)	12	12.5 (9.0, 17.5)	12	28.6 (17.1, 47.9)	9	10.0 (10.0, 10.0)
	2/Day 7	12	167.9 (111.2, 253.5)	12	160.3 (80.1, 320.9)	12	267.1 (172.9, 412.7)	9	10.0 (10.0, 10.0)
	2/Day 14	12	180.1 (107.2, 302.5)	12	202.9 (123.4, 333.4)	12	437.0 (302.6, 631.1)	9	10.0 (10.0, 10.0)
	2/1 Month	12	68.5 (41.8, 112.0)	12	161.2 (102.5, 253.4)	12	180.5 (108.4, 300.7)	9	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 7	12	10.0 (10.0, 10.0)	0	NE (NE, NE)	12	10.0 (10.0, 10.0)	6	10.0 (10.0, 10.0)
	1/Day 21	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	11.9 (9.1, 15.6)	9	10.0 (10.0, 10.0)
	2/Day 7	12	56.8 (35.2, 91.4)	11	67.0 (40.3, 111.3)	12	121.6 (78.8, 187.6)	9	10.0 (10.0, 10.0)
	2/Day 14	12	76.5 (44.4, 131.6)	12	110.4 (71.4, 170.5)	12	188.1 (126.4, 279.8)	9	10.0 (10.0, 10.0)
	2/1 Month	12	37.0 (24.6, 55.5)	11	40.1 (25.0, 64.3)	11	62.0 (35.5, 108.3)	9	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.8 (0.5, 1.1)	12	0.8 (0.6, 1.0)	12	0.8 (0.6, 1.1)	9	1.0 (0.5, 2.0)
	1/Day 7	12	0.8 (0.5, 1.1)	0	NE (NE, NE)	12	0.9 (0.5, 1.4)	6	1.0 (0.5, 2.2)
	1/Day 21	12	294.2 (126.8, 682.8)	12	204.1 (57.5, 723.9)	12	852.7 (479.5, 1516.4)	9	0.8 (0.4, 1.6)
	2/Day 7	12	3868.2 (2052.5, 7290.0)	12	3243.1 (689.9, 15244.1)	12	23516.5 (16552.7, 33409.8)	9	1.2 (0.5, 2.7)
	2/Day 14	12	5120.2 (3529.2, 7428.5)	12	7480.5 (4670.8, 11980.2)	12	13940.1 (9746.7, 19937.5)	9	0.9 (0.5, 1.9)

14.68. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
RBD-binding IgG level assay (U/mL)	2/1 Month	12	2530.8 (1684.3, 3802.5)	12	5329.2 (3789.4, 7494.7)	12	8095.2 (5563.4, 11779.1)	9	0.9 (0.5, 1.7)
	1/Prevax	12	0.8 (0.5, 1.3)	12	1.2 (0.6, 2.6)	12	0.9 (0.5, 1.6)	9	0.8 (0.4, 1.5)
	1/Day 7	12	0.9 (0.5, 1.6)	0	NE (NE, NE)	12	0.8 (0.5, 1.5)	6	0.9 (0.4, 2.1)
	1/Day 21	12	534.4 (244.1, 1169.6)	12	362.5 (89.5, 1468.4)	12	1535.9 (938.1, 2514.6)	9	0.8 (0.5, 1.6)
	2/Day 7	12	4813.1 (2479.5, 9343.1)	12	4033.8 (832.8, 19538.0)	12	27871.8 (19430.0, 39981.4)	9	0.9 (0.5, 1.5)
	2/Day 14	12	5880.4 (4249.8, 8136.8)	12	6376.7 (4314.0, 9425.7)	12	16165.9 (11013.3, 23729.2)	9	0.7 (0.5, 1.0)
	2/1 Month	12	3674.2 (2595.4, 5201.4)	12	6215.2 (4312.8, 8956.8)	12	9489.6 (6258.7, 14388.4)	9	0.7 (0.4, 1.3)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NE = not estimable; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s001_gm_18_b1_aai_p1

14.69. Summary of Geometric Mean Titers/Concentrations – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

Assay	Dose/ Sampling Time Point[a]	Vaccine Group (as Randomized) 100 µg n[b]	100 µg GMT/GMC[c] (95% CI[c])	Placebo n[b]	Placebo GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/1 Week	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/3 Weeks	12	32.5 (17.0, 62.4)	3	10.0 (10.0, 10.0)
	1/5 Weeks	12	13.1 (8.7, 19.9)	3	10.0 (10.0, 10.0)
	1/7 Weeks	12	11.9 (9.1, 15.4)	3	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/1 Week	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/3 Weeks	12	15.0 (9.3, 24.4)	3	10.0 (10.0, 10.0)
	1/5 Weeks	12	11.7 (9.2, 14.9)	3	10.0 (10.0, 10.0)
	1/7 Weeks	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.8 (0.5, 1.2)	3	0.6 (0.6, 0.6)
	1/1 Week	12	0.9 (0.4, 1.9)	3	0.6 (0.6, 0.6)
	1/3 Weeks	12	1074.4 (702.2, 1643.9)	3	0.6 (0.6, 0.6)
	1/4 Weeks	12	976.1 (609.3, 1563.7)	3	0.6 (0.6, 0.6)
	1/5 Weeks	12	660.5 (485.3, 899.1)	3	0.6 (0.6, 0.6)
	1/7 Weeks	12	410.0 (283.9, 592.1)	3	0.6 (0.6, 0.6)
RBD-binding IgG level assay (U/mL)	1/Prevax	12	0.9 (0.5, 1.6)	3	0.6 (0.6, 0.6)
	1/1 Week	12	1.2 (0.6, 2.6)	3	0.8 (0.2, 3.2)
	1/3 Weeks	12	1778.3 (1218.9, 2594.7)	3	0.9 (0.1, 5.0)
	1/4 Weeks	12	1259.8 (793.4, 2000.3)	3	0.8 (0.2, 3.8)

14.69. Summary of Geometric Mean Titers/Concentrations – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	1/5 Weeks	12	919.4 (662.3, 1276.3)	3	0.6 (0.6, 0.6)
	1/7 Weeks	12	548.2 (387.5, 775.5)	3	0.6 (0.6, 0.6)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 100/adva s001 gm 18 b1 aai 100 p1

14.70. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	11.1 (8.8, 13.9)	12	10.0 (10.0, 10.0)	12	12.5 (9.0, 17.4)	9	10.0 (10.0, 10.0)
	2/Day 7	12	20.1 (12.4, 32.4)	12	178.7 (94.5, 337.7)	12	100.8 (45.7, 222.3)	9	10.0 (10.0, 10.0)
	2/Day 14	12	32.5 (15.8, 66.9)	12	104.7 (43.7, 250.5)	12	105.5 (50.0, 222.6)	9	10.0 (10.0, 10.0)
	2/1 Month	12	24.2 (12.7, 45.9)	12	125.3 (74.7, 210.0)	12	144.7 (70.3, 298.1)	9	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	2/Day 7	12	11.9 (9.1, 15.7)	12	73.7 (34.6, 157.1)	12	47.6 (22.1, 102.3)	9	10.0 (10.0, 10.0)
	2/Day 14	12	15.8 (9.7, 25.8)	12	49.0 (25.0, 95.9)	11	50.3 (25.4, 99.5)	9	10.0 (10.0, 10.0)
	2/1 Month	12	13.8 (9.1, 20.9)	12	48.4 (26.0, 90.2)	12	59.9 (30.4, 118.0)	9	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	1.0 (0.5, 1.8)	12	0.8 (0.6, 1.0)	12	0.7 (0.6, 0.8)	9	1.1 (0.6, 2.2)
	1/Day 21	12	35.8 (11.5, 111.9)	12	125.1 (56.2, 278.4)	12	86.3 (27.7, 269.2)	9	1.1 (0.6, 2.3)
	2/Day 7	12	979.9 (437.0, 2197.5)	12	10622.7 (5607.8, 20122.3)	12	6579.6 (2827.6, 15310.2)	9	1.3 (0.5, 3.2)
	2/Day 14	12	1527.4 (847.0, 2754.5)	12	6399.4 (3481.6, 11762.3)	12	4798.4 (2209.3, 10421.9)	9	0.9 (0.5, 1.7)
	2/1 Month	12	1156.4 (622.3, 2149.0)	12	5138.2 (2788.0, 9469.5)	12	4151.0 (1872.9, 9200.2)	9	1.2 (0.6, 2.6)
RBD-binding IgG level assay (U/mL)	1/Prevax	12	1.3 (0.4, 3.7)	12	0.6 (0.6, 0.6)	12	0.6 (0.5, 0.7)	9	1.2 (0.4, 4.0)
	1/Day 21	12	64.7 (20.4, 205.8)	12	234.4 (102.9, 533.9)	12	99.2 (30.3, 324.3)	9	1.2 (0.4, 3.6)

14.70. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Day 7	12	1415.8 (624.9, 3207.6)	12	12932.8 (7091.0, 23587.3)	12	7527.5 (3564.2, 15897.7)	9	1.4 (0.4, 5.0)
	2/Day 14	12	1856.1 (1045.9, 3293.7)	12	6983.1 (3878.5, 12573.1)	12	6006.5 (2821.3, 12787.6)	9	1.4 (0.4, 4.2)
	2/1 Month	12	1595.5 (916.3, 2778.1)	12	5641.9 (3114.1, 10221.3)	12	4488.5 (2131.3, 9452.6)	9	1.2 (0.4, 4.0)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s001 gm 65 b1 aai p1

14.71. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	11	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	7	10.0 (10.0, 10.0)
	1/Day 21	11	16.6 (9.8, 27.9)	12	18.9 (11.1, 32.3)	12	14.4 (10.1, 20.4)	7	10.0 (10.0, 10.0)
	2/Day 7	11	169.0 (102.7, 278.2)	12	362.5 (256.9, 511.6)	11	360.9 (237.4, 548.6)	7	10.0 (10.0, 10.0)
	2/Day 14	11	108.8 (54.7, 216.5)	12	292.1 (179.3, 475.7)	9	161.6 (109.3, 238.8)	7	10.0 (10.0, 10.0)
	2/1 Month	11	105.3 (65.1, 170.6)	11	251.7 (143.5, 441.4)	11	143.6 (103.8, 198.6)	7	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	11	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	7	10.0 (10.0, 10.0)
	1/Day 21	11	10.9 (9.0, 13.2)	12	10.7 (9.2, 12.5)	12	10.8 (9.1, 12.8)	7	10.0 (10.0, 10.0)
	2/Day 7	11	70.1 (42.7, 115.0)	12	142.2 (103.3, 195.7)	11	122.8 (79.2, 190.4)	7	10.0 (10.0, 10.0)
	2/Day 14	11	46.6 (25.1, 86.5)	12	112.7 (73.9, 171.8)	9	54.3 (37.5, 78.6)	7	10.0 (10.0, 10.0)
	2/1 Month	11	34.4 (18.3, 64.7)	11	60.0 (33.3, 108.2)	11	54.7 (41.2, 72.6)	7	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	11	0.6 (0.6, 0.6)	12	0.9 (0.5, 1.4)	12	0.6 (0.6, 0.6)	7	0.6 (0.6, 0.6)
	1/Day 21	11	611.7 (332.0, 1126.8)	12	546.7 (346.3, 863.1)	12	1264.8 (912.6, 1753.1)	7	0.6 (0.6, 0.6)
	2/Day 7	11	6014.0 (4061.6, 8904.9)	12	12464.0 (9249.2, 16796.1)	11	9136.4 (6385.0, 13073.3)	7	0.6 (0.6, 0.6)
	2/Day 14	11	4757.7 (2926.8, 7733.9)	12	7366.9 (4774.3, 11367.4)	9	7639.4 (6308.6, 9251.1)	7	0.6 (0.6, 0.6)
	2/1 Month	11	3098.6 (2088.1, 4598.0)	11	5784.7 (4131.4, 8099.8)	11	5296.0 (4139.6, 6775.4)	7	0.8 (0.5, 1.2)
RBD-binding IgG level assay (U/mL)	1/Prevax	11	0.7 (0.5, 0.9)	12	0.6 (0.5, 0.7)	12	1.1 (0.6, 1.7)	7	0.8 (0.5, 1.3)
	1/Day 21	11	338.9 (172.6, 665.4)	12	347.2 (223.0, 540.4)	12	862.3 (581.2, 1279.5)	7	0.9 (0.5, 1.6)

14.71. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Day 7	11	4926.8 (3239.2, 7493.7)	12	12258.1 (8875.8, 16929.4)	11	7759.7 (5537.3, 10874.0)	7	0.9 (0.5, 1.6)
	2/Day 14	11	3984.8 (2278.2, 6969.9)	12	6383.2 (4422.7, 9212.7)	9	6825.6 (5103.5, 9129.0)	7	0.9 (0.5, 1.7)
	2/1 Month	11	2612.6 (1711.1, 3989.0)	11	4183.7 (3011.7, 5811.6)	11	5059.8 (3974.2, 6442.0)	7	1.0 (0.5, 2.3)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s001 gm 18 b2 eval p1

14.72. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	11	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	11	12.0 (9.0, 16.0)	9	10.0 (10.0, 10.0)
	2/Day 7	12	79.3 (50.6, 124.5)	11	79.3 (40.9, 153.5)	11	155.7 (80.4, 301.7)	9	10.0 (10.0, 10.0)
	2/Day 14	11	111.1 (81.0, 152.3)	11	73.7 (32.8, 165.6)	11	214.1 (105.9, 433.2)	9	10.0 (10.0, 10.0)
	2/1 Month	12	69.6 (43.0, 112.7)	11	49.6 (23.1, 106.6)	11	152.3 (81.2, 285.6)	8	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	11	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	11	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	2/Day 7	12	40.0 (26.5, 60.3)	11	33.4 (18.1, 61.4)	11	53.5 (26.1, 109.4)	9	10.0 (10.0, 10.0)
	2/Day 14	11	56.0 (35.4, 88.6)	11	29.3 (16.3, 52.6)	10	60.3 (25.2, 144.1)	9	10.0 (10.0, 10.0)
	2/1 Month	12	20.2 (12.1, 33.7)	11	24.6 (12.9, 47.0)	11	50.9 (28.3, 91.6)	8	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.8 (0.6, 1.0)	12	0.8 (0.5, 1.3)	11	0.6 (0.6, 0.6)	9	0.8 (0.6, 1.1)
	1/Day 21	12	172.0 (92.0, 321.7)	12	80.9 (31.7, 206.8)	11	283.2 (115.7, 693.2)	9	0.8 (0.6, 1.2)
	2/Day 7	12	3203.3 (2314.5, 4433.4)	11	2734.2 (1211.8, 6169.3)	11	7547.9 (4224.0, 13487.6)	9	0.9 (0.6, 1.5)
	2/Day 14	11	3560.2 (2282.4, 5553.5)	11	2522.7 (1182.4, 5382.1)	11	5844.0 (3620.4, 9433.3)	9	0.8 (0.6, 1.1)
	2/1 Month	12	2350.5 (1787.1, 3091.7)	11	1491.5 (682.0, 3262.0)	11	4592.4 (2874.1, 7337.9)	8	0.8 (0.5, 1.3)
RBD-binding IgG level assay (U/mL)	1/Prevax	12	0.9 (0.6, 1.5)	12	0.8 (0.5, 1.4)	11	0.6 (0.5, 0.8)	9	0.8 (0.5, 1.4)
	1/Day 21	12	83.6 (26.6, 262.6)	12	50.9 (16.7, 155.2)	11	198.6 (67.6, 583.5)	9	1.0 (0.5, 2.1)
	2/Day 7	12	2521.8 (1642.3, 3872.3)	11	2567.2 (979.5, 6728.1)	11	5877.3 (3426.5, 10080.9)	9	1.1 (0.5, 2.6)

14.72. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Day 14	11	2941.7 (1915.7, 4517.2)	11	1734.0 (775.0, 3879.8)	11	5642.0 (3344.2, 9518.5)	9	1.0 (0.5, 2.2)
	2/1 Month	12	2214.5 (1631.6, 3005.7)	11	1272.1 (540.7, 2993.2)	11	3468.6 (1998.4, 6020.4)	8	0.9 (0.4, 1.9)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s001_gm_65_b2_eval_p1

14.73. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	15.9 (9.8, 25.7)	12	18.9 (11.1, 32.3)	12	14.4 (10.1, 20.4)	9	10.0 (10.0, 10.0)
	2/Day 7	12	156.9 (97.2, 253.1)	12	362.5 (256.9, 511.6)	12	267.7 (125.4, 571.5)	9	10.0 (10.0, 10.0)
	2/Day 14	12	96.8 (49.4, 189.5)	12	292.1 (179.3, 475.7)	10	163.5 (115.9, 230.6)	9	10.0 (10.0, 10.0)
	2/1 Month	12	97.6 (61.2, 155.5)	11	251.7 (143.5, 441.4)	12	142.4 (106.2, 190.9)	9	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	10.8 (9.1, 12.8)	12	10.7 (9.2, 12.5)	12	10.8 (9.1, 12.8)	9	10.0 (10.0, 10.0)
	2/Day 7	12	65.7 (41.2, 105.0)	12	142.2 (103.3, 195.7)	12	99.6 (54.3, 182.8)	9	10.0 (10.0, 10.0)
	2/Day 14	12	41.0 (21.9, 76.6)	12	112.7 (73.9, 171.8)	10	56.3 (40.3, 78.6)	9	10.0 (10.0, 10.0)
	2/1 Month	12	31.0 (16.8, 57.3)	11	60.0 (33.3, 108.2)	12	56.1 (43.2, 73.0)	9	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.7 (0.6, 0.8)	12	0.9 (0.5, 1.4)	12	0.6 (0.6, 0.6)	9	0.7 (0.5, 0.9)
	1/Day 21	12	612.0 (352.8, 1061.8)	12	546.7 (346.3, 863.1)	12	1264.8 (912.6, 1753.1)	9	0.7 (0.5, 1.0)
	2/Day 7	12	5781.8 (4016.1, 8323.8)	12	12464.0 (9249.2, 16796.1)	12	8145.2 (5404.5, 12275.9)	9	0.6 (0.6, 0.6)
	2/Day 14	12	4716.9 (3042.4, 7313.2)	12	7366.9 (4774.3, 11367.4)	10	8147.0 (6523.6, 10174.3)	9	0.7 (0.5, 1.1)
	2/1 Month	12	3032.3 (2117.6, 4342.3)	11	5784.7 (4131.4, 8099.8)	12	5580.9 (4345.1, 7168.1)	9	0.8 (0.6, 1.2)
RBD-binding IgG level assay (U/mL)	1/Prevax	12	0.6 (0.5, 0.8)	12	0.6 (0.5, 0.7)	12	1.1 (0.6, 1.7)	9	0.7 (0.5, 1.1)
	1/Day 21	12	331.4 (180.0, 610.1)	12	347.2 (223.0, 540.4)	12	862.3 (581.2, 1279.5)	9	0.9 (0.6, 1.4)

14.73. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Day 7	12	4749.0 (3225.9, 6991.2)	12	12258.1 (8875.8, 16929.4)	12	6944.6 (4701.0, 10259.0)	9	0.8 (0.5, 1.3)
	2/Day 14	12	3878.2 (2334.2, 6443.5)	12	6383.2 (4422.7, 9212.7)	10	7185.7 (5428.8, 9511.1)	9	0.8 (0.5, 1.4)
	2/1 Month	12	2510.5 (1697.1, 3713.8)	11	4183.7 (3011.7, 5811.6)	12	5348.4 (4166.8, 6865.1)	9	0.9 (0.5, 1.6)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s001 gm 18 b2 aai p1

14.74. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	11.8 (9.1, 15.3)	9	10.0 (10.0, 10.0)
	2/Day 7	12	79.3 (50.6, 124.5)	12	83.7 (45.6, 153.8)	12	148.7 (81.2, 272.3)	9	10.0 (10.0, 10.0)
	2/Day 14	11	111.1 (81.0, 152.3)	12	80.5 (37.8, 171.5)	12	206.3 (108.7, 391.4)	9	10.0 (10.0, 10.0)
	2/1 Month	12	69.6 (43.0, 112.7)	12	55.0 (26.6, 113.7)	12	147.6 (83.3, 261.3)	8	10.0 (10.0, 10.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	1/Day 21	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	9	10.0 (10.0, 10.0)
	2/Day 7	12	40.0 (26.5, 60.3)	12	35.3 (20.1, 62.0)	12	52.2 (27.3, 99.8)	9	10.0 (10.0, 10.0)
	2/Day 14	11	56.0 (35.4, 88.6)	12	31.1 (18.1, 53.6)	11	59.5 (27.3, 129.4)	9	10.0 (10.0, 10.0)
	2/1 Month	12	20.2 (12.1, 33.7)	12	27.0 (14.5, 50.1)	12	51.5 (30.3, 87.5)	8	10.0 (10.0, 10.0)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.8 (0.6, 1.0)	12	0.8 (0.5, 1.3)	12	0.6 (0.6, 0.6)	9	0.8 (0.6, 1.1)
	1/Day 21	12	172.0 (92.0, 321.7)	12	80.9 (31.7, 206.8)	12	328.6 (137.5, 785.3)	9	0.8 (0.6, 1.2)
	2/Day 7	12	3203.3 (2314.5, 4433.4)	12	3056.0 (1409.9, 6623.8)	12	7985.3 (4663.0, 13674.7)	9	0.9 (0.6, 1.5)
	2/Day 14	11	3560.2 (2282.4, 5553.5)	12	2656.4 (1328.8, 5310.3)	12	6014.0 (3887.3, 9304.1)	9	0.8 (0.6, 1.1)
	2/1 Month	12	2350.5 (1787.1, 3091.7)	12	1648.8 (787.1, 3453.5)	12	4980.8 (3147.9, 7880.7)	8	0.8 (0.5, 1.3)
RBD-binding IgG level assay (U/mL)	1/Prevax	12	0.9 (0.6, 1.5)	12	0.8 (0.5, 1.4)	12	0.6 (0.5, 0.7)	9	0.8 (0.5, 1.4)
	1/Day 21	12	83.6 (26.6, 262.6)	12	50.9 (16.7, 155.2)	12	237.0 (83.2, 674.9)	9	1.0 (0.5, 2.1)
	2/Day 7	12	2521.8 (1642.3, 3872.3)	12	2826.2 (1155.7, 6911.2)	12	6279.4 (3778.8, 10434.8)	9	1.1 (0.5, 2.6)

14.74. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Day 14	11	2941.7 (1915.7, 4517.2)	12	1876.7 (889.4, 3960.0)	12	5687.4 (3547.7, 9117.5)	9	1.0 (0.5, 2.2)
	2/1 Month	12	2214.5 (1631.6, 3005.7)	12	1394.6 (628.1, 3096.4)	12	3734.2 (2213.2, 6300.4)	8	0.9 (0.4, 1.9)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s001_gm_65_b2_aai_p1

14.75. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 7	12	1.0 (1.0, 1.0)	0	NE (NE, NE)	12	1.0 (1.0, 1.0)	6	1.0 (1.0, 1.0)
	1/Day 21	12	1.3 (1.0, 1.7)	12	1.3 (0.9, 1.8)	12	2.9 (1.7, 4.8)	9	1.0 (1.0, 1.0)
	2/Day 7	12	16.8 (11.1, 25.3)	12	16.0 (8.0, 32.1)	12	26.7 (17.3, 41.3)	9	1.0 (1.0, 1.0)
	2/Day 14	12	18.0 (10.7, 30.3)	12	20.3 (12.3, 33.3)	12	43.7 (30.3, 63.1)	9	1.0 (1.0, 1.0)
	2/1 Month	12	6.8 (4.2, 11.2)	12	16.1 (10.3, 25.3)	12	18.1 (10.8, 30.1)	9	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 7	12	1.0 (1.0, 1.0)	0	NE (NE, NE)	12	1.0 (1.0, 1.0)	6	1.0 (1.0, 1.0)
	1/Day 21	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	12	1.2 (0.9, 1.6)	9	1.0 (1.0, 1.0)
	2/Day 7	12	5.7 (3.5, 9.1)	11	6.7 (4.0, 11.1)	12	12.2 (7.9, 18.8)	9	1.0 (1.0, 1.0)
	2/Day 14	12	7.6 (4.4, 13.2)	12	11.0 (7.1, 17.1)	12	18.8 (12.6, 28.0)	9	1.0 (1.0, 1.0)
	2/1 Month	12	3.7 (2.5, 5.5)	11	4.0 (2.5, 6.4)	11	6.2 (3.5, 10.8)	9	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 7	12	1.0 (1.0, 1.0)	0	NE (NE, NE)	12	1.1 (0.8, 1.3)	6	0.8 (0.5, 1.4)
	1/Day 21	12	387.6 (182.9, 821.1)	12	271.3 (77.3, 951.6)	12	1027.5 (543.5, 1942.4)	9	0.9 (0.7, 1.1)
	2/Day 7	12	5095.8 (2819.1, 9211.0)	12	4311.2 (899.3, 20668.6)	12	28336.5 (17881.6, 44904.3)	9	1.3 (0.9, 1.8)
	2/Day 14	12	6745.2 (4430.5, 10269.0)	12	9944.3 (5315.2, 18604.8)	12	16797.3 (10604.5, 26606.6)	9	1.0 (0.9, 1.0)
	2/1 Month	12	3333.9 (2382.9, 4664.5)	12	7084.4 (4443.5, 11295.0)	12	9754.4 (5820.9, 16346.0)	9	0.9 (0.8, 1.0)
RBD-binding IgG level assay (U/mL)	1/Day 7	12	1.1 (0.8, 1.4)	0	NE (NE, NE)	12	1.0 (0.9, 1.0)	6	1.0 (0.6, 1.7)
	1/Day 21	12	640.7 (321.9, 1275.0)	12	292.9 (71.9, 1193.1)	12	1763.1 (930.9, 3339.4)	9	1.1 (0.8, 1.6)

14.75. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
	2/Day 7	12	5770.9 (2945.0, 11308.3)	12	3258.8 (646.1, 16436.3)	12	31996.2 (16410.0, 62386.2)	9	1.1 (0.7, 1.8)
	2/Day 14	12	7050.6 (4405.1, 11284.8)	12	5151.7 (2469.6, 10747.0)	12	18558.1 (9354.8, 36815.6)	9	0.9 (0.7, 1.2)
	2/1 Month	12	4405.3 (2727.7, 7114.7)	12	5021.3 (2410.1, 10461.6)	12	10893.9 (5125.4, 23154.7)	9	1.0 (0.8, 1.1)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s002_gmfr_18_b1_eval_p1

14.76. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/1 Week	12	1.0 (1.0, 1.0)	3	1.0 (1.0, 1.0)
	1/3 Weeks	12	3.3 (1.7, 6.2)	3	1.0 (1.0, 1.0)
	1/5 Weeks	12	1.3 (0.9, 2.0)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	1.2 (0.9, 1.5)	3	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/1 Week	12	1.0 (1.0, 1.0)	3	1.0 (1.0, 1.0)
	1/3 Weeks	12	1.5 (0.9, 2.4)	3	1.0 (1.0, 1.0)
	1/5 Weeks	12	1.2 (0.9, 1.5)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	1.0 (1.0, 1.0)	3	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/1 Week	12	1.1 (0.9, 1.5)	3	1.0 (1.0, 1.0)
	1/3 Weeks	12	1378.3 (718.0, 2645.9)	3	1.0 (1.0, 1.0)
	1/4 Weeks	12	1252.2 (604.9, 2592.3)	3	1.0 (1.0, 1.0)
	1/5 Weeks	12	847.4 (475.4, 1510.5)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	526.0 (303.0, 913.0)	3	1.0 (1.0, 1.0)
RBD-binding IgG level assay (U/mL)	1/1 Week	12	1.3 (1.0, 1.8)	3	1.4 (0.3, 5.6)
	1/3 Weeks	12	1966.5 (1039.6, 3719.6)	3	1.5 (0.3, 8.7)
	1/4 Weeks	12	1393.0 (661.6, 2933.1)	3	1.4 (0.3, 6.6)
	1/5 Weeks	12	1016.7 (532.6, 1940.8)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	606.2 (328.7, 1118.0)	3	1.0 (1.0, 1.0)

14.76. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 100/adva s002 gmfr 18 b1 eval 100 p1

14.77. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	11	1.1 (0.9, 1.4)	12	1.0 (1.0, 1.0)	12	1.2 (0.9, 1.7)	9	1.0 (1.0, 1.0)
	2/Day 7	11	2.0 (1.2, 3.4)	12	17.9 (9.5, 33.8)	12	10.1 (4.6, 22.2)	9	1.0 (1.0, 1.0)
	2/Day 14	11	2.8 (1.4, 5.9)	12	10.5 (4.4, 25.0)	12	10.5 (5.0, 22.3)	9	1.0 (1.0, 1.0)
	2/1 Month	11	2.3 (1.1, 4.5)	12	12.5 (7.5, 21.0)	12	14.5 (7.0, 29.8)	9	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	11	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	9	1.0 (1.0, 1.0)
	2/Day 7	11	1.2 (0.9, 1.6)	12	7.4 (3.5, 15.7)	12	4.8 (2.2, 10.2)	9	1.0 (1.0, 1.0)
	2/Day 14	11	1.6 (1.0, 2.8)	12	4.9 (2.5, 9.6)	11	5.0 (2.5, 10.0)	9	1.0 (1.0, 1.0)
	2/1 Month	11	1.4 (0.9, 2.2)	12	4.8 (2.6, 9.0)	12	6.0 (3.0, 11.8)	9	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 21	11	34.4 (7.3, 161.9)	12	162.6 (81.8, 323.1)	12	124.8 (41.4, 376.3)	9	1.0 (1.0, 1.1)
	2/Day 7	11	868.3 (276.9, 2722.5)	12	13807.8 (7573.0, 25175.6)	12	9516.4 (4262.5, 21246.3)	9	1.2 (0.9, 1.6)
	2/Day 14	11	1449.3 (521.4, 4028.2)	12	8318.2 (4793.1, 14435.8)	12	6940.3 (3323.6, 14492.3)	9	0.8 (0.6, 1.1)
	2/1 Month	11	1099.4 (364.6, 3314.9)	12	6678.8 (3844.9, 11601.5)	12	6003.8 (2793.3, 12904.6)	9	1.1 (0.9, 1.4)
RBD-binding IgG level assay (U/mL)	1/Day 21	11	44.4 (9.3, 212.1)	12	407.4 (178.8, 928.2)	12	159.6 (49.1, 518.9)	9	1.0 (0.9, 1.0)
	2/Day 7	11	931.4 (217.9, 3982.1)	12	22482.1 (12326.8, 41003.5)	12	12115.3 (5507.4, 26651.4)	9	1.1 (0.9, 1.4)
	2/Day 14	11	1285.8 (329.7, 5015.2)	12	12139.3 (6742.2, 21856.7)	12	9667.2 (4456.0, 20972.9)	9	1.1 (0.8, 1.5)
	2/1 Month	11	1085.2 (274.9, 4283.7)	12	9807.7 (5413.5, 17768.4)	12	7224.1 (3355.8, 15551.5)	9	1.0 (0.9, 1.1)

14.77. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s002_gmfr_65_b1_eval_p1

14.78. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 7	12	1.0 (1.0, 1.0)	0	NE (NE, NE)	12	1.0 (1.0, 1.0)	6	1.0 (1.0, 1.0)
	1/Day 21	12	1.3 (1.0, 1.7)	12	1.3 (0.9, 1.8)	12	2.9 (1.7, 4.8)	9	1.0 (1.0, 1.0)
	2/Day 7	12	16.8 (11.1, 25.3)	12	16.0 (8.0, 32.1)	12	26.7 (17.3, 41.3)	9	1.0 (1.0, 1.0)
	2/Day 14	12	18.0 (10.7, 30.3)	12	20.3 (12.3, 33.3)	12	43.7 (30.3, 63.1)	9	1.0 (1.0, 1.0)
	2/1 Month	12	6.8 (4.2, 11.2)	12	16.1 (10.3, 25.3)	12	18.1 (10.8, 30.1)	9	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 7	12	1.0 (1.0, 1.0)	0	NE (NE, NE)	12	1.0 (1.0, 1.0)	6	1.0 (1.0, 1.0)
	1/Day 21	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	12	1.2 (0.9, 1.6)	9	1.0 (1.0, 1.0)
	2/Day 7	12	5.7 (3.5, 9.1)	11	6.7 (4.0, 11.1)	12	12.2 (7.9, 18.8)	9	1.0 (1.0, 1.0)
	2/Day 14	12	7.6 (4.4, 13.2)	12	11.0 (7.1, 17.1)	12	18.8 (12.6, 28.0)	9	1.0 (1.0, 1.0)
	2/1 Month	12	3.7 (2.5, 5.5)	11	4.0 (2.5, 6.4)	11	6.2 (3.5, 10.8)	9	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 7	12	1.0 (1.0, 1.0)	0	NE (NE, NE)	12	1.1 (0.8, 1.3)	6	0.8 (0.5, 1.4)
	1/Day 21	12	387.6 (182.9, 821.1)	12	271.3 (77.3, 951.6)	12	1027.5 (543.5, 1942.4)	9	0.9 (0.7, 1.1)
	2/Day 7	12	5095.8 (2819.1, 9211.0)	12	4311.2 (899.3, 20668.6)	12	28336.5 (17881.6, 44904.3)	9	1.3 (0.9, 1.8)
	2/Day 14	12	6745.2 (4430.5, 10269.0)	12	9944.3 (5315.2, 18604.8)	12	16797.3 (10604.5, 26606.6)	9	1.0 (0.9, 1.0)
	2/1 Month	12	3333.9 (2382.9, 4664.5)	12	7084.4 (4443.5, 11295.0)	12	9754.4 (5820.9, 16346.0)	9	0.9 (0.8, 1.0)
RBD-binding IgG level assay (U/mL)	1/Day 7	12	1.1 (0.8, 1.4)	0	NE (NE, NE)	12	1.0 (0.9, 1.0)	6	1.0 (0.6, 1.7)

14.78. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
	1/Day 21	12	640.7 (321.9, 1275.0)	12	292.9 (71.9, 1193.1)	12	1763.1 (930.9, 3339.4)	9	1.1 (0.8, 1.6)
	2/Day 7	12	5770.9 (2945.0, 11308.3)	12	3258.8 (646.1, 16436.3)	12	31996.2 (16410.0, 62386.2)	9	1.1 (0.7, 1.8)
	2/Day 14	12	7050.6 (4405.1, 11284.8)	12	5151.7 (2469.6, 10747.0)	12	18558.1 (9354.8, 36815.6)	9	0.9 (0.7, 1.2)
	2/1 Month	12	4405.3 (2727.7, 7114.7)	12	5021.3 (2410.1, 10461.6)	12	10893.9 (5125.4, 23154.7)	9	1.0 (0.8, 1.1)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s002 gmfr 18 b1 aai p1

14.79. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/1 Week	12	1.0 (1.0, 1.0)	3	1.0 (1.0, 1.0)
	1/3 Weeks	12	3.3 (1.7, 6.2)	3	1.0 (1.0, 1.0)
	1/5 Weeks	12	1.3 (0.9, 2.0)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	1.2 (0.9, 1.5)	3	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/1 Week	12	1.0 (1.0, 1.0)	3	1.0 (1.0, 1.0)
	1/3 Weeks	12	1.5 (0.9, 2.4)	3	1.0 (1.0, 1.0)
	1/5 Weeks	12	1.2 (0.9, 1.5)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	1.0 (1.0, 1.0)	3	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/1 Week	12	1.1 (0.9, 1.5)	3	1.0 (1.0, 1.0)
	1/3 Weeks	12	1378.3 (718.0, 2645.9)	3	1.0 (1.0, 1.0)
	1/4 Weeks	12	1252.2 (604.9, 2592.3)	3	1.0 (1.0, 1.0)
	1/5 Weeks	12	847.4 (475.4, 1510.5)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	526.0 (303.0, 913.0)	3	1.0 (1.0, 1.0)
RBD-binding IgG level assay (U/mL)	1/1 Week	12	1.3 (1.0, 1.8)	3	1.4 (0.3, 5.6)
	1/3 Weeks	12	1966.5 (1039.6, 3719.6)	3	1.5 (0.3, 8.7)
	1/4 Weeks	12	1393.0 (661.6, 2933.1)	3	1.4 (0.3, 6.6)
	1/5 Weeks	12	1016.7 (532.6, 1940.8)	3	1.0 (1.0, 1.0)
	1/7 Weeks	12	606.2 (328.7, 1118.0)	3	1.0 (1.0, 1.0)

14.79. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 100/adva s002 gmfr 18 b1 aai 100 p1

14.80. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	1.1 (0.9, 1.4)	12	1.0 (1.0, 1.0)	12	1.2 (0.9, 1.7)	9	1.0 (1.0, 1.0)
	2/Day 7	12	2.0 (1.2, 3.2)	12	17.9 (9.5, 33.8)	12	10.1 (4.6, 22.2)	9	1.0 (1.0, 1.0)
	2/Day 14	12	3.3 (1.6, 6.7)	12	10.5 (4.4, 25.0)	12	10.5 (5.0, 22.3)	9	1.0 (1.0, 1.0)
	2/1 Month	12	2.4 (1.3, 4.6)	12	12.5 (7.5, 21.0)	12	14.5 (7.0, 29.8)	9	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	9	1.0 (1.0, 1.0)
	2/Day 7	12	1.2 (0.9, 1.6)	12	7.4 (3.5, 15.7)	12	4.8 (2.2, 10.2)	9	1.0 (1.0, 1.0)
	2/Day 14	12	1.6 (1.0, 2.6)	12	4.9 (2.5, 9.6)	11	5.0 (2.5, 10.0)	9	1.0 (1.0, 1.0)
	2/1 Month	12	1.4 (0.9, 2.1)	12	4.8 (2.6, 9.0)	12	6.0 (3.0, 11.8)	9	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 21	12	37.5 (9.2, 153.2)	12	162.6 (81.8, 323.1)	12	124.8 (41.4, 376.3)	9	1.0 (1.0, 1.1)
	2/Day 7	12	1026.2 (343.6, 3064.7)	12	13807.8 (7573.0, 25175.6)	12	9516.4 (4262.5, 21246.3)	9	1.2 (0.9, 1.6)
	2/Day 14	12	1599.5 (620.4, 4123.8)	12	8318.2 (4793.1, 14435.8)	12	6940.3 (3323.6, 14492.3)	9	0.8 (0.6, 1.1)
	2/1 Month	12	1211.0 (437.7, 3350.8)	12	6678.8 (3844.9, 11601.5)	12	6003.8 (2793.3, 12904.6)	9	1.1 (0.9, 1.4)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	50.5 (12.0, 213.0)	12	407.4 (178.8, 928.2)	12	159.6 (49.1, 518.9)	9	1.0 (0.9, 1.0)
	2/Day 7	12	1105.0 (282.8, 4318.1)	12	22482.1 (12326.8, 41003.5)	12	12115.3 (5507.4, 26651.4)	9	1.1 (0.9, 1.4)
	2/Day 14	12	1448.6 (412.9, 5081.8)	12	12139.3 (6742.2, 21856.7)	12	9667.2 (4456.0, 20972.9)	9	1.1 (0.8, 1.5)
	2/1 Month	12	1245.2 (348.1, 4454.7)	12	9807.7 (5413.5, 17768.4)	12	7224.1 (3355.8, 15551.5)	9	1.0 (0.9, 1.1)

14.80. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s002_gmfr_65_b1_aai_p1

14.81. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	11	1.7 (1.0, 2.8)	12	1.9 (1.1, 3.2)	12	1.4 (1.0, 2.0)	7	1.0 (1.0, 1.0)
	2/Day 7	11	16.9 (10.3, 27.8)	12	36.3 (25.7, 51.2)	11	36.1 (23.7, 54.9)	7	1.0 (1.0, 1.0)
	2/Day 14	11	10.9 (5.5, 21.7)	12	29.2 (17.9, 47.6)	9	16.2 (10.9, 23.9)	7	1.0 (1.0, 1.0)
	2/1 Month	11	10.5 (6.5, 17.1)	11	25.2 (14.3, 44.1)	11	14.4 (10.4, 19.9)	7	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	11	1.1 (0.9, 1.3)	12	1.1 (0.9, 1.2)	12	1.1 (0.9, 1.3)	7	1.0 (1.0, 1.0)
	2/Day 7	11	7.0 (4.3, 11.5)	12	14.2 (10.3, 19.6)	11	12.3 (7.9, 19.0)	7	1.0 (1.0, 1.0)
	2/Day 14	11	4.7 (2.5, 8.7)	12	11.3 (7.4, 17.2)	9	5.4 (3.8, 7.9)	7	1.0 (1.0, 1.0)
	2/1 Month	11	3.4 (1.8, 6.5)	11	6.0 (3.3, 10.8)	11	5.5 (4.1, 7.3)	7	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 21	11	965.9 (524.4, 1779.4)	12	636.8 (296.9, 1365.6)	12	1997.4 (1441.1, 2768.4)	7	1.0 (1.0, 1.0)
	2/Day 7	11	9497.1 (6413.9, 14062.2)	12	14516.5 (9188.0, 22935.3)	11	14427.7 (10082.9, 20644.7)	7	1.0 (1.0, 1.0)
	2/Day 14	11	7513.2 (4621.9, 12213.0)	12	8580.1 (5164.3, 14255.0)	9	12063.8 (9962.2, 14608.8)	7	1.0 (1.0, 1.0)
	2/1 Month	11	4893.1 (3297.4, 7261.0)	11	6553.4 (3787.8, 11338.5)	11	8363.2 (6537.1, 10699.5)	7	1.2 (0.8, 1.9)
RBD-binding IgG level assay (U/mL)	1/Day 21	11	516.9 (230.3, 1160.4)	12	557.1 (347.7, 892.7)	12	821.1 (456.9, 1475.9)	7	1.2 (0.7, 1.8)
	2/Day 7	11	7514.3 (4609.8, 12249.0)	12	19671.3 (12848.3, 30117.6)	11	8442.8 (4885.5, 14590.4)	7	1.1 (0.6, 2.1)
	2/Day 14	11	6077.6 (3328.1, 11098.6)	12	10243.4 (6509.5, 16119.2)	9	8213.0 (5507.4, 12247.7)	7	1.2 (0.8, 1.7)
	2/1 Month	11	3984.7 (2412.4, 6581.7)	11	6665.1 (4292.1, 10350.2)	11	5505.3 (3394.8, 8927.8)	7	1.3 (0.7, 2.3)

14.81. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s002_gmfr_18_b2_eval_p1

14.82. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	11	1.2 (0.9, 1.6)	9	1.0 (1.0, 1.0)
	2/Day 7	12	7.9 (5.1, 12.4)	11	7.9 (4.1, 15.3)	11	15.6 (8.0, 30.2)	9	1.0 (1.0, 1.0)
	2/Day 14	11	11.1 (8.1, 15.2)	11	7.4 (3.3, 16.6)	11	21.4 (10.6, 43.3)	9	1.0 (1.0, 1.0)
	2/1 Month	12	7.0 (4.3, 11.3)	11	5.0 (2.3, 10.7)	11	15.2 (8.1, 28.6)	8	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	11	1.0 (1.0, 1.0)	9	1.0 (1.0, 1.0)
	2/Day 7	12	4.0 (2.7, 6.0)	11	3.3 (1.8, 6.1)	11	5.3 (2.6, 10.9)	9	1.0 (1.0, 1.0)
	2/Day 14	11	5.6 (3.5, 8.9)	11	2.9 (1.6, 5.3)	10	6.0 (2.5, 14.4)	9	1.0 (1.0, 1.0)
	2/1 Month	12	2.0 (1.2, 3.4)	11	2.5 (1.3, 4.7)	11	5.1 (2.8, 9.2)	8	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 21	12	223.5 (112.1, 445.8)	12	98.2 (36.4, 265.2)	11	447.2 (182.6, 1094.7)	9	1.0 (1.0, 1.1)
	2/Day 7	12	4162.5 (2679.8, 6465.4)	11	3240.5 (1349.3, 7782.7)	11	11919.3 (6670.3, 21299.0)	9	1.2 (0.9, 1.6)
	2/Day 14	11	4545.1 (2529.5, 8166.6)	11	2989.8 (1255.2, 7121.5)	11	9228.6 (5717.2, 14896.6)	9	1.0 (0.9, 1.1)
	2/1 Month	12	3054.4 (2015.9, 4627.9)	11	1767.7 (700.5, 4460.6)	11	7252.1 (4538.7, 11587.7)	8	1.0 (0.6, 1.7)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	89.6 (30.5, 263.0)	12	62.9 (17.4, 227.0)	11	316.3 (116.5, 858.6)	9	1.2 (0.7, 2.2)
	2/Day 7	12	2703.3 (1629.0, 4486.1)	11	3070.3 (905.7, 10408.5)	11	9357.1 (6075.0, 14412.3)	9	1.4 (0.7, 2.8)
	2/Day 14	11	3017.9 (1697.6, 5364.9)	11	2073.9 (698.9, 6153.9)	11	8982.5 (5966.6, 13522.8)	9	1.2 (0.6, 2.6)
	2/1 Month	12	2373.9 (1454.3, 3875.1)	11	1521.5 (511.7, 4523.9)	11	5522.3 (3610.4, 8446.6)	8	1.3 (0.6, 2.8)

14.82. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s002_gmfr_65_b2_eval_p1

14.83. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	1.6 (1.0, 2.6)	12	1.9 (1.1, 3.2)	12	1.4 (1.0, 2.0)	9	1.0 (1.0, 1.0)
	2/Day 7	12	15.7 (9.7, 25.3)	12	36.3 (25.7, 51.2)	12	26.8 (12.5, 57.2)	9	1.0 (1.0, 1.0)
	2/Day 14	12	9.7 (4.9, 18.9)	12	29.2 (17.9, 47.6)	10	16.3 (11.6, 23.1)	9	1.0 (1.0, 1.0)
	2/1 Month	12	9.8 (6.1, 15.6)	11	25.2 (14.3, 44.1)	12	14.2 (10.6, 19.1)	9	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	1.1 (0.9, 1.3)	12	1.1 (0.9, 1.2)	12	1.1 (0.9, 1.3)	9	1.0 (1.0, 1.0)
	2/Day 7	12	6.6 (4.1, 10.5)	12	14.2 (10.3, 19.6)	12	10.0 (5.4, 18.3)	9	1.0 (1.0, 1.0)
	2/Day 14	12	4.1 (2.2, 7.7)	12	11.3 (7.4, 17.2)	10	5.6 (4.0, 7.9)	9	1.0 (1.0, 1.0)
	2/1 Month	12	3.1 (1.7, 5.7)	11	6.0 (3.3, 10.8)	12	5.6 (4.3, 7.3)	9	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 21	12	908.2 (515.0, 1601.8)	12	636.8 (296.9, 1365.6)	12	1997.4 (1441.1, 2768.4)	9	1.0 (1.0, 1.0)
	2/Day 7	12	8580.1 (5645.5, 13040.2)	12	14516.5 (9188.0, 22935.3)	12	12862.6 (8534.5, 19385.6)	9	0.9 (0.7, 1.2)
	2/Day 14	12	6999.9 (4397.0, 11143.6)	12	8580.1 (5164.3, 14255.0)	10	12865.3 (10301.8, 16066.7)	9	1.0 (0.6, 1.7)
	2/1 Month	12	4500.0 (3014.0, 6718.7)	11	6553.4 (3787.8, 11338.5)	12	8813.1 (6861.6, 11319.6)	9	1.1 (0.8, 1.6)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	510.9 (246.3, 1059.9)	12	557.1 (347.7, 892.7)	12	821.1 (456.9, 1475.9)	9	1.2 (0.8, 1.8)
	2/Day 7	12	7322.5 (4695.8, 11418.4)	12	19671.3 (12848.3, 30117.6)	12	6612.8 (3187.7, 13718.2)	9	1.1 (0.7, 1.7)
	2/Day 14	12	5979.8 (3470.1, 10304.8)	12	10243.4 (6509.5, 16119.2)	10	7294.0 (4690.2, 11343.5)	9	1.1 (0.9, 1.5)
	2/1 Month	12	3870.9 (2451.0, 6113.4)	11	6665.1 (4292.1, 10350.2)	12	5092.9 (3188.1, 8135.9)	9	1.2 (0.8, 1.9)

14.83. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s002_gmfr_18_b2_aai_p1

14.84. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	12	1.2 (0.9, 1.5)	9	1.0 (1.0, 1.0)
	2/Day 7	12	7.9 (5.1, 12.4)	12	8.4 (4.6, 15.4)	12	14.9 (8.1, 27.2)	9	1.0 (1.0, 1.0)
	2/Day 14	11	11.1 (8.1, 15.2)	12	8.1 (3.8, 17.2)	12	20.6 (10.9, 39.1)	9	1.0 (1.0, 1.0)
	2/1 Month	12	7.0 (4.3, 11.3)	12	5.5 (2.7, 11.4)	12	14.8 (8.3, 26.1)	8	1.0 (1.0, 1.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	12	1.0 (1.0, 1.0)	9	1.0 (1.0, 1.0)
	2/Day 7	12	4.0 (2.7, 6.0)	12	3.5 (2.0, 6.2)	12	5.2 (2.7, 10.0)	9	1.0 (1.0, 1.0)
	2/Day 14	11	5.6 (3.5, 8.9)	12	3.1 (1.8, 5.4)	11	5.9 (2.7, 12.9)	9	1.0 (1.0, 1.0)
	2/1 Month	12	2.0 (1.2, 3.4)	12	2.7 (1.5, 5.0)	12	5.1 (3.0, 8.8)	8	1.0 (1.0, 1.0)
S1-binding IgG level assay (U/mL)	1/Day 21	12	223.5 (112.1, 445.8)	12	98.2 (36.4, 265.2)	12	518.9 (217.1, 1240.1)	9	1.0 (1.0, 1.1)
	2/Day 7	12	4162.5 (2679.8, 6465.4)	12	3709.6 (1594.7, 8629.2)	12	12610.0 (7363.6, 21594.4)	9	1.2 (0.9, 1.6)
	2/Day 14	11	4545.1 (2529.5, 8166.6)	12	3224.5 (1448.7, 7176.9)	12	9497.1 (6138.7, 14692.7)	9	1.0 (0.9, 1.1)
	2/1 Month	12	3054.4 (2015.9, 4627.9)	12	2001.4 (831.6, 4816.8)	12	7865.4 (4971.1, 12444.9)	8	1.0 (0.6, 1.7)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	89.6 (30.5, 263.0)	12	62.9 (17.4, 227.0)	12	380.1 (141.6, 1020.4)	9	1.2 (0.7, 2.2)
	2/Day 7	12	2703.3 (1629.0, 4486.1)	12	3487.1 (1119.7, 10859.6)	12	10070.8 (6605.3, 15354.5)	9	1.4 (0.7, 2.8)
	2/Day 14	11	3017.9 (1697.6, 5364.9)	12	2315.6 (843.1, 6359.7)	12	9121.3 (6297.6, 13211.2)	9	1.2 (0.6, 2.6)
	2/1 Month	12	2373.9 (1454.3, 3875.1)	12	1720.7 (620.9, 4768.3)	12	5988.8 (3924.1, 9139.9)	8	1.3 (0.6, 2.8)

14.84. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:32)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s002_gmfr_65_b2_aai_p1

14.85. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	1 (8.3) (0.2, 38.5)	12	3 (25.0) (5.5, 57.2)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	11 (91.7) (61.5, 99.8)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	10 (83.3) (51.6, 97.9)	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	10 (83.3) (51.6, 97.9)	11	9 (81.8) (48.2, 97.7)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	10 (83.3) (51.6, 97.9)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	5 (41.7) (15.2, 72.3)	11	6 (54.5) (23.4, 83.3)	11	7 (63.6) (30.8, 89.1)	9	0 (0.0) (0.0, 33.6)
S1-binding IgG level assay (U/mL)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
RBD-binding IgG level assay (U/mL)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)

14.85. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_18_b1_eval_p1

14.86. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/1 Week	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	6 (50.0) (21.1, 78.9)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	1 (8.3) (0.2, 38.5)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/1 Week	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	2 (16.7) (2.1, 48.4)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
S1-binding IgG level assay (U/mL)	1/1 Week	12	1 (8.3) (0.2, 38.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/4 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
RBD-binding IgG level assay (U/mL)	1/1 Week	12	1 (8.3) (0.2, 38.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/4 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)

14.86. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_100/adva_s003_fr4_18_b1_eval_100_p1

14.87. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	11	0 (0.0) (0.0, 28.5)	12	0 (0.0) (0.0, 26.5)	12	1 (8.3) (0.2, 38.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	11	1 (9.1) (0.2, 41.3)	12	11 (91.7) (61.5, 99.8)	12	9 (75.0) (42.8, 94.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	4 (36.4) (10.9, 69.2)	12	9 (75.0) (42.8, 94.5)	12	10 (83.3) (51.6, 97.9)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	11	2 (18.2) (2.3, 51.8)	12	11 (91.7) (61.5, 99.8)	12	10 (83.3) (51.6, 97.9)	9	0 (0.0) (0.0, 33.6)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	11	0 (0.0) (0.0, 28.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	11	0 (0.0) (0.0, 28.5)	12	8 (66.7) (34.9, 90.1)	12	7 (58.3) (27.7, 84.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	2 (18.2) (2.3, 51.8)	12	7 (58.3) (27.7, 84.8)	11	7 (63.6) (30.8, 89.1)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	11	1 (9.1) (0.2, 41.3)	12	8 (66.7) (34.9, 90.1)	12	8 (66.7) (34.9, 90.1)	9	0 (0.0) (0.0, 33.6)
S1-binding IgG level assay (U/mL)	1/Day 21	11	8 (72.7) (39.0, 94.0)	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
RBD-binding IgG level assay (U/mL)	1/Day 21	11	8 (72.7) (39.0, 94.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)

14.87. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_65_b1_eval_p1

14.88. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	1 (8.3) (0.2, 38.5)	12	3 (25.0) (5.5, 57.2)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	11 (91.7) (61.5, 99.8)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	10 (83.3) (51.6, 97.9)	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	10 (83.3) (51.6, 97.9)	11	9 (81.8) (48.2, 97.7)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	10 (83.3) (51.6, 97.9)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	5 (41.7) (15.2, 72.3)	11	6 (54.5) (23.4, 83.3)	11	7 (63.6) (30.8, 89.1)	9	0 (0.0) (0.0, 33.6)
S1-binding IgG level assay (U/mL)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
RBD-binding IgG level assay (U/mL)	1/Day 7	12	0 (0.0) (0.0, 26.5)	0	0 (NE) (NE, NE)	12	0 (0.0) (0.0, 26.5)	6	0 (0.0) (0.0, 45.9)
	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)

14.88. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer;
NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_18_b1_aai_p1

14.89. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/1 Week	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	6 (50.0) (21.1, 78.9)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	1 (8.3) (0.2, 38.5)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/1 Week	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	2 (16.7) (2.1, 48.4)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	0 (0.0) (0.0, 26.5)	3	0 (0.0) (0.0, 70.8)
S1-binding IgG level assay (U/mL)	1/1 Week	12	1 (8.3) (0.2, 38.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/4 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
RBD-binding IgG level assay (U/mL)	1/1 Week	12	1 (8.3) (0.2, 38.5)	3	0 (0.0) (0.0, 70.8)
	1/3 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/4 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/5 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	1/7 Weeks	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)

14.89. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_100/adva_s003_fr4_18_b1_aai_100_p1

14.90. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	12	1 (8.3) (0.2, 38.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	1 (8.3) (0.2, 38.5)	12	11 (91.7) (61.5, 99.8)	12	9 (75.0) (42.8, 94.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	5 (41.7) (15.2, 72.3)	12	9 (75.0) (42.8, 94.5)	12	10 (83.3) (51.6, 97.9)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	3 (25.0) (5.5, 57.2)	12	11 (91.7) (61.5, 99.8)	12	10 (83.3) (51.6, 97.9)	9	0 (0.0) (0.0, 33.6)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	0 (0.0) (0.0, 26.5)	12	8 (66.7) (34.9, 90.1)	12	7 (58.3) (27.7, 84.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	2 (16.7) (2.1, 48.4)	12	7 (58.3) (27.7, 84.8)	11	7 (63.6) (30.8, 89.1)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	1 (8.3) (0.2, 38.5)	12	8 (66.7) (34.9, 90.1)	12	8 (66.7) (34.9, 90.1)	9	0 (0.0) (0.0, 33.6)
S1-binding IgG level assay (U/mL)	1/Day 21	12	9 (75.0) (42.8, 94.5)	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	9 (75.0) (42.8, 94.5)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)

14.90. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_65_b1_aai_p1

14.91. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	11	2 (18.2) (2.3, 51.8)	12	3 (25.0) (5.5, 57.2)	12	0 (0.0) (0.0, 26.5)	7	0 (0.0) (0.0, 41.0)
	2/Day 7	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/Day 14	11	10 (90.9) (58.7, 99.8)	12	12 (100.0) (73.5, 100.0)	9	9 (100.0) (66.4, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	7	0 (0.0) (0.0, 41.0)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	11	0 (0.0) (0.0, 28.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	7	0 (0.0) (0.0, 41.0)
	2/Day 7	11	9 (81.8) (48.2, 97.7)	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/Day 14	11	5 (45.5) (16.7, 76.6)	12	11 (91.7) (61.5, 99.8)	9	6 (66.7) (29.9, 92.5)	7	0 (0.0) (0.0, 41.0)
	2/1 Month	11	5 (45.5) (16.7, 76.6)	11	9 (81.8) (48.2, 97.7)	11	8 (72.7) (39.0, 94.0)	7	0 (0.0) (0.0, 41.0)
S1-binding IgG level assay (U/mL)	1/Day 21	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/Day 7	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	9 (100.0) (66.4, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	7	0 (0.0) (0.0, 41.0)
RBD-binding IgG level assay (U/mL)	1/Day 21	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/Day 7	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	9 (100.0) (66.4, 100.0)	7	0 (0.0) (0.0, 41.0)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	7	0 (0.0) (0.0, 41.0)

14.91. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_18_b2_eval_p1

14.92. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	11	0 (0.0) (0.0, 28.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	10 (83.3) (51.6, 97.9)	11	9 (81.8) (48.2, 97.7)	11	10 (90.9) (58.7, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	11	8 (72.7) (39.0, 94.0)	11	11 (100.0) (71.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	9 (75.0) (42.8, 94.5)	11	6 (54.5) (23.4, 83.3)	11	11 (100.0) (71.5, 100.0)	8	0 (0.0) (0.0, 36.9)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	11	0 (0.0) (0.0, 28.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	5 (41.7) (15.2, 72.3)	11	5 (45.5) (16.7, 76.6)	11	7 (63.6) (30.8, 89.1)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	9 (81.8) (48.2, 97.7)	11	3 (27.3) (6.0, 61.0)	10	6 (60.0) (26.2, 87.8)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	2 (16.7) (2.1, 48.4)	11	3 (27.3) (6.0, 61.0)	11	7 (63.6) (30.8, 89.1)	8	0 (0.0) (0.0, 36.9)
S1-binding IgG level assay (U/mL)	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	11	11 (100.0) (71.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	8	0 (0.0) (0.0, 36.9)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	11 (91.7) (61.5, 99.8)	12	10 (83.3) (51.6, 97.9)	11	11 (100.0) (71.5, 100.0)	9	1 (11.1) (0.3, 48.2)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	9	1 (11.1) (0.3, 48.2)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	9	1 (11.1) (0.3, 48.2)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	11	11 (100.0) (71.5, 100.0)	8	1 (12.5) (0.3, 52.7)

14.92. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_65_b2_eval_p1

14.93. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	2 (16.7) (2.1, 48.4)	12	3 (25.0) (5.5, 57.2)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	10 (83.3) (51.6, 97.9)	12	12 (100.0) (73.5, 100.0)	10	10 (100.0) (69.2, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	9 (75.0) (42.8, 94.5)	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	5 (41.7) (15.2, 72.3)	12	11 (91.7) (61.5, 99.8)	10	7 (70.0) (34.8, 93.3)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	5 (41.7) (15.2, 72.3)	11	9 (81.8) (48.2, 97.7)	12	9 (75.0) (42.8, 94.5)	9	0 (0.0) (0.0, 33.6)
S1-binding IgG level assay (U/mL)	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	10	10 (100.0) (69.2, 100.0)	9	1 (11.1) (0.3, 48.2)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	10	10 (100.0) (69.2, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)

14.93. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_18_b2_aai_p1

14.94. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	10 (83.3) (51.6, 97.9)	12	10 (83.3) (51.6, 97.9)	12	11 (91.7) (61.5, 99.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	12	9 (75.0) (42.8, 94.5)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	9 (75.0) (42.8, 94.5)	12	7 (58.3) (27.7, 84.8)	12	12 (100.0) (73.5, 100.0)	8	0 (0.0) (0.0, 36.9)
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Day 21	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	12	0 (0.0) (0.0, 26.5)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	5 (41.7) (15.2, 72.3)	12	6 (50.0) (21.1, 78.9)	12	7 (58.3) (27.7, 84.8)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	9 (81.8) (48.2, 97.7)	12	4 (33.3) (9.9, 65.1)	11	7 (63.6) (30.8, 89.1)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	2 (16.7) (2.1, 48.4)	12	4 (33.3) (9.9, 65.1)	12	8 (66.7) (34.9, 90.1)	8	0 (0.0) (0.0, 36.9)
S1-binding IgG level assay (U/mL)	1/Day 21	12	12 (100.0) (73.5, 100.0)	12	11 (91.7) (61.5, 99.8)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	0 (0.0) (0.0, 33.6)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	8	0 (0.0) (0.0, 36.9)
RBD-binding IgG level assay (U/mL)	1/Day 21	12	11 (91.7) (61.5, 99.8)	12	10 (83.3) (51.6, 97.9)	12	12 (100.0) (73.5, 100.0)	9	1 (11.1) (0.3, 48.2)
	2/Day 7	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	1 (11.1) (0.3, 48.2)
	2/Day 14	11	11 (100.0) (71.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	9	1 (11.1) (0.3, 48.2)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	12	12 (100.0) (73.5, 100.0)	8	1 (12.5) (0.3, 52.7)

14.94. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer;
RBD = receptor-binding domain; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from prevaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s003_fr4_65_b2_aai_p1

14.95. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	13.174 (8.840, 19.632)	12	13.294 (10.244, 17.251)	12	12.050 (8.747, 16.599)	9	10.315 (4.942, 21.533)
	1/Day 7	12	13.324 (9.166, 19.367)	0	NE (NE, NE)	12	11.431 (7.022, 18.608)	6	9.921 (4.570, 21.540)
	1/Day 21	12	0.043 (0.020, 0.092)	12	0.061 (0.018, 0.207)	12	0.034 (0.025, 0.046)	9	11.879 (6.162, 22.903)
	2/Day 7	12	0.043 (0.028, 0.067)	12	0.049 (0.018, 0.136)	12	0.011 (0.008, 0.016)	9	8.202 (3.671, 18.324)
	2/Day 14	12	0.035 (0.027, 0.046)	12	0.027 (0.020, 0.037)	12	0.031 (0.026, 0.037)	9	10.676 (5.218, 21.843)
	2/1 Month	12	0.027 (0.020, 0.036)	12	0.030 (0.023, 0.040)	12	0.022 (0.017, 0.030)	9	11.091 (5.854, 21.013)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	13.174 (8.840, 19.632)	12	13.294 (10.244, 17.251)	12	12.050 (8.747, 16.599)	9	10.315 (4.942, 21.533)
	1/Day 7	12	13.324 (9.166, 19.367)	0	NE (NE, NE)	12	11.431 (7.022, 18.608)	6	9.921 (4.570, 21.540)
	1/Day 21	12	0.034 (0.015, 0.079)	12	0.049 (0.014, 0.174)	12	0.014 (0.008, 0.024)	9	11.879 (6.162, 22.903)
	2/Day 7	12	0.015 (0.011, 0.020)	11	0.023 (0.006, 0.084)	12	0.005 (0.004, 0.007)	9	8.202 (3.671, 18.324)
	2/Day 14	12	0.015 (0.011, 0.021)	12	0.015 (0.011, 0.020)	12	0.014 (0.011, 0.016)	9	10.676 (5.218, 21.843)
	2/1 Month	12	0.015 (0.012, 0.017)	11	0.008 (0.006, 0.011)	11	0.008 (0.006, 0.011)	9	11.091 (5.854, 21.013)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	11.990 (7.563, 19.009)	12	8.079 (3.894, 16.761)	12	11.480 (6.138, 21.470)	9	13.029 (6.701, 25.334)
	1/Day 7	12	11.302 (6.358, 20.091)	0	NE (NE, NE)	12	11.893 (6.631, 21.330)	6	10.834 (4.655, 25.211)
	1/Day 21	12	0.024 (0.012, 0.048)	12	0.035 (0.009, 0.133)	12	0.019 (0.013, 0.027)	9	11.769 (6.357, 21.787)
	2/Day 7	12	0.035 (0.021, 0.058)	12	0.040 (0.014, 0.110)	12	0.010 (0.007, 0.013)	9	11.381 (6.801, 19.044)

14.95. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	2/Day 14	12	0.031 (0.023, 0.041)	12	0.032 (0.023, 0.044)	12	0.027 (0.022, 0.033)	9	14.544 (9.640, 21.943)
	2/1 Month	12	0.019 (0.013, 0.027)	12	0.026 (0.021, 0.031)	12	0.019 (0.015, 0.025)	9	13.708 (7.927, 23.706)
	1/Prevax	12	11.990 (7.563, 19.009)	12	8.079 (3.894, 16.761)	12	11.480 (6.138, 21.470)	9	13.029 (6.701, 25.334)
	1/Day 7	12	11.302 (6.358, 20.091)	0	NE (NE, NE)	12	11.893 (6.631, 21.330)	6	10.834 (4.655, 25.211)
	1/Day 21	12	0.019 (0.009, 0.041)	12	0.028 (0.007, 0.112)	12	0.008 (0.005, 0.013)	9	11.769 (6.357, 21.787)
	2/Day 7	12	0.012 (0.008, 0.017)	11	0.019 (0.005, 0.070)	12	0.004 (0.003, 0.006)	9	11.381 (6.801, 19.044)
	2/Day 14	12	0.013 (0.009, 0.019)	12	0.017 (0.012, 0.024)	12	0.012 (0.010, 0.014)	9	14.544 (9.640, 21.943)
	2/1 Month	12	0.010 (0.008, 0.013)	11	0.007 (0.005, 0.009)	11	0.007 (0.005, 0.009)	9	13.708 (7.927, 23.706)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s004 gm 18 b1 eval p1

14.96. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	11	10.088 (5.162, 19.717)	12	12.998 (9.735, 17.356)	12	14.464 (11.921, 17.549)	9	9.072 (4.604, 17.879)
	1/Day 21	11	0.328 (0.102, 1.058)	12	0.080 (0.036, 0.178)	12	0.145 (0.048, 0.439)	9	8.812 (4.328, 17.938)
	2/Day 7	11	0.023 (0.012, 0.043)	12	0.017 (0.015, 0.019)	12	0.015 (0.011, 0.021)	9	7.650 (3.141, 18.629)
	2/Day 14	11	0.020 (0.012, 0.032)	12	0.016 (0.010, 0.028)	12	0.022 (0.016, 0.030)	9	10.738 (5.941, 19.409)
	2/1 Month	11	0.021 (0.015, 0.029)	12	0.024 (0.019, 0.031)	12	0.035 (0.020, 0.059)	9	8.282 (3.914, 17.523)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	11	10.088 (5.162, 19.717)	12	12.998 (9.735, 17.356)	12	14.464 (11.921, 17.549)	9	9.072 (4.604, 17.879)
	1/Day 21	11	0.293 (0.083, 1.031)	12	0.080 (0.036, 0.178)	12	0.116 (0.037, 0.362)	9	8.812 (4.328, 17.938)
	2/Day 7	11	0.014 (0.007, 0.030)	12	0.007 (0.005, 0.009)	12	0.007 (0.005, 0.011)	9	7.650 (3.141, 18.629)
	2/Day 14	11	0.011 (0.008, 0.017)	12	0.008 (0.006, 0.010)	11	0.009 (0.007, 0.014)	9	10.738 (5.941, 19.409)
	2/1 Month	11	0.013 (0.009, 0.020)	12	0.009 (0.007, 0.012)	12	0.014 (0.009, 0.024)	9	8.282 (3.914, 17.523)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	11	7.257 (2.262, 23.284)	12	17.384 (17.384, 17.384)	12	16.095 (13.584, 19.069)	9	8.129 (2.493, 26.507)
	1/Day 21	11	0.183 (0.055, 0.606)	12	0.043 (0.019, 0.097)	12	0.126 (0.037, 0.433)	9	8.499 (2.768, 26.099)
	2/Day 7	11	0.015 (0.008, 0.031)	12	0.014 (0.012, 0.016)	12	0.013 (0.010, 0.018)	9	7.071 (1.991, 25.104)
	2/Day 14	11	0.016 (0.010, 0.027)	12	0.015 (0.009, 0.025)	12	0.018 (0.014, 0.022)	9	7.321 (2.353, 22.780)
	2/1 Month	11	0.015 (0.010, 0.022)	12	0.022 (0.018, 0.027)	12	0.032 (0.019, 0.055)	9	8.133 (2.525, 26.196)

14.96. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	11	7.257 (2.262, 23.284)	12	17.384 (17.384, 17.384)	12	16.095 (13.584, 19.069)	9	8.129 (2.493, 26.507)
	1/Day 21	11	0.164 (0.046, 0.585)	12	0.043 (0.019, 0.097)	12	0.101 (0.031, 0.330)	9	8.499 (2.768, 26.099)
	2/Day 7	11	0.009 (0.004, 0.021)	12	0.006 (0.004, 0.007)	12	0.006 (0.004, 0.009)	9	7.071 (1.991, 25.104)
	2/Day 14	11	0.009 (0.006, 0.014)	12	0.007 (0.005, 0.009)	11	0.008 (0.005, 0.010)	9	7.321 (2.353, 22.780)
	2/1 Month	11	0.010 (0.007, 0.013)	12	0.009 (0.007, 0.011)	12	0.013 (0.008, 0.022)	9	8.133 (2.525, 26.196)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s004_gm_65_b1_eval_p1

14.97. Summary of Geometric Mean Ratios – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

Comparison	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized) 100 µg n[b]	100 µg GMR[c] (95% CI[c])	Placebo n[b]	Placebo GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.829 (8.121, 20.267)	3	15.792 (15.792, 15.792)
	1/1 Week	12	11.230 (5.303, 23.781)	3	15.792 (15.792, 15.792)
	1/3 Weeks	12	0.030 (0.019, 0.048)	3	15.792 (15.792, 15.792)
	1/5 Weeks	12	0.020 (0.013, 0.031)	3	15.792 (15.792, 15.792)
	1/7 Weeks	12	0.029 (0.019, 0.043)	3	15.792 (15.792, 15.792)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.829 (8.121, 20.267)	3	15.792 (15.792, 15.792)
	1/1 Week	12	11.230 (5.303, 23.781)	3	15.792 (15.792, 15.792)
	1/3 Weeks	12	0.014 (0.009, 0.021)	3	15.792 (15.792, 15.792)
	1/5 Weeks	12	0.018 (0.012, 0.025)	3	15.792 (15.792, 15.792)
	1/7 Weeks	12	0.024 (0.017, 0.035)	3	15.792 (15.792, 15.792)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	11.058 (6.387, 19.146)	3	17.384 (17.384, 17.384)
	1/1 Week	12	8.331 (3.869, 17.941)	3	12.577 (3.124, 50.627)
	1/3 Weeks	12	0.018 (0.011, 0.029)	3	11.552 (1.991, 67.028)
	1/5 Weeks	12	0.014 (0.009, 0.022)	3	17.384 (17.384, 17.384)
	1/7 Weeks	12	0.022 (0.015, 0.031)	3	17.384 (17.384, 17.384)
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	11.058 (6.387, 19.146)	3	17.384 (17.384, 17.384)
	1/1 Week	12	8.331 (3.869, 17.941)	3	12.577 (3.124, 50.627)
	1/3 Weeks	12	0.008 (0.005, 0.013)	3	11.552 (1.991, 67.028)
	1/5 Weeks	12	0.013 (0.009, 0.018)	3	17.384 (17.384, 17.384)
	1/7 Weeks	12	0.018 (0.013, 0.026)	3	17.384 (17.384, 17.384)

14.97. Summary of Geometric Mean Ratios – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Comparison	**Dose/Sampling Time Point[a]**	**n[b]**	**GMR[c] (95% CI[c])**	**n[b]**	**GMR[c] (95% CI[c])**

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 100/adva s004 gm 18 b1 eval 100 p1

14.98. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	13.174 (8.840, 19.632)	12	13.294 (10.244, 17.251)	12	12.050 (8.747, 16.599)	9	10.315 (4.942, 21.533)
	1/Day 7	12	13.324 (9.166, 19.367)	0	NE (NE, NE)	12	11.431 (7.022, 18.608)	6	9.921 (4.570, 21.540)
	1/Day 21	12	0.043 (0.020, 0.092)	12	0.061 (0.018, 0.207)	12	0.034 (0.025, 0.046)	9	11.879 (6.162, 22.903)
	2/Day 7	12	0.043 (0.028, 0.067)	12	0.049 (0.018, 0.136)	12	0.011 (0.008, 0.016)	9	8.202 (3.671, 18.324)
	2/Day 14	12	0.035 (0.027, 0.046)	12	0.027 (0.020, 0.037)	12	0.031 (0.026, 0.037)	9	10.676 (5.218, 21.843)
	2/1 Month	12	0.027 (0.020, 0.036)	12	0.030 (0.023, 0.040)	12	0.022 (0.017, 0.030)	9	11.091 (5.854, 21.013)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	13.174 (8.840, 19.632)	12	13.294 (10.244, 17.251)	12	12.050 (8.747, 16.599)	9	10.315 (4.942, 21.533)
	1/Day 7	12	13.324 (9.166, 19.367)	0	NE (NE, NE)	12	11.431 (7.022, 18.608)	6	9.921 (4.570, 21.540)
	1/Day 21	12	0.034 (0.015, 0.079)	12	0.049 (0.014, 0.174)	12	0.014 (0.008, 0.024)	9	11.879 (6.162, 22.903)
	2/Day 7	12	0.015 (0.011, 0.020)	11	0.023 (0.006, 0.084)	12	0.005 (0.004, 0.007)	9	8.202 (3.671, 18.324)
	2/Day 14	12	0.015 (0.011, 0.021)	12	0.015 (0.011, 0.020)	12	0.014 (0.011, 0.016)	9	10.676 (5.218, 21.843)
	2/1 Month	12	0.015 (0.012, 0.017)	11	0.008 (0.006, 0.011)	11	0.008 (0.006, 0.011)	9	11.091 (5.854, 21.013)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	11.990 (7.563, 19.009)	12	8.079 (3.894, 16.761)	12	11.480 (6.138, 21.470)	9	13.029 (6.701, 25.334)
	1/Day 7	12	11.302 (6.358, 20.091)	0	NE (NE, NE)	12	11.893 (6.631, 21.330)	6	10.834 (4.655, 25.211)
	1/Day 21	12	0.024 (0.012, 0.048)	12	0.035 (0.009, 0.133)	12	0.019 (0.013, 0.027)	9	11.769 (6.357, 21.787)
	2/Day 7	12	0.035 (0.021, 0.058)	12	0.040 (0.014, 0.110)	12	0.010 (0.007, 0.013)	9	11.381 (6.801, 19.044)

14.98. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	2/Day 14	12	0.031 (0.023, 0.041)	12	0.032 (0.023, 0.044)	12	0.027 (0.022, 0.033)	9	14.544 (9.640, 21.943)
	2/1 Month	12	0.019 (0.013, 0.027)	12	0.026 (0.021, 0.031)	12	0.019 (0.015, 0.025)	9	13.708 (7.927, 23.706)
	1/Prevax	12	11.990 (7.563, 19.009)	12	8.079 (3.894, 16.761)	12	11.480 (6.138, 21.470)	9	13.029 (6.701, 25.334)
	1/Day 7	12	11.302 (6.358, 20.091)	0	NE (NE, NE)	12	11.893 (6.631, 21.330)	6	10.834 (4.655, 25.211)
	1/Day 21	12	0.019 (0.009, 0.041)	12	0.028 (0.007, 0.112)	12	0.008 (0.005, 0.013)	9	11.769 (6.357, 21.787)
	2/Day 7	12	0.012 (0.008, 0.017)	11	0.019 (0.005, 0.070)	12	0.004 (0.003, 0.006)	9	11.381 (6.801, 19.044)
	2/Day 14	12	0.013 (0.009, 0.019)	12	0.017 (0.012, 0.024)	12	0.012 (0.010, 0.014)	9	14.544 (9.640, 21.943)
	2/1 Month	12	0.010 (0.008, 0.013)	11	0.007 (0.005, 0.009)	11	0.007 (0.005, 0.009)	9	13.708 (7.927, 23.706)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s004 gm 18 b1 aai p1

14.99. Summary of Geometric Mean Ratios – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.829 (8.121, 20.267)	3	15.792 (15.792, 15.792)
	1/1 Week	12	11.230 (5.303, 23.781)	3	15.792 (15.792, 15.792)
	1/3 Weeks	12	0.030 (0.019, 0.048)	3	15.792 (15.792, 15.792)
	1/5 Weeks	12	0.020 (0.013, 0.031)	3	15.792 (15.792, 15.792)
	1/7 Weeks	12	0.029 (0.019, 0.043)	3	15.792 (15.792, 15.792)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.829 (8.121, 20.267)	3	15.792 (15.792, 15.792)
	1/1 Week	12	11.230 (5.303, 23.781)	3	15.792 (15.792, 15.792)
	1/3 Weeks	12	0.014 (0.009, 0.021)	3	15.792 (15.792, 15.792)
	1/5 Weeks	12	0.018 (0.012, 0.025)	3	15.792 (15.792, 15.792)
	1/7 Weeks	12	0.024 (0.017, 0.035)	3	15.792 (15.792, 15.792)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	11.058 (6.387, 19.146)	3	17.384 (17.384, 17.384)
	1/1 Week	12	8.331 (3.869, 17.941)	3	12.577 (3.124, 50.627)
	1/3 Weeks	12	0.018 (0.011, 0.029)	3	11.552 (1.991, 67.028)
	1/5 Weeks	12	0.014 (0.009, 0.022)	3	17.384 (17.384, 17.384)
	1/7 Weeks	12	0.022 (0.015, 0.031)	3	17.384 (17.384, 17.384)
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	11.058 (6.387, 19.146)	3	17.384 (17.384, 17.384)
	1/1 Week	12	8.331 (3.869, 17.941)	3	12.577 (3.124, 50.627)
	1/3 Weeks	12	0.008 (0.005, 0.013)	3	11.552 (1.991, 67.028)
	1/5 Weeks	12	0.013 (0.009, 0.018)	3	17.384 (17.384, 17.384)
	1/7 Weeks	12	0.018 (0.013, 0.026)	3	17.384 (17.384, 17.384)

14.99. Summary of Geometric Mean Ratios – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)			
		100 µg		Placebo	
Comparison	**Dose/Sampling Time Point[a]**	**n[b]**	**GMR[c] (95% CI[c])**	**n[b]**	**GMR[c] (95% CI[c])**

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 21SEP2020 (21:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 100/adva s004 gm 18 b1 aai 100 p1

14.100. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	10.472 (5.691, 19.270)	12	12.998 (9.735, 17.356)	12	14.464 (11.921, 17.549)	9	9.072 (4.604, 17.879)
	1/Day 21	12	0.310 (0.107, 0.898)	12	0.080 (0.036, 0.178)	12	0.145 (0.048, 0.439)	9	8.812 (4.328, 17.938)
	2/Day 7	12	0.020 (0.011, 0.038)	12	0.017 (0.015, 0.019)	12	0.015 (0.011, 0.021)	9	7.650 (3.141, 18.629)
	2/Day 14	12	0.021 (0.013, 0.034)	12	0.016 (0.010, 0.028)	12	0.022 (0.016, 0.030)	9	10.738 (5.941, 19.409)
	2/1 Month	12	0.021 (0.016, 0.028)	12	0.024 (0.019, 0.031)	12	0.035 (0.020, 0.059)	9	8.282 (3.914, 17.523)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	10.472 (5.691, 19.270)	12	12.998 (9.735, 17.356)	12	14.464 (11.921, 17.549)	9	9.072 (4.604, 17.879)
	1/Day 21	12	0.279 (0.089, 0.873)	12	0.080 (0.036, 0.178)	12	0.116 (0.037, 0.362)	9	8.812 (4.328, 17.938)
	2/Day 7	12	0.012 (0.006, 0.026)	12	0.007 (0.005, 0.009)	12	0.007 (0.005, 0.011)	9	7.650 (3.141, 18.629)
	2/Day 14	12	0.010 (0.007, 0.016)	12	0.008 (0.006, 0.010)	11	0.009 (0.007, 0.014)	9	10.738 (5.941, 19.409)
	2/1 Month	12	0.012 (0.008, 0.018)	12	0.009 (0.007, 0.012)	12	0.014 (0.009, 0.024)	9	8.282 (3.914, 17.523)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	7.805 (2.695, 22.605)	12	17.384 (17.384, 17.384)	12	16.095 (13.584, 19.069)	9	8.129 (2.493, 26.507)
	1/Day 21	12	0.171 (0.058, 0.510)	12	0.043 (0.019, 0.097)	12	0.126 (0.037, 0.433)	9	8.499 (2.768, 26.099)
	2/Day 7	12	0.014 (0.007, 0.027)	12	0.014 (0.012, 0.016)	12	0.013 (0.010, 0.018)	9	7.071 (1.991, 25.104)
	2/Day 14	12	0.018 (0.011, 0.029)	12	0.015 (0.009, 0.025)	12	0.018 (0.014, 0.022)	9	7.321 (2.353, 22.780)
	2/1 Month	12	0.015 (0.011, 0.021)	12	0.022 (0.018, 0.027)	12	0.032 (0.019, 0.055)	9	8.133 (2.525, 26.196)

14.100. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	7.805 (2.695, 22.605)	12	17.384 (17.384, 17.384)	12	16.095 (13.584, 19.069)	9	8.129 (2.493, 26.507)
	1/Day 21	12	0.155 (0.049, 0.491)	12	0.043 (0.019, 0.097)	12	0.101 (0.031, 0.330)	9	8.499 (2.768, 26.099)
	2/Day 7	12	0.008 (0.004, 0.018)	12	0.006 (0.004, 0.007)	12	0.006 (0.004, 0.009)	9	7.071 (1.991, 25.104)
	2/Day 14	12	0.008 (0.006, 0.013)	12	0.007 (0.005, 0.009)	11	0.008 (0.005, 0.010)	9	7.321 (2.353, 22.780)
	2/1 Month	12	0.009 (0.006, 0.012)	12	0.009 (0.007, 0.011)	12	0.013 (0.008, 0.022)	9	8.133 (2.525, 26.196)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s004_gm_65_b1_aai_p1

14.101. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	11	15.792 (15.792, 15.792)	12	11.647 (7.071, 19.184)	12	15.792 (15.792, 15.792)	7	15.792 (15.792, 15.792)
	1/Day 21	11	0.027 (0.018, 0.041)	12	0.035 (0.023, 0.052)	12	0.011 (0.009, 0.015)	7	15.792 (15.792, 15.792)
	2/Day 7	11	0.028 (0.021, 0.037)	12	0.029 (0.022, 0.038)	11	0.040 (0.033, 0.047)	7	15.792 (15.792, 15.792)
	2/Day 14	11	0.023 (0.010, 0.052)	12	0.040 (0.031, 0.051)	9	0.021 (0.016, 0.029)	7	15.792 (15.792, 15.792)
	2/1 Month	11	0.034 (0.020, 0.059)	11	0.044 (0.027, 0.070)	11	0.027 (0.021, 0.035)	7	13.023 (8.126, 20.871)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	11	15.792 (15.792, 15.792)	12	11.647 (7.071, 19.184)	12	15.792 (15.792, 15.792)	7	15.792 (15.792, 15.792)
	1/Day 21	11	0.018 (0.010, 0.031)	12	0.020 (0.012, 0.031)	12	0.009 (0.006, 0.012)	7	15.792 (15.792, 15.792)
	2/Day 7	11	0.012 (0.009, 0.016)	12	0.011 (0.009, 0.015)	11	0.013 (0.010, 0.018)	7	15.792 (15.792, 15.792)
	2/Day 14	11	0.010 (0.005, 0.020)	12	0.015 (0.013, 0.019)	9	0.007 (0.005, 0.010)	7	15.792 (15.792, 15.792)
	2/1 Month	11	0.011 (0.007, 0.017)	11	0.010 (0.006, 0.018)	11	0.010 (0.008, 0.013)	7	13.023 (8.126, 20.871)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	11	15.252 (11.395, 20.414)	12	16.048 (13.457, 19.136)	12	9.522 (5.719, 15.855)	7	12.629 (7.606, 20.968)
	1/Day 21	11	0.049 (0.031, 0.076)	12	0.054 (0.037, 0.080)	12	0.017 (0.012, 0.023)	7	10.892 (6.267, 18.931)
	2/Day 7	11	0.034 (0.024, 0.049)	12	0.030 (0.022, 0.040)	11	0.047 (0.037, 0.058)	7	11.739 (6.206, 22.205)
	2/Day 14	11	0.027 (0.011, 0.065)	12	0.046 (0.038, 0.056)	9	0.024 (0.016, 0.035)	7	10.694 (5.749, 19.892)
	2/1 Month	11	0.040 (0.022, 0.073)	11	0.060 (0.036, 0.100)	11	0.028 (0.022, 0.037)	7	9.863 (4.436, 21.927)

14.101. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	11	15.252 (11.395, 20.414)	12	16.048 (13.457, 19.136)	12	9.522 (5.719, 15.855)	7	12.629 (7.606, 20.968)
	1/Day 21	11	0.032 (0.017, 0.061)	12	0.031 (0.019, 0.049)	12	0.013 (0.009, 0.018)	7	10.892 (6.267, 18.931)
	2/Day 7	11	0.014 (0.009, 0.022)	12	0.012 (0.009, 0.015)	11	0.016 (0.011, 0.022)	7	11.739 (6.206, 22.205)
	2/Day 14	11	0.012 (0.006, 0.025)	12	0.018 (0.015, 0.021)	9	0.008 (0.005, 0.013)	7	10.694 (5.749, 19.892)
	2/1 Month	11	0.013 (0.008, 0.021)	11	0.014 (0.008, 0.024)	11	0.011 (0.008, 0.014)	7	9.863 (4.436, 21.927)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s004 gm 18 b2 eval p1

14.102. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.995 (9.708, 17.393)	12	12.139 (7.820, 18.842)	11	15.792 (15.792, 15.792)	9	12.590 (8.893, 17.824)
	1/Day 21	12	0.058 (0.031, 0.109)	12	0.124 (0.048, 0.316)	11	0.042 (0.020, 0.089)	9	12.260 (8.321, 18.065)
	2/Day 7	12	0.025 (0.018, 0.034)	11	0.029 (0.020, 0.043)	11	0.021 (0.016, 0.027)	9	10.787 (6.587, 17.663)
	2/Day 14	11	0.031 (0.020, 0.048)	11	0.029 (0.017, 0.050)	11	0.037 (0.025, 0.053)	9	12.691 (9.073, 17.753)
	2/1 Month	12	0.030 (0.022, 0.040)	11	0.033 (0.019, 0.059)	11	0.033 (0.024, 0.047)	8	11.863 (7.514, 18.727)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.995 (9.708, 17.393)	12	12.139 (7.820, 18.842)	11	15.792 (15.792, 15.792)	9	12.590 (8.893, 17.824)
	1/Day 21	12	0.058 (0.031, 0.109)	12	0.124 (0.048, 0.316)	11	0.035 (0.014, 0.086)	9	12.260 (8.321, 18.065)
	2/Day 7	12	0.012 (0.010, 0.016)	11	0.012 (0.007, 0.021)	11	0.007 (0.005, 0.010)	9	10.787 (6.587, 17.663)
	2/Day 14	11	0.016 (0.010, 0.026)	11	0.012 (0.007, 0.019)	10	0.009 (0.006, 0.015)	9	12.691 (9.073, 17.753)
	2/1 Month	12	0.009 (0.006, 0.012)	11	0.017 (0.008, 0.034)	11	0.011 (0.008, 0.015)	8	11.863 (7.514, 18.727)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	10.720 (6.631, 17.329)	12	12.339 (7.401, 20.570)	11	15.921 (13.089, 19.366)	9	11.834 (7.080, 19.780)
	1/Day 21	12	0.120 (0.038, 0.376)	12	0.196 (0.064, 0.598)	11	0.061 (0.024, 0.154)	9	9.829 (4.796, 20.146)
	2/Day 7	12	0.031 (0.024, 0.042)	11	0.031 (0.019, 0.050)	11	0.026 (0.021, 0.034)	9	8.761 (3.903, 19.664)
	2/Day 14	11	0.038 (0.023, 0.061)	11	0.043 (0.024, 0.076)	11	0.038 (0.027, 0.053)	9	9.665 (4.582, 20.389)
	2/1 Month	12	0.031 (0.023, 0.044)	11	0.039 (0.020, 0.075)	11	0.044 (0.032, 0.060)	8	10.902 (5.206, 22.830)

14.102. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	10.720 (6.631, 17.329)	12	12.339 (7.401, 20.570)	11	15.921 (13.089, 19.366)	9	11.834 (7.080, 19.780)
	1/Day 21	12	0.120 (0.038, 0.376)	12	0.196 (0.064, 0.598)	11	0.050 (0.017, 0.148)	9	9.829 (4.796, 20.146)
	2/Day 7	12	0.016 (0.013, 0.020)	11	0.013 (0.006, 0.026)	11	0.009 (0.007, 0.013)	9	8.761 (3.903, 19.664)
	2/Day 14	11	0.019 (0.011, 0.033)	11	0.017 (0.009, 0.030)	10	0.010 (0.006, 0.015)	9	9.665 (4.582, 20.389)
	2/1 Month	12	0.009 (0.006, 0.013)	11	0.019 (0.009, 0.043)	11	0.015 (0.011, 0.020)	8	10.902 (5.206, 22.830)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 evaluable population was used for time points from Day 1 to before Dose 2 and Dose 2 evaluable population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s004_gm_65_b2_eval_p1

14.103. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	14.840 (12.943, 17.015)	12	11.647 (7.071, 19.184)	12	15.792 (15.792, 15.792)	9	14.042 (10.711, 18.409)
	1/Day 21	12	0.026 (0.017, 0.038)	12	0.035 (0.023, 0.052)	12	0.011 (0.009, 0.015)	9	13.965 (10.519, 18.541)
	2/Day 7	12	0.027 (0.021, 0.035)	12	0.029 (0.022, 0.038)	12	0.033 (0.021, 0.051)	9	15.792 (15.792, 15.792)
	2/Day 14	12	0.021 (0.009, 0.045)	12	0.040 (0.031, 0.051)	10	0.020 (0.015, 0.027)	9	13.537 (9.490, 19.310)
	2/1 Month	12	0.032 (0.019, 0.054)	11	0.044 (0.027, 0.070)	12	0.026 (0.020, 0.033)	9	12.470 (8.556, 18.174)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	14.840 (12.943, 17.015)	12	11.647 (7.071, 19.184)	12	15.792 (15.792, 15.792)	9	14.042 (10.711, 18.409)
	1/Day 21	12	0.018 (0.011, 0.029)	12	0.020 (0.012, 0.031)	12	0.009 (0.006, 0.012)	9	13.965 (10.519, 18.541)
	2/Day 7	12	0.011 (0.009, 0.015)	12	0.011 (0.009, 0.015)	12	0.012 (0.009, 0.017)	9	15.792 (15.792, 15.792)
	2/Day 14	12	0.009 (0.004, 0.017)	12	0.015 (0.013, 0.019)	10	0.007 (0.005, 0.009)	9	13.537 (9.490, 19.310)
	2/1 Month	12	0.010 (0.007, 0.016)	11	0.010 (0.006, 0.018)	12	0.010 (0.008, 0.013)	9	12.470 (8.556, 18.174)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	15.419 (11.842, 20.077)	12	16.048 (13.457, 19.136)	12	9.522 (5.719, 15.855)	9	13.558 (9.266, 19.840)
	1/Day 21	12	0.048 (0.032, 0.072)	12	0.054 (0.037, 0.080)	12	0.017 (0.012, 0.023)	9	10.875 (7.020, 16.846)
	2/Day 7	12	0.033 (0.024, 0.046)	12	0.030 (0.022, 0.040)	12	0.039 (0.024, 0.061)	9	12.809 (7.944, 20.653)
	2/Day 14	12	0.025 (0.011, 0.056)	12	0.046 (0.038, 0.056)	10	0.023 (0.016, 0.032)	9	11.913 (7.400, 19.178)
	2/1 Month	12	0.039 (0.022, 0.067)	11	0.060 (0.036, 0.100)	12	0.027 (0.020, 0.035)	9	11.186 (6.100, 20.512)

14.103. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	15.419 (11.842, 20.077)	12	16.048 (13.457, 19.136)	12	9.522 (5.719, 15.855)	9	13.558 (9.266, 19.840)
	1/Day 21	12	0.033 (0.018, 0.058)	12	0.031 (0.019, 0.049)	12	0.013 (0.009, 0.018)	9	10.875 (7.020, 16.846)
	2/Day 7	12	0.014 (0.009, 0.020)	12	0.012 (0.009, 0.015)	12	0.014 (0.010, 0.021)	9	12.809 (7.944, 20.653)
	2/Day 14	12	0.011 (0.005, 0.022)	12	0.018 (0.015, 0.021)	10	0.008 (0.005, 0.012)	9	11.913 (7.400, 19.178)
	2/1 Month	12	0.012 (0.008, 0.019)	11	0.014 (0.008, 0.024)	12	0.011 (0.008, 0.013)	9	11.186 (6.100, 20.512)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File:
./nda3/C4591001 IA P1 Serology/adva s004 gm 18 b2 aai p1

14.104. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.995 (9.708, 17.393)	12	12.139 (7.820, 18.842)	12	15.792 (15.792, 15.792)	9	12.590 (8.893, 17.824)
	1/Day 21	12	0.058 (0.031, 0.109)	12	0.124 (0.048, 0.316)	12	0.036 (0.017, 0.077)	9	12.260 (8.321, 18.065)
	2/Day 7	12	0.025 (0.018, 0.034)	12	0.027 (0.019, 0.040)	12	0.019 (0.013, 0.026)	9	10.787 (6.587, 17.663)
	2/Day 14	11	0.031 (0.020, 0.048)	12	0.030 (0.018, 0.050)	12	0.034 (0.024, 0.050)	9	12.691 (9.073, 17.753)
	2/1 Month	12	0.030 (0.022, 0.040)	12	0.033 (0.020, 0.056)	12	0.030 (0.020, 0.044)	8	11.863 (7.514, 18.727)
SARS-CoV-2 neutralization assay - NT90 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	12.995 (9.708, 17.393)	12	12.139 (7.820, 18.842)	12	15.792 (15.792, 15.792)	9	12.590 (8.893, 17.824)
	1/Day 21	12	0.058 (0.031, 0.109)	12	0.124 (0.048, 0.316)	12	0.030 (0.013, 0.073)	9	12.260 (8.321, 18.065)
	2/Day 7	12	0.012 (0.010, 0.016)	12	0.012 (0.007, 0.020)	12	0.007 (0.005, 0.009)	9	10.787 (6.587, 17.663)
	2/Day 14	11	0.016 (0.010, 0.026)	12	0.012 (0.007, 0.018)	11	0.009 (0.006, 0.014)	9	12.691 (9.073, 17.753)
	2/1 Month	12	0.009 (0.006, 0.012)	12	0.016 (0.009, 0.031)	12	0.010 (0.007, 0.014)	8	11.863 (7.514, 18.727)
SARS-CoV-2 neutralization assay - NT50 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	10.720 (6.631, 17.329)	12	12.339 (7.401, 20.570)	12	16.038 (13.431, 19.150)	9	11.834 (7.080, 19.780)
	1/Day 21	12	0.120 (0.038, 0.376)	12	0.196 (0.064, 0.598)	12	0.050 (0.019, 0.128)	9	9.829 (4.796, 20.146)
	2/Day 7	12	0.031 (0.024, 0.042)	12	0.030 (0.019, 0.046)	12	0.024 (0.017, 0.033)	9	8.761 (3.903, 19.664)
	2/Day 14	11	0.038 (0.023, 0.061)	12	0.043 (0.025, 0.073)	12	0.036 (0.026, 0.050)	9	9.665 (4.582, 20.389)
	2/1 Month	12	0.031 (0.023, 0.044)	12	0.039 (0.022, 0.071)	12	0.040 (0.027, 0.057)	8	10.902 (5.206, 22.830)

14.104. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		10 µg		20 µg		30 µg		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer) to RBD-binding IgG level assay (U/mL)	1/Prevax	12	10.720 (6.631, 17.329)	12	12.339 (7.401, 20.570)	12	16.038 (13.431, 19.150)	9	11.834 (7.080, 19.780)
	1/Day 21	12	0.120 (0.038, 0.376)	12	0.196 (0.064, 0.598)	12	0.042 (0.015, 0.120)	9	9.829 (4.796, 20.146)
	2/Day 7	12	0.016 (0.013, 0.020)	12	0.012 (0.007, 0.024)	12	0.008 (0.006, 0.012)	9	8.761 (3.903, 19.664)
	2/Day 14	11	0.019 (0.011, 0.033)	12	0.017 (0.010, 0.028)	11	0.010 (0.006, 0.015)	9	9.665 (4.582, 20.389)
	2/1 Month	12	0.009 (0.006, 0.013)	12	0.019 (0.009, 0.040)	12	0.014 (0.010, 0.019)	8	10.902 (5.206, 22.830)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; S1 = spike protein S1 subunit;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dose 1 all-available population was used for time points from Day 1 to before Dose 2 and Dose 2 all-available population was used for time points after Dose 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:42)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_s004_gm_65_b2_aai_p1

Local Reactions

14.105. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	12	12 (100.0)	(73.5, 100.0)	9	0	(0.0, 33.6)
	Mild	12	7 (58.3)	(27.7, 84.8)	12	6 (50.0)	(21.1, 78.9)	12	5 (41.7)	(15.2, 72.3)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	12	12 (100.0)	(73.5, 100.0)	9	0	(0.0, 33.6)

14.105. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
2	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	10 (83.3)	(51.6, 97.9)	12	11 (91.7)	(61.5, 99.8)	12	12 (100.0)	(73.5, 100.0)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	9 (75.0)	(42.8, 94.5)	12	10 (83.3)	(51.6, 97.9)	12	8 (66.7)	(34.9, 90.1)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	10 (83.3)	(51.6, 97.9)	12	11 (91.7)	(61.5, 99.8)	12	12 (100.0)	(73.5, 100.0)	9	2 (22.2)	(2.8, 60.0)
Any dose	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)

14.105. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	0	(0.0, 26.5)	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	10 (83.3)	(51.6, 97.9)	12	11 (91.7)	(61.5, 99.8)	12	12 (100.0)	(73.5, 100.0)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	9 (75.0)	(42.8, 94.5)	12	7 (58.3)	(27.7, 84.8)	12	4 (33.3)	(9.9, 65.1)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	12	8 (66.7)	(34.9, 90.1)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	10 (83.3)	(51.6, 97.9)	12	11 (91.7)	(61.5, 99.8)	12	12 (100.0)	(73.5, 100.0)	9	2 (22.2)	(2.8, 60.0)

14.105. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (08:06)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s010_lr_18_b1_p1

14.106. Local Reactions, by Maximum Severity, Within 7 Days After Dose 1 – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

		Vaccine Group (as Administered)					
		100 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	12	4 (33.3)	(9.9, 65.1)	3	0	(0.0, 70.8)
	Mild	12	2 (16.7)	(2.1, 48.4)	3	0	(0.0, 70.8)
	Moderate	12	2 (16.7)	(2.1, 48.4)	3	0	(0.0, 70.8)
	Severe	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Swelling[d]						
	Any	12	5 (41.7)	(15.2, 72.3)	3	0	(0.0, 70.8)
	Mild	12	3 (25.0)	(5.5, 57.2)	3	0	(0.0, 70.8)
	Moderate	12	2 (16.7)	(2.1, 48.4)	3	0	(0.0, 70.8)
	Severe	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Pain at the injection site[e]						
	Any	12	12 (100.0)	(73.5, 100.0)	3	2 (66.7)	(9.4, 99.2)
	Mild	12	4 (33.3)	(9.9, 65.1)	3	2 (66.7)	(9.4, 99.2)
	Moderate	12	7 (58.3)	(27.7, 84.8)	3	0	(0.0, 70.8)
	Severe	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Any local reaction[f]	12	12 (100.0)	(73.5, 100.0)	3	2 (66.7)	(9.4, 99.2)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 21SEP2020 (22:25)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adce s010 lr 18 b1 100 p1

14.107. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	7 (58.3)	(27.7, 84.8)	12	11 (91.7)	(61.5, 99.8)	12	11 (91.7)	(61.5, 99.8)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	7 (58.3)	(27.7, 84.8)	12	10 (83.3)	(51.6, 97.9)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	7 (58.3)	(27.7, 84.8)	12	11 (91.7)	(61.5, 99.8)	12	11 (91.7)	(61.5, 99.8)	9	1 (11.1)	(0.3, 48.2)
2	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)

14.107. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	8 (66.7)	(34.9, 90.1)	12	9 (75.0)	(42.8, 94.5)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
	Mild	12	6 (50.0)	(21.1, 78.9)	12	8 (66.7)	(34.9, 90.1)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	Moderate	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	8 (66.7)	(34.9, 90.1)	12	9 (75.0)	(42.8, 94.5)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
Any dose	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	9 (75.0)	(42.8, 94.5)	12	12 (100.0)	(73.5, 100.0)	12	11 (91.7)	(61.5, 99.8)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	7 (58.3)	(27.7, 84.8)	12	10 (83.3)	(51.6, 97.9)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)

14.107. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	9 (75.0)	(42.8, 94.5)	12	12 (100.0)	(73.5, 100.0)	12	11 (91.7)	(61.5, 99.8)	9	1 (11.1)	(0.3, 48.2)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (08:14)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s010 lr 65 b1 p1

14.108. Onset Days for Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	2	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (0.00)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 2)	(NE, NE)
	Swelling				
	n[a]	0	3	2	0
	Mean (SD)	NE (NE)	1.7 (0.58)	2.0 (0.00)	NE (NE)
	Median	NE	2.0	2.0	NE
	Min, max	(NE, NE)	(1, 2)	(2, 2)	(NE, NE)
	Pain at the injection site				
	n[a]	7	9	12	0
	Mean (SD)	1.1 (0.38)	1.1 (0.33)	1.4 (0.51)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 2)	(1, 2)	(NE, NE)
	Any local reaction[b]				
	n[a]	7	9	12	0
	Mean (SD)	1.1 (0.38)	1.1 (0.33)	1.4 (0.51)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 2)	(1, 2)	(NE, NE)
2	Redness				
	n[a]	0	0	2	0
	Mean (SD)	NE (NE)	NE (NE)	2.5 (0.71)	NE (NE)
	Median	NE	NE	2.5	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 3)	(NE, NE)
	Swelling				
	n[a]	0	1	3	0
	Mean (SD)	NE (NE)	1.0 (NE)	2.7 (2.08)	NE (NE)
	Median	NE	1.0	2.0	NE
	Min, max	(NE, NE)	(1, 1)	(1, 5)	(NE, NE)
	Pain at the injection site				
	n[a]	10	11	12	2
	Mean (SD)	1.3 (0.48)	1.5 (0.93)	1.3 (0.45)	1.5 (0.71)
	Median	1.0	1.0	1.0	1.5
	Min, max	(1, 2)	(1, 4)	(1, 2)	(1, 2)

14.108. Onset Days for Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Any local reaction[b]				
	n[a]	10	11	12	2
	Mean (SD)	1.3 (0.48)	1.3 (0.47)	1.3 (0.45)	1.5 (0.71)
	Median	1.0	1.0	1.0	1.5
	Min, max	(1, 2)	(1, 2)	(1, 2)	(1, 2)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:52)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s050_lr_onset_18_b1_p1

14.109. Onset Days for Local Reactions – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 100 µg	Placebo
1	Redness		
	n[a]	4	0
	Mean (SD)	3.0 (0.82)	NE (NE)
	Median	3.0	NE
	Min, max	(2, 4)	(NE, NE)
	Swelling		
	n[a]	5	0
	Mean (SD)	2.0 (0.71)	NE (NE)
	Median	2.0	NE
	Min, max	(1, 3)	(NE, NE)
	Pain at the injection site		
	n[a]	12	2
	Mean (SD)	1.0 (0.00)	1.0 (0.00)
	Median	1.0	1.0
	Min, max	(1, 1)	(1, 1)
	Any local reaction[b]		
	n[a]	12	2
	Mean (SD)	1.0 (0.00)	1.0 (0.00)
	Median	1.0	1.0
	Min, max	(1, 1)	(1, 1)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 19SEP2020 (08:23)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
./nda3/C4591001 IA P1 100/adce s050 lr onset 18 b1 100 p1

14.110. Onset Days for Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	1	1	2	0
	Mean (SD)	1.0 (NE)	2.0 (NE)	1.0 (0.00)	NE (NE)
	Median	1.0	2.0	1.0	NE
	Min, max	(1, 1)	(2, 2)	(1, 1)	(NE, NE)
	Pain at the injection site				
	n[a]	7	11	11	1
	Mean (SD)	1.3 (0.49)	1.4 (0.50)	1.3 (0.47)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 2)	(1, 2)	(1, 2)	(1, 1)
	Any local reaction[b]				
	n[a]	7	11	11	1
	Mean (SD)	1.3 (0.49)	1.4 (0.50)	1.3 (0.47)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 2)	(1, 2)	(1, 2)	(1, 1)
2	Redness				
	n[a]	0	1	1	0
	Mean (SD)	NE (NE)	4.0 (NE)	5.0 (NE)	NE (NE)
	Median	NE	4.0	5.0	NE
	Min, max	(NE, NE)	(4, 4)	(5, 5)	(NE, NE)
	Swelling				
	n[a]	1	2	3	0
	Mean (SD)	1.0 (NE)	3.0 (1.41)	2.7 (2.08)	NE (NE)
	Median	1.0	3.0	2.0	NE
	Min, max	(1, 1)	(2, 4)	(1, 5)	(NE, NE)
	Pain at the injection site				
	n[a]	8	9	9	0
	Mean (SD)	1.5 (0.53)	1.3 (0.50)	1.2 (0.44)	NE (NE)
	Median	1.5	1.0	1.0	NE
	Min, max	(1, 2)	(1, 2)	(1, 2)	(NE, NE)
	Any local reaction[b]				
	n[a]	8	9	9	0
	Mean (SD)	1.5 (0.53)	1.3 (0.50)	1.2 (0.44)	NE (NE)

14.110. Onset Days for Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Median	1.5	1.0	1.0	NE
	Min, max	(1, 2)	(1, 2)	(1, 2)	(NE, NE)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:52)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s050 lr onset 65 b1 p1

14.111. Duration (Days) From First to Last Day of Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	2	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (1.41)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 3)	(NE, NE)
	Swelling				
	n[a]	0	3	2	0
	Mean (SD)	NE (NE)	1.0 (0.00)	2.0 (0.00)	NE (NE)
	Median	NE	1.0	2.0	NE
	Min, max	(NE, NE)	(1, 1)	(2, 2)	(NE, NE)
	Pain at the injection site				
	n[a]	7	9	12	0
	Mean (SD)	1.4 (0.53)	2.8 (1.09)	2.1 (1.16)	NE (NE)
	Median	1.0	3.0	2.0	NE
	Min, max	(1, 2)	(1, 4)	(1, 4)	(NE, NE)
2	Redness				
	n[a]	0	0	2	0
	Mean (SD)	NE (NE)	NE (NE)	3.5 (0.71)	NE (NE)
	Median	NE	NE	3.5	NE
	Min, max	(NE, NE)	(NE, NE)	(3, 4)	(NE, NE)
	Swelling				
	n[a]	0	1	3	0
	Mean (SD)	NE (NE)	1.0 (NE)	1.0 (0.00)	NE (NE)
	Median	NE	1.0	1.0	NE
	Min, max	(NE, NE)	(1, 1)	(1, 1)	(NE, NE)
	Pain at the injection site				
	n[a]	10	11	12	2
	Mean (SD)	2.0 (1.25)	2.8 (1.47)	3.8 (1.71)	6.5 (7.78)
	Median	1.5	3.0	4.0	6.5
	Min, max	(1, 4)	(1, 6)	(1, 6)	(1, 12)

14.111. Duration (Days) From First to Last Day of Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)			
Dose	**Local Reaction**	**10 µg**	**20 µg**	**30 µg**	**Placebo**

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (00:38)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s030_lr_dur_18_b1_p1

14.112. Duration (Days) From First to Last Day of Local Reactions – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 100 µg	Placebo
1	Redness		
	n[a]	4	0
	Mean (SD)	3.3 (0.96)	NE (NE)
	Median	3.5	NE
	Min, max	(2, 4)	(NE, NE)
	Swelling		
	n[a]	5	0
	Mean (SD)	2.2 (0.84)	NE (NE)
	Median	2.0	NE
	Min, max	(1, 3)	(NE, NE)
	Pain at the injection site		
	n[a]	12	2
	Mean (SD)	3.8 (1.14)	1.5 (0.71)
	Median	4.0	1.5
	Min, max	(2, 6)	(1, 2)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 21SEP2020 (22:39)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adce_s030_lr_dur_18_b1_100_p1

14.113. Duration (Days) From First to Last Day of Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	1	1	2	0
	Mean (SD)	1.0 (NE)	3.0 (NE)	3.5 (0.71)	NE (NE)
	Median	1.0	3.0	3.5	NE
	Min, max	(1, 1)	(3, 3)	(3, 4)	(NE, NE)
	Pain at the injection site				
	n[a]	7	11	11	1
	Mean (SD)	2.3 (1.50)	1.9 (0.94)	2.1 (0.83)	1.0 (NE)
	Median	2.0	2.0	2.0	1.0
	Min, max	(1, 5)	(1, 4)	(1, 3)	(1, 1)
2	Redness				
	n[a]	0	1	1	0
	Mean (SD)	NE (NE)	2.0 (NE)	4.0 (NE)	NE (NE)
	Median	NE	2.0	4.0	NE
	Min, max	(NE, NE)	(2, 2)	(4, 4)	(NE, NE)
	Swelling				
	n[a]	1	2	3	0
	Mean (SD)	1.0 (NE)	3.0 (1.41)	2.0 (0.00)	NE (NE)
	Median	1.0	3.0	2.0	NE
	Min, max	(1, 1)	(2, 4)	(2, 2)	(NE, NE)
	Pain at the injection site				
	n[a]	8	9	9	0
	Mean (SD)	2.1 (1.36)	3.2 (3.23)	2.6 (2.07)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(1, 5)	(1, 11)	(1, 6)	(NE, NE)

14.113. Duration (Days) From First to Last Day of Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)			
Dose	**Local Reaction**	**10 µg**	**20 µg**	**30 µg**	**Placebo**

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (00:38)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s030_lr_dur_65_b1_p1

14.114. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	8 (66.7)	(34.9, 90.1)	12	8 (66.7)	(34.9, 90.1)	12	11 (91.7)	(61.5, 99.8)	9	0	(0.0, 33.6)
	Mild	12	7 (58.3)	(27.7, 84.8)	12	6 (50.0)	(21.1, 78.9)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	8 (66.7)	(34.9, 90.1)	12	8 (66.7)	(34.9, 90.1)	12	11 (91.7)	(61.5, 99.8)	9	0	(0.0, 33.6)
2	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												

14.114. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	7 (58.3)	(27.7, 84.8)	12	10 (83.3)	(51.6, 97.9)	12	10 (83.3)	(51.6, 97.9)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	6 (50.0)	(21.1, 78.9)	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	7 (58.3)	(27.7, 84.8)	12	10 (83.3)	(51.6, 97.9)	12	10 (83.3)	(51.6, 97.9)	9	2 (22.2)	(2.8, 60.0)
Any dose	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												

14.114. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	12	9 (75.0)	(42.8, 94.5)	12	10 (83.3)	(51.6, 97.9)	12	12 (100.0)	(73.5, 100.0)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	8 (66.7)	(34.9, 90.1)	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	9 (75.0)	(42.8, 94.5)	12	10 (83.3)	(51.6, 97.9)	12	12 (100.0)	(73.5, 100.0)	9	2 (22.2)	(2.8, 60.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s010_lr_18_b2_p1

14.115. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	4 (33.3)	(9.9, 65.1)	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
2	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)

14.115. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Pain at the injection site[e]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	7 (58.3)	(27.7, 84.8)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	7 (58.3)	(27.7, 84.8)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	4 (33.3)	(9.9, 65.1)	12	7 (58.3)	(27.7, 84.8)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)
Any dose	Redness[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]												
	Any	12	6 (50.0)	(21.1, 78.9)	12	9 (75.0)	(42.8, 94.5)	12	11 (91.7)	(61.5, 99.8)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	5 (41.7)	(15.2, 72.3)	12	9 (75.0)	(42.8, 94.5)	12	9 (75.0)	(42.8, 94.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	6 (50.0)	(21.1, 78.9)	12	9 (75.0)	(42.8, 94.5)	12	11 (91.7)	(61.5, 99.8)	9	1 (11.1)	(0.3, 48.2)

14.115. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (07:54)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s010_lr_65_b2_p1

14.116. Onset Days for Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (NE)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 2)	(NE, NE)
	Swelling				
	n[a]	2	0	0	0
	Mean (SD)	1.5 (0.71)	NE (NE)	NE (NE)	NE (NE)
	Median	1.5	NE	NE	NE
	Min, max	(1, 2)	(NE, NE)	(NE, NE)	(NE, NE)
	Pain at the injection site				
	n[a]	8	8	11	0
	Mean (SD)	1.3 (0.46)	1.0 (0.00)	1.2 (0.40)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 1)	(1, 2)	(NE, NE)
	Any local reaction[b]				
	n[a]	8	8	11	0
	Mean (SD)	1.3 (0.46)	1.0 (0.00)	1.2 (0.40)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 1)	(1, 2)	(NE, NE)
2	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	0	0	0	0
	Pain at the injection site				
	n[a]	7	10	10	2
	Mean (SD)	1.1 (0.38)	1.0 (0.00)	1.4 (0.52)	1.5 (0.71)
	Median	1.0	1.0	1.0	1.5
	Min, max	(1, 2)	(1, 1)	(1, 2)	(1, 2)
	Any local reaction[b]				
	n[a]	7	10	10	2
	Mean (SD)	1.1 (0.38)	1.0 (0.00)	1.4 (0.52)	1.5 (0.71)
	Median	1.0	1.0	1.0	1.5
	Min, max	(1, 2)	(1, 1)	(1, 2)	(1, 2)

14.116. Onset Days for Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)			
Dose	**Local Reaction**	**10 µg**	**20 µg**	**30 µg**	**Placebo**

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:53)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s050 lr onset 18 b2 p1

14.117. Onset Days for Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	0	0	0	0
	Pain at the injection site				
	n[a]	4	7	9	0
	Mean (SD)	1.3 (0.50)	1.9 (0.38)	1.6 (0.53)	NE (NE)
	Median	1.0	2.0	2.0	NE
	Min, max	(1, 2)	(1, 2)	(1, 2)	(NE, NE)
	Any local reaction[b]				
	n[a]	4	7	9	0
	Mean (SD)	1.3 (0.50)	1.9 (0.38)	1.6 (0.53)	NE (NE)
	Median	1.0	2.0	2.0	NE
	Min, max	(1, 2)	(1, 2)	(1, 2)	(NE, NE)
2	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	0	0	0	0
	Pain at the injection site				
	n[a]	4	7	8	1
	Mean (SD)	1.3 (0.50)	1.6 (0.53)	1.5 (0.53)	1.0 (NE)
	Median	1.0	2.0	1.5	1.0
	Min, max	(1, 2)	(1, 2)	(1, 2)	(1, 1)
	Any local reaction[b]				
	n[a]	4	7	8	1
	Mean (SD)	1.3 (0.50)	1.6 (0.53)	1.5 (0.53)	1.0 (NE)
	Median	1.0	2.0	1.5	1.0
	Min, max	(1, 2)	(1, 2)	(1, 2)	(1, 1)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:53)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s050 lr onset 65 b2 p1

14.118. Duration (Days) From First to Last Day of Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (NE)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 2)	(NE, NE)
	Swelling				
	n[a]	2	0	0	0
	Mean (SD)	1.0 (0.00)	NE (NE)	NE (NE)	NE (NE)
	Median	1.0	NE	NE	NE
	Min, max	(1, 1)	(NE, NE)	(NE, NE)	(NE, NE)
	Pain at the injection site				
	n[a]	8	8	11	0
	Mean (SD)	2.0 (1.07)	1.9 (0.35)	2.1 (0.83)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(1, 4)	(1, 2)	(1, 4)	(NE, NE)
2	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	0	0	0	0
	Pain at the injection site				
	n[a]	7	10	10	2
	Mean (SD)	2.1 (1.46)	1.7 (0.48)	1.8 (0.92)	1.0 (0.00)
	Median	1.0	2.0	1.5	1.0
	Min, max	(1, 4)	(1, 2)	(1, 3)	(1, 1)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (00:38)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s030 lr dur 18 b2 p1

14.119. Duration (Days) From First to Last Day of Local Reactions – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Local Reaction	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	0	0	0	0
	Pain at the injection site				
	n[a]	4	7	9	0
	Mean (SD)	1.5 (0.58)	1.3 (0.49)	1.2 (0.44)	NE (NE)
	Median	1.5	1.0	1.0	NE
	Min, max	(1, 2)	(1, 2)	(1, 2)	(NE, NE)
2	Redness				
	n[a]	0	0	0	0
	Swelling				
	n[a]	0	0	0	0
	Pain at the injection site				
	n[a]	4	7	8	1
	Mean (SD)	2.3 (0.50)	2.0 (1.53)	1.5 (0.76)	1.0 (NE)
	Median	2.0	1.0	1.0	1.0
	Min, max	(2, 3)	(1, 5)	(1, 3)	(1, 1)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (00:38)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s030_lr_dur_65_b2_p1

Systemic Events

14.120. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever												
	≥38.0°C	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	8 (66.7)	(34.9, 90.1)	12	6 (50.0)	(21.1, 78.9)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	5 (41.7)	(15.2, 72.3)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	6 (50.0)	(21.1, 78.9)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	5 (41.7)	(15.2, 72.3)	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)

14.120. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	7 (58.3)	(27.7, 84.8)	12	10 (83.3)	(51.6, 97.9)	12	11 (91.7)	(61.5, 99.8)	9	4 (44.4)	(13.7, 78.8)

14.120. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
2	Fever												
	≥38.0°C	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	8 (66.7)	(34.9, 90.1)	12	10 (83.3)	(51.6, 97.9)	12	10 (83.3)	(51.6, 97.9)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	10 (83.3)	(51.6, 97.9)	12	8 (66.7)	(34.9, 90.1)	12	12 (100.0)	(73.5, 100.0)	9	0	(0.0, 33.6)
	Mild	12	7 (58.3)	(27.7, 84.8)	12	6 (50.0)	(21.1, 78.9)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	Moderate	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	12	8 (66.7)	(34.9, 90.1)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	9	0	(0.0, 33.6)
	Moderate	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)

14.120. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	9 (75.0)	(42.8, 94.5)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	7 (58.3)	(27.7, 84.8)	12	5 (41.7)	(15.2, 72.3)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	6 (50.0)	(21.1, 78.9)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	11 (91.7)	(61.5, 99.8)	12	11 (91.7)	(61.5, 99.8)	12	12 (100.0)	(73.5, 100.0)	9	2 (22.2)	(2.8, 60.0)

14.120. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	6 (50.0)	(21.1, 78.9)	12	9 (75.0)	(42.8, 94.5)	12	10 (83.3)	(51.6, 97.9)	9	0	(0.0, 33.6)
Any dose	Fever												
	≥38.0°C	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	9 (75.0)	(42.8, 94.5)	12	10 (83.3)	(51.6, 97.9)	12	10 (83.3)	(51.6, 97.9)	9	3 (33.3)	(7.5, 70.1)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	12	1 (8.3)	(0.2, 38.5)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	4 (33.3)	(9.9, 65.1)	12	5 (41.7)	(15.2, 72.3)	12	9 (75.0)	(42.8, 94.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	10 (83.3)	(51.6, 97.9)	12	9 (75.0)	(42.8, 94.5)	12	12 (100.0)	(73.5, 100.0)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	7 (58.3)	(27.7, 84.8)	12	6 (50.0)	(21.1, 78.9)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	8 (66.7)	(34.9, 90.1)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Moderate	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)

14.120. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	10 (83.3)	(51.6, 97.9)	12	8 (66.7)	(34.9, 90.1)	9	0	(0.0, 33.6)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	7 (58.3)	(27.7, 84.8)	12	5 (41.7)	(15.2, 72.3)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	6 (50.0)	(21.1, 78.9)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	11 (91.7)	(61.5, 99.8)	12	11 (91.7)	(61.5, 99.8)	12	12 (100.0)	(73.5, 100.0)	9	4 (44.4)	(13.7, 78.8)

14.120. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	12	10 (83.3)	(51.6, 97.9)	9	1 (11.1)	(0.3, 48.2)

Note: Events were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (08:17)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adce s020 se 18 b1 p1

14.121. Systemic Events, by Maximum Severity, Within 7 Days After Dose 1 – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

		Vaccine Group (as Administered)					
		100 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	≥38.0°C	12	6 (50.0)	(21.1, 78.9)	3	0	(0.0, 70.8)
	38.0°C to 38.4°C	12	4 (33.3)	(9.9, 65.1)	3	0	(0.0, 70.8)
	>38.4°C to 38.9°C	12	2 (16.7)	(2.1, 48.4)	3	0	(0.0, 70.8)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	>40.0°C	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Fatigue[d]						
	Any	12	10 (83.3)	(51.6, 97.9)	3	1 (33.3)	(0.8, 90.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	3	1 (33.3)	(0.8, 90.6)
	Moderate	12	6 (50.0)	(21.1, 78.9)	3	0	(0.0, 70.8)
	Severe	12	2 (16.7)	(2.1, 48.4)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Headache[d]						
	Any	12	9 (75.0)	(42.8, 94.5)	3	2 (66.7)	(9.4, 99.2)
	Mild	12	5 (41.7)	(15.2, 72.3)	3	2 (66.7)	(9.4, 99.2)
	Moderate	12	3 (25.0)	(5.5, 57.2)	3	0	(0.0, 70.8)
	Severe	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Chills[d]						
	Any	12	10 (83.3)	(51.6, 97.9)	3	0	(0.0, 70.8)
	Mild	12	5 (41.7)	(15.2, 72.3)	3	0	(0.0, 70.8)
	Moderate	12	4 (33.3)	(9.9, 65.1)	3	0	(0.0, 70.8)
	Severe	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Vomiting[e]						
	Any	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Mild	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Moderate	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Severe	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Diarrhea[f]						
	Any	12	4 (33.3)	(9.9, 65.1)	3	0	(0.0, 70.8)
	Mild	12	4 (33.3)	(9.9, 65.1)	3	0	(0.0, 70.8)

14.121. Systemic Events, by Maximum Severity, Within 7 Days After Dose 1 – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

		Vaccine Group (as Administered)					
		100 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Severe	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	New or worsened muscle pain[d]						
	Any	12	7 (58.3)	(27.7, 84.8)	3	0	(0.0, 70.8)
	Mild	12	5 (41.7)	(15.2, 72.3)	3	0	(0.0, 70.8)
	Moderate	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Severe	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	New or worsened joint pain[d]						
	Any	12	3 (25.0)	(5.5, 57.2)	3	0	(0.0, 70.8)
	Mild	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Moderate	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Severe	12	1 (8.3)	(0.2, 38.5)	3	0	(0.0, 70.8)
	Grade 4	12	0	(0.0, 26.5)	3	0	(0.0, 70.8)
	Any systemic event[g]	12	12 (100.0)	(73.5, 100.0)	3	2 (66.7)	(9.4, 99.2)
	Use of antipyretic or pain medication[h]	12	10 (83.3)	(51.6, 97.9)	3	1 (33.3)	(0.8, 90.6)

Note: Events were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 21SEP2020 (22:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adce s020 se 18 b1 100 p1

14.122. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	7 (58.3)	(27.7, 84.8)	12	6 (50.0)	(21.1, 78.9)	9	4 (44.4)	(13.7, 78.8)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	12	2 (16.7)	(2.1, 48.4)	9	3 (33.3)	(7.5, 70.1)
	Moderate	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	6 (50.0)	(21.1, 78.9)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)

14.122. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	6 (50.0)	(21.1, 78.9)	12	9 (75.0)	(42.8, 94.5)	12	11 (91.7)	(61.5, 99.8)	9	4 (44.4)	(13.7, 78.8)

14.122. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	9 (75.0)	(42.8, 94.5)	9	0	(0.0, 33.6)
2	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	6 (50.0)	(21.1, 78.9)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	7 (58.3)	(27.7, 84.8)	12	8 (66.7)	(34.9, 90.1)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	5 (41.7)	(15.2, 72.3)	12	4 (33.3)	(9.9, 65.1)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	9 (75.0)	(42.8, 94.5)	12	9 (75.0)	(42.8, 94.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	7 (58.3)	(27.7, 84.8)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)

14.122. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	8 (66.7)	(34.9, 90.1)	12	10 (83.3)	(51.6, 97.9)	12	9 (75.0)	(42.8, 94.5)	9	3 (33.3)	(7.5, 70.1)

14.122. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	5 (41.7)	(15.2, 72.3)	12	9 (75.0)	(42.8, 94.5)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)
Any dose	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	6 (50.0)	(21.1, 78.9)	12	6 (50.0)	(21.1, 78.9)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	8 (66.7)	(34.9, 90.1)	12	10 (83.3)	(51.6, 97.9)	9	5 (55.6)	(21.2, 86.3)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	9	3 (33.3)	(7.5, 70.1)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	5 (41.7)	(15.2, 72.3)	12	6 (50.0)	(21.1, 78.9)	9	2 (22.2)	(2.8, 60.0)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	9 (75.0)	(42.8, 94.5)	12	9 (75.0)	(42.8, 94.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	7 (58.3)	(27.7, 84.8)	12	5 (41.7)	(15.2, 72.3)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	1 (8.3)	(0.2, 38.5)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)

14.122. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	6 (50.0)	(21.1, 78.9)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	10 (83.3)	(51.6, 97.9)	12	10 (83.3)	(51.6, 97.9)	12	11 (91.7)	(61.5, 99.8)	9	6 (66.7)	(29.9, 92.5)

14.122. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	6 (50.0)	(21.1, 78.9)	12	9 (75.0)	(42.8, 94.5)	12	10 (83.3)	(51.6, 97.9)	9	1 (11.1)	(0.3, 48.2)

Note: Events were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (08:23)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adce s020 se 65 b1 p1

14.123. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Fever (≥38.0°C)				
	n[a]	1	0	1	0
	Mean (SD)	2.0 (NE)	NE (NE)	1.0 (NE)	NE (NE)
	Median	2.0	NE	1.0	NE
	Min, max	(2, 2)	(NE, NE)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	4	8	6	2
	Mean (SD)	1.5 (0.58)	1.8 (0.46)	1.7 (0.52)	2.5 (2.12)
	Median	1.5	2.0	2.0	2.5
	Min, max	(1, 2)	(1, 2)	(1, 2)	(1, 4)
	Headache				
	n[a]	5	6	6	1
	Mean (SD)	2.6 (1.52)	2.0 (0.00)	2.0 (0.00)	2.0 (NE)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 5)	(2, 2)	(2, 2)	(2, 2)
	Chills				
	n[a]	1	3	7	0
	Mean (SD)	2.0 (NE)	1.7 (0.58)	1.9 (0.38)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(2, 2)	(1, 2)	(1, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	2	0	1	0
	Mean (SD)	6.5 (0.71)	NE (NE)	2.0 (NE)	NE (NE)
	Median	6.5	NE	2.0	NE
	Min, max	(6, 7)	(NE, NE)	(2, 2)	(NE, NE)
	New or worsened muscle pain				
	n[a]	1	4	3	0
	Mean (SD)	2.0 (NE)	2.0 (0.82)	2.0 (0.00)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(2, 2)	(1, 3)	(2, 2)	(NE, NE)
	New or worsened joint pain				
	n[a]	2	1	0	1
	Mean (SD)	1.5 (0.71)	2.0 (NE)	NE (NE)	1.0 (NE)

14.123. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Median	1.5	2.0	NE	1.0
	Min, max	(1, 2)	(2, 2)	(NE, NE)	(1, 1)
	Any systemic event[b]				
	n[a]	7	10	11	4
	Mean (SD)	2.0 (1.41)	1.8 (0.63)	1.8 (0.40)	2.0 (1.41)
	Median	2.0	2.0	2.0	1.5
	Min, max	(1, 5)	(1, 3)	(1, 2)	(1, 4)
	Use of antipyretic or pain medication				
	n[a]	2	3	6	1
	Mean (SD)	2.0 (0.00)	1.7 (0.58)	2.2 (0.41)	1.0 (NE)
	Median	2.0	2.0	2.0	1.0
	Min, max	(2, 2)	(1, 2)	(2, 3)	(1, 1)
2	Fever (≥38.0°C)				
	n[a]	1	2	9	0
	Mean (SD)	2.0 (NE)	2.0 (0.00)	1.8 (0.67)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(2, 2)	(2, 2)	(1, 3)	(NE, NE)
	Fatigue				
	n[a]	8	10	10	2
	Mean (SD)	1.9 (0.35)	1.5 (0.53)	1.9 (0.88)	1.5 (0.71)
	Median	2.0	1.5	2.0	1.5
	Min, max	(1, 2)	(1, 2)	(1, 4)	(1, 2)
	Headache				
	n[a]	10	8	12	0
	Mean (SD)	2.0 (0.00)	2.6 (1.77)	1.8 (0.58)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(2, 2)	(2, 7)	(1, 3)	(NE, NE)
	Chills				
	n[a]	3	6	8	0
	Mean (SD)	2.0 (0.00)	2.7 (2.16)	1.5 (0.53)	NE (NE)
	Median	2.0	2.0	1.5	NE
	Min, max	(2, 2)	(1, 7)	(1, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	0	1	1	0
	Mean (SD)	NE (NE)	2.0 (NE)	4.0 (NE)	NE (NE)

14.123. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Median	NE	2.0	4.0	NE
	Min, max	(NE, NE)	(2, 2)	(4, 4)	(NE, NE)
	New or worsened muscle pain				
	n[a]	5	9	7	0
	Mean (SD)	2.0 (0.00)	2.6 (1.88)	1.9 (0.38)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(2, 2)	(1, 7)	(1, 2)	(NE, NE)
	New or worsened joint pain				
	n[a]	4	6	3	0
	Mean (SD)	2.0 (0.00)	2.7 (2.16)	2.0 (0.00)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(2, 2)	(1, 7)	(2, 2)	(NE, NE)
	Any systemic event[b]				
	n[a]	11	11	12	2
	Mean (SD)	1.9 (0.30)	1.5 (0.52)	1.5 (0.67)	1.5 (0.71)
	Median	2.0	2.0	1.0	1.5
	Min, max	(1, 2)	(1, 2)	(1, 3)	(1, 2)
	Use of antipyretic or pain medication				
	n[a]	6	9	10	0
	Mean (SD)	1.8 (0.41)	2.4 (1.74)	1.7 (0.67)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(1, 2)	(1, 7)	(1, 3)	(NE, NE)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:52)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s060_se_onset_18_b1_p1

14.124. Onset Days for Systemic Events – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 100 µg	Placebo
1	Fever (≥38.0°C)		
	n[a]	6	0
	Mean (SD)	1.5 (0.55)	NE (NE)
	Median	1.5	NE
	Min, max	(1, 2)	(NE, NE)
	Fatigue		
	n[a]	10	1
	Mean (SD)	1.8 (1.23)	1.0 (NE)
	Median	1.0	1.0
	Min, max	(1, 4)	(1, 1)
	Headache		
	n[a]	9	2
	Mean (SD)	1.4 (0.53)	1.0 (0.00)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 1)
	Chills		
	n[a]	10	0
	Mean (SD)	1.4 (0.52)	NE (NE)
	Median	1.0	NE
	Min, max	(1, 2)	(NE, NE)
	Vomiting		
	n[a]	0	0
	Diarrhea		
	n[a]	4	0
	Mean (SD)	3.0 (0.82)	NE (NE)
	Median	3.0	NE
	Min, max	(2, 4)	(NE, NE)
	New or worsened muscle pain		
	n[a]	7	0
	Mean (SD)	1.6 (0.53)	NE (NE)
	Median	2.0	NE
	Min, max	(1, 2)	(NE, NE)
	New or worsened joint pain		
	n[a]	3	0
	Mean (SD)	1.7 (0.58)	NE (NE)

14.124. Onset Days for Systemic Events – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 100 µg	Placebo
	Median	2.0	NE
	Min, max	(1, 2)	(NE, NE)
	Any systemic event[b]		
	n[a]	12	2
	Mean (SD)	1.3 (0.45)	1.0 (0.00)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 1)
	Use of antipyretic or pain medication		
	n[a]	10	1
	Mean (SD)	1.5 (0.53)	6.0 (NE)
	Median	1.5	6.0
	Min, max	(1, 2)	(6, 6)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 19SEP2020 (08:23)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adce_s060_se_onset_18_b1_100_p1

14.125. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Fever (≥38.0°C)				
	n[a]	1	0	1	0
	Mean (SD)	2.0 (NE)	NE (NE)	1.0 (NE)	NE (NE)
	Median	2.0	NE	1.0	NE
	Min, max	(2, 2)	(NE, NE)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	4	8	6	2
	Mean (SD)	4.0 (2.58)	1.5 (0.76)	2.5 (2.26)	5.5 (6.36)
	Median	4.0	1.0	2.0	5.5
	Min, max	(1, 7)	(1, 3)	(1, 7)	(1, 10)
	Headache				
	n[a]	5	6	6	1
	Mean (SD)	2.4 (1.95)	1.3 (0.52)	1.3 (0.52)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 2)	(1, 2)	(1, 1)
	Chills				
	n[a]	1	3	7	0
	Mean (SD)	1.0 (NE)	1.0 (0.00)	1.0 (0.00)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 1)	(1, 1)	(1, 1)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	2	0	1	0
	Mean (SD)	1.5 (0.71)	NE (NE)	1.0 (NE)	NE (NE)
	Median	1.5	NE	1.0	NE
	Min, max	(1, 2)	(NE, NE)	(1, 1)	(NE, NE)
	New or worsened muscle pain				
	n[a]	1	4	3	0
	Mean (SD)	1.0 (NE)	1.0 (0.00)	1.0 (0.00)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 1)	(1, 1)	(1, 1)	(NE, NE)
	New or worsened joint pain				

14.125. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	n[a]	2	1	0	1
	Mean (SD)	1.0 (0.00)	1.0 (NE)	NE (NE)	1.0 (NE)
	Median	1.0	1.0	NE	1.0
	Min, max	(1, 1)	(1, 1)	(NE, NE)	(1, 1)
	Use of antipyretic or pain medication				
	n[a]	2	3	6	1
	Mean (SD)	1.5 (0.71)	1.7 (0.58)	1.0 (0.00)	1.0 (NE)
	Median	1.5	2.0	1.0	1.0
	Min, max	(1, 2)	(1, 2)	(1, 1)	(1, 1)
2	Fever (≥38.0°C)				
	n[a]	1	2	9	0
	Mean (SD)	1.0 (NE)	1.0 (0.00)	1.3 (0.50)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 1)	(1, 1)	(1, 2)	(NE, NE)
	Fatigue				
	n[a]	8	10	10	2
	Mean (SD)	1.5 (0.53)	3.1 (3.03)	1.7 (0.82)	4.0 (1.41)
	Median	1.5	1.5	1.5	4.0
	Min, max	(1, 2)	(1, 9)	(1, 3)	(3, 5)
	Headache				
	n[a]	10	8	12	0
	Mean (SD)	1.7 (1.06)	2.1 (2.03)	1.8 (0.72)	NE (NE)
	Median	1.0	1.5	2.0	NE
	Min, max	(1, 4)	(1, 7)	(1, 3)	(NE, NE)
	Chills				
	n[a]	3	6	8	0
	Mean (SD)	1.0 (0.00)	1.5 (0.55)	1.4 (0.52)	NE (NE)
	Median	1.0	1.5	1.0	NE
	Min, max	(1, 1)	(1, 2)	(1, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	0	1	1	0
	Mean (SD)	NE (NE)	1.0 (NE)	1.0 (NE)	NE (NE)
	Median	NE	1.0	1.0	NE
	Min, max	(NE, NE)	(1, 1)	(1, 1)	(NE, NE)
	New or worsened muscle pain				

14.125. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	n[a]	5	9	7	0
	Mean (SD)	1.2 (0.45)	2.2 (1.39)	1.1 (0.38)	NE (NE)
	Median	1.0	2.0	1.0	NE
	Min, max	(1, 2)	(1, 5)	(1, 2)	(NE, NE)
	New or worsened joint pain				
	n[a]	4	6	3	0
	Mean (SD)	1.0 (0.00)	1.5 (0.55)	1.3 (0.58)	NE (NE)
	Median	1.0	1.5	1.0	NE
	Min, max	(1, 1)	(1, 2)	(1, 2)	(NE, NE)
	Use of antipyretic or pain medication				
	n[a]	6	9	10	0
	Mean (SD)	1.7 (1.21)	1.7 (1.00)	1.9 (0.88)	NE (NE)
	Median	1.0	1.0	2.0	NE
	Min, max	(1, 4)	(1, 4)	(1, 3)	(NE, NE)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive.
Note: Events were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (02:38)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s040_se_dur_18_b1_p1

14.126. Duration (Days) From First to Last Day of Systemic Events – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 100 µg	Placebo
1	Fever (≥38.0°C)		
	n[a]	6	0
	Mean (SD)	1.3 (0.52)	NE (NE)
	Median	1.0	NE
	Min, max	(1, 2)	(NE, NE)
	Fatigue		
	n[a]	10	1
	Mean (SD)	3.0 (3.92)	4.0 (NE)
	Median	2.0	4.0
	Min, max	(1, 14)	(4, 4)
	Headache		
	n[a]	9	2
	Mean (SD)	1.8 (1.39)	5.0 (1.41)
	Median	1.0	5.0
	Min, max	(1, 5)	(4, 6)
	Chills		
	n[a]	10	0
	Mean (SD)	1.6 (0.70)	NE (NE)
	Median	1.5	NE
	Min, max	(1, 3)	(NE, NE)
	Vomiting		
	n[a]	0	0
	Diarrhea		
	n[a]	4	0
	Mean (SD)	1.8 (1.50)	NE (NE)
	Median	1.0	NE
	Min, max	(1, 4)	(NE, NE)
	New or worsened muscle pain		
	n[a]	7	0
	Mean (SD)	1.3 (0.49)	NE (NE)
	Median	1.0	NE
	Min, max	(1, 2)	(NE, NE)
	New or worsened joint pain		
	n[a]	3	0
	Mean (SD)	1.3 (0.58)	NE (NE)

14.126. Duration (Days) From First to Last Day of Systemic Events – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 100 µg	Placebo
	Median	1.0	NE
	Min, max	(1, 2)	(NE, NE)
	Use of antipyretic or pain medication		
	n[a]	10	1
	Mean (SD)	2.2 (1.32)	1.0 (NE)
	Median	2.0	1.0
	Min, max	(1, 5)	(1, 1)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive.
Note: Events were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 21SEP2020 (22:34)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adce_s040_se_dur_18_b1_100_p1

14.127. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Fever (≥38.0°C)				
	n[a]	0	0	3	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (0.00)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 2)	(NE, NE)
	Fatigue				
	n[a]	2	7	6	4
	Mean (SD)	3.5 (0.71)	2.3 (0.76)	2.7 (2.16)	1.8 (0.50)
	Median	3.5	2.0	2.0	2.0
	Min, max	(3, 4)	(2, 4)	(1, 7)	(1, 2)
	Headache				
	n[a]	3	4	6	0
	Mean (SD)	3.7 (1.15)	2.0 (0.00)	1.8 (0.41)	NE (NE)
	Median	3.0	2.0	2.0	NE
	Min, max	(3, 5)	(2, 2)	(1, 2)	(NE, NE)
	Chills				
	n[a]	1	1	2	2
	Mean (SD)	2.0 (NE)	1.0 (NE)	2.0 (0.00)	2.5 (0.71)
	Median	2.0	1.0	2.0	2.5
	Min, max	(2, 2)	(1, 1)	(2, 2)	(2, 3)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	1	1	0	0
	Mean (SD)	4.0 (NE)	6.0 (NE)	NE (NE)	NE (NE)
	Median	4.0	6.0	NE	NE
	Min, max	(4, 4)	(6, 6)	(NE, NE)	(NE, NE)
	New or worsened muscle pain				
	n[a]	2	2	5	1
	Mean (SD)	2.5 (0.71)	2.0 (0.00)	2.0 (0.00)	3.0 (NE)
	Median	2.5	2.0	2.0	3.0
	Min, max	(2, 3)	(2, 2)	(2, 2)	(3, 3)
	New or worsened joint pain				
	n[a]	2	1	1	0
	Mean (SD)	5.0 (2.83)	7.0 (NE)	1.0 (NE)	NE (NE)

14.127. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Median	5.0	7.0	1.0	NE
	Min, max	(3, 7)	(7, 7)	(1, 1)	(NE, NE)
	Any systemic event[b]				
	n[a]	6	9	11	4
	Mean (SD)	3.2 (1.17)	2.1 (0.78)	1.7 (0.47)	1.8 (0.50)
	Median	3.0	2.0	2.0	2.0
	Min, max	(2, 5)	(1, 4)	(1, 2)	(1, 2)
	Use of antipyretic or pain medication				
	n[a]	3	4	9	0
	Mean (SD)	2.7 (0.58)	2.0 (0.00)	2.6 (1.51)	NE (NE)
	Median	3.0	2.0	2.0	NE
	Min, max	(2, 3)	(2, 2)	(1, 6)	(NE, NE)
2	Fever (≥38.0°C)				
	n[a]	0	6	4	0
	Mean (SD)	NE (NE)	2.0 (0.00)	2.0 (0.00)	NE (NE)
	Median	NE	2.0	2.0	NE
	Min, max	(NE, NE)	(2, 2)	(2, 2)	(NE, NE)
	Fatigue				
	n[a]	3	7	8	2
	Mean (SD)	2.0 (0.00)	1.9 (0.38)	1.8 (0.46)	3.0 (2.83)
	Median	2.0	2.0	2.0	3.0
	Min, max	(2, 2)	(1, 2)	(1, 2)	(1, 5)
	Headache				
	n[a]	5	9	9	1
	Mean (SD)	2.0 (1.22)	2.4 (1.74)	1.7 (0.50)	4.0 (NE)
	Median	2.0	2.0	2.0	4.0
	Min, max	(1, 4)	(1, 7)	(1, 2)	(4, 4)
	Chills				
	n[a]	3	7	4	0
	Mean (SD)	2.0 (0.00)	1.9 (0.38)	1.5 (0.58)	NE (NE)
	Median	2.0	2.0	1.5	NE
	Min, max	(2, 2)	(1, 2)	(1, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	1.0 (NE)	NE (NE)
	Median	NE	NE	1.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 1)	(NE, NE)

14.127. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Diarrhea				
	n[a]	0	1	2	0
	Mean (SD)	NE (NE)	2.0 (NE)	3.0 (2.83)	NE (NE)
	Median	NE	2.0	3.0	NE
	Min, max	(NE, NE)	(2, 2)	(1, 5)	(NE, NE)
	New or worsened muscle pain				
	n[a]	4	4	4	0
	Mean (SD)	1.8 (0.50)	2.0 (0.00)	1.8 (0.50)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(1, 2)	(2, 2)	(1, 2)	(NE, NE)
	New or worsened joint pain				
	n[a]	3	3	2	0
	Mean (SD)	2.0 (0.00)	2.3 (0.58)	2.0 (0.00)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(2, 2)	(2, 3)	(2, 2)	(NE, NE)
	Any systemic event[b]				
	n[a]	8	10	9	3
	Mean (SD)	2.0 (0.93)	2.3 (1.70)	1.3 (0.50)	3.3 (2.08)
	Median	2.0	2.0	1.0	4.0
	Min, max	(1, 4)	(1, 7)	(1, 2)	(1, 5)
	Use of antipyretic or pain medication				
	n[a]	5	9	8	1
	Mean (SD)	2.2 (0.45)	1.9 (0.33)	1.9 (0.35)	4.0 (NE)
	Median	2.0	2.0	2.0	4.0
	Min, max	(2, 3)	(1, 2)	(1, 2)	(4, 4)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:52)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s060_se_onset_65_b1_p1

14.128. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Fever (≥38.0°C)				
	n[a]	0	0	3	0
	Mean (SD)	NE (NE)	NE (NE)	1.0 (0.00)	NE (NE)
	Median	NE	NE	1.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	2	7	6	4
	Mean (SD)	1.0 (0.00)	2.0 (1.91)	2.5 (1.38)	1.5 (0.58)
	Median	1.0	1.0	2.5	1.5
	Min, max	(1, 1)	(1, 6)	(1, 4)	(1, 2)
	Headache				
	n[a]	3	4	6	0
	Mean (SD)	1.0 (0.00)	1.0 (0.00)	1.5 (0.55)	NE (NE)
	Median	1.0	1.0	1.5	NE
	Min, max	(1, 1)	(1, 1)	(1, 2)	(NE, NE)
	Chills				
	n[a]	1	1	2	2
	Mean (SD)	1.0 (NE)	3.0 (NE)	2.0 (1.41)	1.0 (0.00)
	Median	1.0	3.0	2.0	1.0
	Min, max	(1, 1)	(3, 3)	(1, 3)	(1, 1)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	1	1	0	0
	Mean (SD)	2.0 (NE)	1.0 (NE)	NE (NE)	NE (NE)
	Median	2.0	1.0	NE	NE
	Min, max	(2, 2)	(1, 1)	(NE, NE)	(NE, NE)
	New or worsened muscle pain				
	n[a]	2	2	5	1
	Mean (SD)	1.0 (0.00)	4.0 (2.83)	1.6 (0.89)	1.0 (NE)
	Median	1.0	4.0	1.0	1.0
	Min, max	(1, 1)	(2, 6)	(1, 3)	(1, 1)
	New or worsened joint pain				
	n[a]	2	1	1	0
	Mean (SD)	1.5 (0.71)	1.0 (NE)	6.0 (NE)	NE (NE)

14.128. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Median	1.5	1.0	6.0	NE
	Min, max	(1, 2)	(1, 1)	(6, 6)	(NE, NE)
	Use of antipyretic or pain medication				
	n[a]	3	4	9	0
	Mean (SD)	1.0 (0.00)	1.0 (0.00)	1.2 (0.44)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 1)	(1, 1)	(1, 2)	(NE, NE)
2	Fever (≥38.0°C)				
	n[a]	0	6	4	0
	Mean (SD)	NE (NE)	1.0 (0.00)	1.0 (0.00)	NE (NE)
	Median	NE	1.0	1.0	NE
	Min, max	(NE, NE)	(1, 1)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	3	7	8	2
	Mean (SD)	2.3 (2.31)	1.7 (1.50)	2.7 (2.36)	1.0 (0.00)
	Median	1.0	1.0	2.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 7)	(1, 1)
	Unknown[b]	0	0	1	0
	Headache				
	n[a]	5	9	9	1
	Mean (SD)	3.4 (1.67)	1.2 (0.67)	1.9 (1.62)	1.0 (NE)
	Median	3.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 3)	(1, 6)	(1, 1)
	Chills				
	n[a]	3	7	4	0
	Mean (SD)	1.0 (0.00)	1.1 (0.38)	1.5 (0.58)	NE (NE)
	Median	1.0	1.0	1.5	NE
	Min, max	(1, 1)	(1, 2)	(1, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	1.0 (NE)	NE (NE)
	Median	NE	NE	1.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 1)	(NE, NE)
	Diarrhea				
	n[a]	0	1	2	0
	Mean (SD)	NE (NE)	1.0 (NE)	1.0 (0.00)	NE (NE)
	Median	NE	1.0	1.0	NE

14.128. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Min, max	(NE, NE)	(1, 1)	(1, 1)	(NE, NE)
	New or worsened muscle pain				
	n[a]	4	4	4	0
	Mean (SD)	1.3 (0.50)	1.0 (0.00)	1.0 (0.00)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 1)	(1, 1)	(NE, NE)
	New or worsened joint pain				
	n[a]	3	3	2	0
	Mean (SD)	1.0 (0.00)	1.0 (0.00)	1.0 (0.00)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 1)	(1, 1)	(1, 1)	(NE, NE)
	Use of antipyretic or pain medication				
	n[a]	5	9	8	1
	Mean (SD)	1.6 (1.34)	1.7 (1.41)	1.8 (1.39)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 4)	(1, 5)	(1, 5)	(1, 1)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive.
Note: Events were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (02:48)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s040_se_dur_65_b1_p1

14.129. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	5 (41.7)	(15.2, 72.3)	12	5 (41.7)	(15.2, 72.3)	9	3 (33.3)	(7.5, 70.1)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	2 (16.7)	(2.1, 48.4)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	12	6 (50.0)	(21.1, 78.9)	9	3 (33.3)	(7.5, 70.1)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)

14.129. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	6 (50.0)	(21.1, 78.9)	12	8 (66.7)	(34.9, 90.1)	12	9 (75.0)	(42.8, 94.5)	9	5 (55.6)	(21.2, 86.3)
	Use of antipyretic or pain medication[h]	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)

14.129. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
2	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	7 (58.3)	(27.7, 84.8)	12	9 (75.0)	(42.8, 94.5)	9	5 (55.6)	(21.2, 86.3)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	4 (44.4)	(13.7, 78.8)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	5 (41.7)	(15.2, 72.3)	12	7 (58.3)	(27.7, 84.8)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)

14.129. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	5 (41.7)	(15.2, 72.3)	12	7 (58.3)	(27.7, 84.8)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	5 (41.7)	(15.2, 72.3)	12	9 (75.0)	(42.8, 94.5)	12	12 (100.0)	(73.5, 100.0)	9	5 (55.6)	(21.2, 86.3)
	Use of antipyretic or pain medication[h]	12	1 (8.3)	(0.2, 38.5)	12	5 (41.7)	(15.2, 72.3)	12	7 (58.3)	(27.7, 84.8)	9	1 (11.1)	(0.3, 48.2)

14.129. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Any dose	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	6 (50.0)	(21.1, 78.9)	12	7 (58.3)	(27.7, 84.8)	12	10 (83.3)	(51.6, 97.9)	9	6 (66.7)	(29.9, 92.5)
	Mild	12	5 (41.7)	(15.2, 72.3)	12	3 (25.0)	(5.5, 57.2)	12	6 (50.0)	(21.1, 78.9)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	4 (44.4)	(13.7, 78.8)
	Severe	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	6 (50.0)	(21.1, 78.9)	12	6 (50.0)	(21.1, 78.9)	12	10 (83.3)	(51.6, 97.9)	9	3 (33.3)	(7.5, 70.1)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	12	6 (50.0)	(21.1, 78.9)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	5 (41.7)	(15.2, 72.3)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												

14.129. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	5 (41.7)	(15.2, 72.3)	12	8 (66.7)	(34.9, 90.1)	9	0	(0.0, 33.6)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	8 (66.7)	(34.9, 90.1)	12	10 (83.3)	(51.6, 97.9)	12	12 (100.0)	(73.5, 100.0)	9	7 (77.8)	(40.0, 97.2)

14.129. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	3 (25.0)	(5.5, 57.2)	12	7 (58.3)	(27.7, 84.8)	12	8 (66.7)	(34.9, 90.1)	9	1 (11.1)	(0.3, 48.2)

Note: Events were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (08:20)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adce s020 se 18 b2 p1

14.130. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	4 (33.3)	(9.9, 65.1)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	2 (22.2)	(2.8, 60.0)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												

14.130. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	3 (33.3)	(7.5, 70.1)
	Use of antipyretic or pain medication[h]	12	0	(0.0, 26.5)	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
2	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	6 (50.0)	(21.1, 78.9)	12	5 (41.7)	(15.2, 72.3)	9	1 (11.1)	(0.3, 48.2)

14.130. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	4 (33.3)	(9.9, 65.1)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	3 (25.0)	(5.5, 57.2)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)

14.130. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	5 (41.7)	(15.2, 72.3)	12	7 (58.3)	(27.7, 84.8)	12	7 (58.3)	(27.7, 84.8)	9	2 (22.2)	(2.8, 60.0)
	Use of antipyretic or pain medication[h]	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	12	4 (33.3)	(9.9, 65.1)	9	1 (11.1)	(0.3, 48.2)
Any dose	Fever												
	≥38.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	38.0°C to 38.4°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	7 (58.3)	(27.7, 84.8)	12	5 (41.7)	(15.2, 72.3)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	2 (22.2)	(2.8, 60.0)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[d]												
	Any	12	5 (41.7)	(15.2, 72.3)	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)

14.130. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Chills[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[e]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[f]												
	Any	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[d]												
	Any	12	2 (16.7)	(2.1, 48.4)	12	2 (16.7)	(2.1, 48.4)	12	3 (25.0)	(5.5, 57.2)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	2 (16.7)	(2.1, 48.4)	12	1 (8.3)	(0.2, 38.5)	12	2 (16.7)	(2.1, 48.4)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[d]												
	Any	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	1 (8.3)	(0.2, 38.5)	12	1 (8.3)	(0.2, 38.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[g]	12	5 (41.7)	(15.2, 72.3)	12	7 (58.3)	(27.7, 84.8)	12	7 (58.3)	(27.7, 84.8)	9	3 (33.3)	(7.5, 70.1)

14.130. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)											
		10 µg			20 µg			30 µg			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[h]	12	4 (33.3)	(9.9, 65.1)	12	3 (25.0)	(5.5, 57.2)	12	5 (41.7)	(15.2, 72.3)	9	1 (11.1)	(0.3, 48.2)

Note: Events were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (08:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s020 se 65 b2 p1

14.131. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Fever (≥38.0°C)				
	n[a]	0	0	2	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (0.00)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 2)	(NE, NE)
	Fatigue				
	n[a]	3	5	5	3
	Mean (SD)	3.0 (1.73)	1.4 (0.55)	1.6 (0.55)	2.7 (2.89)
	Median	4.0	1.0	2.0	1.0
	Min, max	(1, 4)	(1, 2)	(1, 2)	(1, 6)
	Headache				
	n[a]	4	4	6	3
	Mean (SD)	3.0 (1.41)	3.5 (1.91)	2.5 (1.87)	5.0 (1.00)
	Median	3.5	3.0	2.0	5.0
	Min, max	(1, 4)	(2, 6)	(1, 6)	(4, 6)
	Chills				
	n[a]	0	0	4	0
	Mean (SD)	NE (NE)	NE (NE)	1.8 (0.50)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	7.0 (NE)	NE (NE)
	Median	NE	NE	7.0	NE
	Min, max	(NE, NE)	(NE, NE)	(7, 7)	(NE, NE)
	Diarrhea				
	n[a]	0	1	1	0
	Mean (SD)	NE (NE)	1.0 (NE)	2.0 (NE)	NE (NE)
	Median	NE	1.0	2.0	NE
	Min, max	(NE, NE)	(1, 1)	(2, 2)	(NE, NE)
	New or worsened muscle pain				
	n[a]	3	2	3	0
	Mean (SD)	5.7 (2.31)	2.0 (0.00)	2.0 (0.00)	NE (NE)
	Median	7.0	2.0	2.0	NE
	Min, max	(3, 7)	(2, 2)	(2, 2)	(NE, NE)

14.131. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	New or worsened joint pain				
	n[a]	1	0	2	0
	Mean (SD)	7.0 (NE)	NE (NE)	2.0 (0.00)	NE (NE)
	Median	7.0	NE	2.0	NE
	Min, max	(7, 7)	(NE, NE)	(2, 2)	(NE, NE)
	Any systemic event[b]				
	n[a]	6	8	9	5
	Mean (SD)	3.7 (1.97)	2.4 (1.77)	2.1 (1.54)	3.4 (2.30)
	Median	3.5	2.0	2.0	4.0
	Min, max	(1, 7)	(1, 6)	(1, 6)	(1, 6)
	Use of antipyretic or pain medication				
	n[a]	2	5	4	0
	Mean (SD)	4.5 (0.71)	3.0 (2.00)	3.5 (2.38)	NE (NE)
	Median	4.5	2.0	2.5	NE
	Min, max	(4, 5)	(1, 6)	(2, 7)	(NE, NE)
2	Fever (≥38.0°C)				
	n[a]	0	1	2	0
	Mean (SD)	NE (NE)	2.0 (NE)	2.0 (0.00)	NE (NE)
	Median	NE	2.0	2.0	NE
	Min, max	(NE, NE)	(2, 2)	(2, 2)	(NE, NE)
	Fatigue				
	n[a]	4	7	9	5
	Mean (SD)	2.5 (2.38)	1.1 (0.38)	2.0 (0.00)	2.4 (2.61)
	Median	1.5	1.0	2.0	1.0
	Min, max	(1, 6)	(1, 2)	(2, 2)	(1, 7)
	Headache				
	n[a]	3	4	8	1
	Mean (SD)	2.7 (1.15)	1.8 (0.50)	2.1 (0.35)	1.0 (NE)
	Median	2.0	2.0	2.0	1.0
	Min, max	(2, 4)	(1, 2)	(2, 3)	(1, 1)
	Chills				
	n[a]	1	5	7	1
	Mean (SD)	2.0 (NE)	1.6 (0.55)	2.0 (0.00)	1.0 (NE)
	Median	2.0	2.0	2.0	1.0
	Min, max	(2, 2)	(1, 2)	(2, 2)	(1, 1)
	Vomiting				
	n[a]	1	0	0	1

14.131. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	Mean (SD)	2.0 (NE)	NE (NE)	NE (NE)	1.0 (NE)
	Median	2.0	NE	NE	1.0
	Min, max	(2, 2)	(NE, NE)	(NE, NE)	(1, 1)
	Diarrhea				
	n[a]	0	0	0	0
	New or worsened muscle pain				
	n[a]	2	5	7	0
	Mean (SD)	1.5 (0.71)	1.6 (0.55)	2.0 (0.00)	NE (NE)
	Median	1.5	2.0	2.0	NE
	Min, max	(1, 2)	(1, 2)	(2, 2)	(NE, NE)
	New or worsened joint pain				
	n[a]	1	0	2	0
	Mean (SD)	2.0 (NE)	NE (NE)	2.0 (0.00)	NE (NE)
	Median	2.0	NE	2.0	NE
	Min, max	(2, 2)	(NE, NE)	(2, 2)	(NE, NE)
	Any systemic event[b]				
	n[a]	5	9	12	5
	Mean (SD)	2.0 (1.22)	1.2 (0.44)	2.1 (0.29)	2.4 (2.61)
	Median	2.0	1.0	2.0	1.0
	Min, max	(1, 4)	(1, 2)	(2, 3)	(1, 7)
	Use of antipyretic or pain medication				
	n[a]	1	5	7	1
	Mean (SD)	2.0 (NE)	1.6 (0.55)	2.1 (0.38)	2.0 (NE)
	Median	2.0	2.0	2.0	2.0
	Min, max	(2, 2)	(1, 2)	(2, 3)	(2, 2)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:53)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adce s060 se onset 18 b2 p1

14.132. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Fever (≥38.0°C)				
	n[a]	0	0	2	0
	Mean (SD)	NE (NE)	NE (NE)	1.0 (0.00)	NE (NE)
	Median	NE	NE	1.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	3	5	5	3
	Mean (SD)	1.0 (0.00)	1.6 (0.89)	1.4 (0.55)	2.7 (1.53)
	Median	1.0	1.0	1.0	3.0
	Min, max	(1, 1)	(1, 3)	(1, 2)	(1, 4)
	Headache				
	n[a]	4	4	6	3
	Mean (SD)	1.0 (0.00)	1.0 (0.00)	2.7 (2.25)	1.0 (0.00)
	Median	1.0	1.0	2.0	1.0
	Min, max	(1, 1)	(1, 1)	(1, 7)	(1, 1)
	Chills				
	n[a]	0	0	4	0
	Mean (SD)	NE (NE)	NE (NE)	1.0 (0.00)	NE (NE)
	Median	NE	NE	1.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 1)	(NE, NE)
	Vomiting				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (NE)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 2)	(NE, NE)
	Diarrhea				
	n[a]	0	1	1	0
	Mean (SD)	NE (NE)	1.0 (NE)	1.0 (NE)	NE (NE)
	Median	NE	1.0	1.0	NE
	Min, max	(NE, NE)	(1, 1)	(1, 1)	(NE, NE)
	New or worsened muscle pain				
	n[a]	3	2	3	0
	Mean (SD)	1.7 (0.58)	1.0 (0.00)	1.0 (0.00)	NE (NE)
	Median	2.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 1)	(1, 1)	(NE, NE)

14.132. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	New or worsened joint pain				
	n[a]	1	0	2	0
	Mean (SD)	2.0 (NE)	NE (NE)	1.0 (0.00)	NE (NE)
	Median	2.0	NE	1.0	NE
	Min, max	(2, 2)	(NE, NE)	(1, 1)	(NE, NE)
	Use of antipyretic or pain medication				
	n[a]	2	5	4	0
	Mean (SD)	1.5 (0.71)	1.0 (0.00)	1.5 (1.00)	NE (NE)
	Median	1.5	1.0	1.0	NE
	Min, max	(1, 2)	(1, 1)	(1, 3)	(NE, NE)
2	Fever (≥38.0°C)				
	n[a]	0	1	2	0
	Mean (SD)	NE (NE)	1.0 (NE)	1.0 (0.00)	NE (NE)
	Median	NE	1.0	1.0	NE
	Min, max	(NE, NE)	(1, 1)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	4	7	9	5
	Mean (SD)	3.5 (3.32)	2.1 (1.07)	1.1 (0.33)	1.8 (0.84)
	Median	2.5	2.0	1.0	2.0
	Min, max	(1, 8)	(1, 4)	(1, 2)	(1, 3)
	Headache				
	n[a]	3	4	8	1
	Mean (SD)	3.3 (4.04)	1.3 (0.50)	2.1 (1.46)	2.0 (NE)
	Median	1.0	1.0	1.5	2.0
	Min, max	(1, 8)	(1, 2)	(1, 5)	(2, 2)
	Chills				
	n[a]	1	5	7	1
	Mean (SD)	1.0 (NE)	1.0 (0.00)	1.0 (0.00)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 1)	(1, 1)	(1, 1)	(1, 1)
	Vomiting				
	n[a]	1	0	0	1
	Mean (SD)	1.0 (NE)	NE (NE)	NE (NE)	1.0 (NE)
	Median	1.0	NE	NE	1.0
	Min, max	(1, 1)	(NE, NE)	(NE, NE)	(1, 1)
	Diarrhea				
	n[a]	0	0	0	0

14.132. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	New or worsened muscle pain				
	n[a]	2	5	7	0
	Mean (SD)	1.0 (0.00)	1.2 (0.45)	1.0 (0.00)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 1)	(1, 2)	(1, 1)	(NE, NE)
	New or worsened joint pain				
	n[a]	1	0	2	0
	Mean (SD)	1.0 (NE)	NE (NE)	1.0 (0.00)	NE (NE)
	Median	1.0	NE	1.0	NE
	Min, max	(1, 1)	(NE, NE)	(1, 1)	(NE, NE)
	Use of antipyretic or pain medication				
	n[a]	1	5	7	1
	Mean (SD)	1.0 (NE)	1.4 (0.55)	1.0 (0.00)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 1)	(1, 2)	(1, 1)	(1, 1)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive.
Note: Events were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (02:38)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s040_se_dur_18_b2_p1

14.133. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
1	Fever (≥38.0°C)				
	n[a]	0	0	0	0
	Fatigue				

14.133. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	n[a]	1	4	3	2
	Mean (SD)	5.0 (NE)	1.8 (0.50)	3.7 (2.89)	1.0 (0.00)
	Median	5.0	2.0	2.0	1.0
	Min, max	(5, 5)	(1, 2)	(2, 7)	(1, 1)
	Headache				
	n[a]	1	3	0	1
	Mean (SD)	5.0 (NE)	1.7 (0.58)	NE (NE)	2.0 (NE)
	Median	5.0	2.0	NE	2.0
	Min, max	(5, 5)	(1, 2)	(NE, NE)	(2, 2)
	Chills				
	n[a]	0	2	0	0
	Mean (SD)	NE (NE)	2.0 (1.41)	NE (NE)	NE (NE)
	Median	NE	2.0	NE	NE
	Min, max	(NE, NE)	(1, 3)	(NE, NE)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	0	0	0	1
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	7.0 (NE)
	Median	NE	NE	NE	7.0
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(7, 7)
	New or worsened muscle pain				
	n[a]	1	1	0	2
	Mean (SD)	6.0 (NE)	3.0 (NE)	NE (NE)	3.5 (2.12)
	Median	6.0	3.0	NE	3.5
	Min, max	(6, 6)	(3, 3)	(NE, NE)	(2, 5)
	New or worsened joint pain				
	n[a]	0	0	0	1
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	6.0 (NE)
	Median	NE	NE	NE	6.0
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(6, 6)
	Any systemic event[b]				
	n[a]	2	4	3	3
	Mean (SD)	5.5 (0.71)	1.5 (0.58)	3.7 (2.89)	2.3 (2.31)
	Median	5.5	1.5	2.0	1.0
	Min, max	(5, 6)	(1, 2)	(2, 7)	(1, 5)
	Use of antipyretic or pain medication				

14.133. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	n[a]	0	2	2	1
	Mean (SD)	NE (NE)	2.0 (0.00)	4.0 (2.83)	7.0 (NE)
	Median	NE	2.0	4.0	7.0
	Min, max	(NE, NE)	(2, 2)	(2, 6)	(7, 7)
2	Fever (≥38.0°C)				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	2.0 (NE)	NE (NE)
	Median	NE	NE	2.0	NE
	Min, max	(NE, NE)	(NE, NE)	(2, 2)	(NE, NE)
	Fatigue				
	n[a]	2	6	5	1
	Mean (SD)	2.0 (0.00)	1.8 (0.41)	2.4 (0.55)	3.0 (NE)
	Median	2.0	2.0	2.0	3.0
	Min, max	(2, 2)	(1, 2)	(2, 3)	(3, 3)
	Headache				
	n[a]	4	4	3	1
	Mean (SD)	1.5 (0.58)	1.8 (0.50)	2.0 (0.00)	3.0 (NE)
	Median	1.5	2.0	2.0	3.0
	Min, max	(1, 2)	(1, 2)	(2, 2)	(3, 3)
	Chills				
	n[a]	2	1	2	0
	Mean (SD)	2.0 (0.00)	2.0 (NE)	1.5 (0.71)	NE (NE)
	Median	2.0	2.0	1.5	NE
	Min, max	(2, 2)	(2, 2)	(1, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	0	0	0	1
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	2.0 (NE)
	Median	NE	NE	NE	2.0
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(2, 2)
	New or worsened muscle pain				
	n[a]	1	1	3	1
	Mean (SD)	2.0 (NE)	2.0 (NE)	2.0 (0.00)	4.0 (NE)
	Median	2.0	2.0	2.0	4.0
	Min, max	(2, 2)	(2, 2)	(2, 2)	(4, 4)
	New or worsened joint pain				

14.133. Onset Days for Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	n[a]	1	1	1	1
	Mean (SD)	2.0 (NE)	2.0 (NE)	2.0 (NE)	4.0 (NE)
	Median	2.0	2.0	2.0	4.0
	Min, max	(2, 2)	(2, 2)	(2, 2)	(4, 4)
	Any systemic event[b]				
	n[a]	5	7	7	2
	Mean (SD)	1.6 (0.55)	1.7 (0.49)	2.0 (0.58)	2.5 (0.71)
	Median	2.0	2.0	2.0	2.5
	Min, max	(1, 2)	(1, 2)	(1, 3)	(2, 3)
	Use of antipyretic or pain medication				
	n[a]	4	3	4	1
	Mean (SD)	1.8 (0.50)	1.7 (0.58)	2.0 (0.00)	4.0 (NE)
	Median	2.0	2.0	2.0	4.0
	Min, max	(1, 2)	(1, 2)	(2, 2)	(4, 4)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:52)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s060_se_onset_65_b2_p1

14.134. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

		Vaccine Group (as Administered)			
Dose	**Systemic Event**	**10 µg**	**20 µg**	**30 µg**	**Placebo**
1	Fever (≥38.0°C)				
	n[a]	0	0	0	0
	Fatigue				
	n[a]	1	4	3	2
	Mean (SD)	1.0 (NE)	1.5 (1.00)	1.0 (0.00)	7.5 (2.12)
	Median	1.0	1.0	1.0	7.5
	Min, max	(1, 1)	(1, 3)	(1, 1)	(6, 9)
	Headache				
	n[a]	1	3	0	1
	Mean (SD)	1.0 (NE)	3.0 (3.46)	NE (NE)	10.0 (NE)
	Median	1.0	1.0	NE	10.0
	Min, max	(1, 1)	(1, 7)	(NE, NE)	(10, 10)
	Chills				
	n[a]	0	2	0	0
	Mean (SD)	NE (NE)	1.0 (0.00)	NE (NE)	NE (NE)
	Median	NE	1.0	NE	NE
	Min, max	(NE, NE)	(1, 1)	(NE, NE)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	0	0	0	1
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	2.0 (NE)
	Median	NE	NE	NE	2.0
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(2, 2)
	New or worsened muscle pain				
	n[a]	1	1	0	2
	Mean (SD)	1.0 (NE)	1.0 (NE)	NE (NE)	4.0 (4.24)
	Median	1.0	1.0	NE	4.0
	Min, max	(1, 1)	(1, 1)	(NE, NE)	(1, 7)
	New or worsened joint pain				
	n[a]	0	0	0	1
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	1.0 (NE)
	Median	NE	NE	NE	1.0
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(1, 1)
	Use of antipyretic or pain medication				

14.134. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	n[a]	0	2	2	1
	Mean (SD)	NE (NE)	3.5 (3.54)	1.0 (0.00)	1.0 (NE)
	Median	NE	3.5	1.0	1.0
	Min, max	(NE, NE)	(1, 6)	(1, 1)	(1, 1)
2	Fever (≥38.0°C)				
	n[a]	0	0	1	0
	Mean (SD)	NE (NE)	NE (NE)	1.0 (NE)	NE (NE)
	Median	NE	NE	1.0	NE
	Min, max	(NE, NE)	(NE, NE)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	2	6	5	1
	Mean (SD)	1.0 (0.00)	1.3 (0.52)	1.0 (0.00)	7.0 (NE)
	Median	1.0	1.0	1.0	7.0
	Min, max	(1, 1)	(1, 2)	(1, 1)	(7, 7)
	Headache				
	n[a]	4	4	3	1
	Mean (SD)	2.3 (2.50)	3.0 (2.45)	1.0 (0.00)	10.0 (NE)
	Median	1.0	2.5	1.0	10.0
	Min, max	(1, 6)	(1, 6)	(1, 1)	(10, 10)
	Chills				
	n[a]	2	1	2	0
	Mean (SD)	1.0 (0.00)	1.0 (NE)	2.0 (0.00)	NE (NE)
	Median	1.0	1.0	2.0	NE
	Min, max	(1, 1)	(1, 1)	(2, 2)	(NE, NE)
	Vomiting				
	n[a]	0	0	0	0
	Diarrhea				
	n[a]	0	0	0	1
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	1.0 (NE)
	Median	NE	NE	NE	1.0
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(1, 1)
	New or worsened muscle pain				
	n[a]	1	1	3	1
	Mean (SD)	1.0 (NE)	1.0 (NE)	1.0 (0.00)	3.0 (NE)
	Median	1.0	1.0	1.0	3.0
	Min, max	(1, 1)	(1, 1)	(1, 1)	(3, 3)
	New or worsened joint pain				

14.134. Duration (Days) From First to Last Day of Systemic Events – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) 10 µg	20 µg	30 µg	Placebo
	n[a]	1	1	1	1
	Mean (SD)	1.0 (NE)	1.0 (NE)	1.0 (NE)	6.0 (NE)
	Median	1.0	1.0	1.0	6.0
	Min, max	(1, 1)	(1, 1)	(1, 1)	(6, 6)
	Use of antipyretic or pain medication				
	n[a]	4	3	4	1
	Mean (SD)	1.0 (0.00)	2.0 (1.73)	1.0 (0.00)	3.0 (NE)
	Median	1.0	1.0	1.0	3.0
	Min, max	(1, 1)	(1, 4)	(1, 1)	(3, 3)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive.
Note: Events were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each vaccination. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adcevd Table Generation: 29AUG2020 (02:37)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_s040_se_dur_65_b2_p1

Adverse Events

14.135. Number (%) of Subjects Reporting at Least 1 Adverse Event After Dose 1 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)			
	10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)
Adverse Event	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Any event	6 (50.0)	5 (41.7)	6 (50.0)	2 (22.2)
Related[c]	3 (25.0)	4 (33.3)	6 (50.0)	1 (11.1)
Severe	0	0	1 (8.3)	0
Life-threatening	0	0	0	0
Any serious adverse event	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Death	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (08:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adae s130 18 b1 p1

14.136. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Before Dose 2 – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

	Vaccine Group (as Administered)	
	100 µg (N^a=12)	Placebo (N^a=3)
Adverse Event	**n^b (%)**	**n^b (%)**
Any event	8 (66.7)	1 (33.3)
Related[c]	6 (50.0)	1 (33.3)
Severe	1 (8.3)	0
Life-threatening	0	0
Any serious adverse event	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any adverse event leading to withdrawal	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 adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 19SEP2020 (00:11)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adae_s130_18_b1_100_p1

14.137. Number (%) of Subjects Reporting at Least 1 Adverse Event After Dose 1 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)			
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)
Adverse Event	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**
Any event	7 (58.3)	7 (58.3)	3 (25.0)	4 (44.4)
Related[c]	3 (25.0)	4 (33.3)	2 (16.7)	1 (11.1)
Severe	0	1 (8.3)	1 (8.3)	0
Life-threatening	0	0	0	0
Any serious adverse event	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Death	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (08:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_s130_65_b1_p1

14.138. Number (%) of Subjects Reporting at Least 1 Adverse Event After Dose 1 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)			
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)
Adverse Event	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**
Any event	4 (33.3)	5 (41.7)	5 (41.7)	2 (22.2)
Related[c]	2 (16.7)	4 (33.3)	3 (25.0)	1 (11.1)
Severe	0	0	1 (8.3)	0
Life-threatening	0	0	0	0
Any serious adverse event	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Death	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (08:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_s130_18_b2_p1

14.139. Number (%) of Subjects Reporting at Least 1 Adverse Event After Dose 1 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)			
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)
Adverse Event	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**
Any event	1 (8.3)	2 (16.7)	3 (25.0)	2 (22.2)
Related[c]	0	1 (8.3)	0	0
Severe	0	0	1 (8.3)	1 (11.1)
Life-threatening	0	0	0	0
Any serious adverse event	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Death	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (08:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_s130_65_b2_p1

14.140. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020) – Phase 1 – 18-55 Years of Age – BNT162b2 (30 µg) – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	30 µg (N[a]=12) n[b] (%)	Placebo (N[a]=3) n[b] (%)
Any event	6 (50.0)	0
Related[c]	3 (25.0)	0
Severe	2 (16.7)	0
Life-threatening	0	0
Any serious adverse event	1 (8.3)	0
Related[c]	0	0
Severe	1 (8.3)	0
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_18_p1_saf

14.141. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020) – Phase 1 – 65-85 Years of Age – BNT162b2 (30 µg) – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	30 µg (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)
Any event	3 (25.0)	0
Related[c]	0	0
Severe	1 (8.3)	0
Life-threatening	0	0
Any serious adverse event	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any adverse event leading to withdrawal	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 = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_65_p1_saf

14.142. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6 (50.0)	(21.1, 78.9)	5 (41.7)	(15.2, 72.3)	6 (50.0)	(21.1, 78.9)	2 (22.2)	(2.8, 60.0)
Cardiac disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Tachycardia	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Eye disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Retinal tear	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Gastrointestinal disorders	2 (16.7)	(2.1, 48.4)	2 (16.7)	(2.1, 48.4)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Diarrhoea	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nausea	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Abdominal discomfort	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Abdominal pain lower	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
General disorders and administration site conditions	2 (16.7)	(2.1, 48.4)	1 (8.3)	(0.2, 38.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Injection site pain	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Pyrexia	0	(0.0, 26.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Chills	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Fatigue	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site swelling	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Malaise	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Immune system disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Seasonal allergy	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Injury, poisoning and procedural complications	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Muscle strain	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 26.5)	0	(0.0, 33.6)
Contusion	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Metabolism and nutrition disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Decreased appetite	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Musculoskeletal and connective tissue disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Arthralgia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Back pain	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Musculoskeletal pain	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)

14.142. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myalgia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	4 (33.3)	(9.9, 65.1)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Paraesthesia	0	(0.0, 26.5)	3 (25.0)	(5.5, 57.2)	0	(0.0, 26.5)	0	(0.0, 33.6)
Headache	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Disturbance in attention	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Dizziness	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Neuropathy peripheral	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Psychiatric disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Sleep disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Insomnia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Respiratory, thoracic and mediastinal disorders	2 (16.7)	(2.1, 48.4)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Cough	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Dyspnoea	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nasal congestion	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Throat irritation	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Skin and subcutaneous tissue disorders	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Rash	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Dermatitis	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Hand dermatitis	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Papule	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (01:47)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_s150_1md2_soc_18_b1_p1

14.143. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 3 Weeks After Dose 1, by System Organ Class and Preferred Term – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

	Vaccine Group (as Administered)			
	100 µg (N[a]=12)		Placebo (N[a]=3)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6 (50.0)	(21.1, 78.9)	1 (33.3)	(0.8, 90.6)
Cardiac disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Tachycardia	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Gastrointestinal disorders	2 (16.7)	(2.1, 48.4)	1 (33.3)	(0.8, 90.6)
Nausea	2 (16.7)	(2.1, 48.4)	0	(0.0, 70.8)
Paraesthesia oral	0	(0.0, 26.5)	1 (33.3)	(0.8, 90.6)
General disorders and administration site conditions	2 (16.7)	(2.1, 48.4)	0	(0.0, 70.8)
Injection site erythema	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Injection site pain	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Infections and infestations	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Urinary tract infection	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Metabolism and nutrition disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Decreased appetite	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Musculoskeletal and connective tissue disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Myalgia	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Psychiatric disorders	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)
Sleep disorder	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)
Respiratory, thoracic and mediastinal disorders	0	(0.0, 26.5)	1 (33.3)	(0.8, 90.6)
Pharyngeal paraesthesia	0	(0.0, 26.5)	1 (33.3)	(0.8, 90.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 19SEP2020 (00:12)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adae_s150_1md2_soc_18_b1_100_p1

14.144. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6 (50.0)	(21.1, 78.9)	7 (58.3)	(27.7, 84.8)	3 (25.0)	(5.5, 57.2)	4 (44.4)	(13.7, 78.8)
Blood and lymphatic system disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Anaemia	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Eye disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Eye paraesthesia	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Gastrointestinal disorders	1 (8.3)	(0.2, 38.5)	2 (16.7)	(2.1, 48.4)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Abdominal discomfort	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Aphthous ulcer	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nausea	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Toothache	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
General disorders and administration site conditions	1 (8.3)	(0.2, 38.5)	2 (16.7)	(2.1, 48.4)	3 (25.0)	(5.5, 57.2)	0	(0.0, 33.6)
Fatigue	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site bruising	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site pain	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Oedema peripheral	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Peripheral swelling	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Infections and infestations	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Herpes zoster	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Injury, poisoning and procedural complications	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Fall	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Contusion	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Fibula fracture	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Road traffic accident	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Skin abrasion	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Skin laceration	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Venomous sting	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Metabolism and nutrition disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Decreased appetite	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)

14.144. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Musculoskeletal and connective tissue disorders	2 (16.7)	(2.1, 48.4)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	2 (22.2)	(2.8, 60.0)
Myalgia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Back pain	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Muscle spasms	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Musculoskeletal pain	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Pain in extremity	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nervous system disorders	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Dizziness	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Headache	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Psychiatric disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Irritability	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Sleep disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Respiratory, thoracic and mediastinal disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Dyspnoea	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Oropharyngeal pain	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Skin and subcutaneous tissue disorders	2 (16.7)	(2.1, 48.4)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Dermatitis contact	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Ecchymosis	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Hyperhidrosis	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Surgical and medical procedures	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Suture insertion	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Tooth extraction	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (01:39)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adae s150 1md2 soc 65 b1 p1

14.145. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4 (33.3)	(9.9, 65.1)	5 (41.7)	(15.2, 72.3)	5 (41.7)	(15.2, 72.3)	2 (22.2)	(2.8, 60.0)
Blood and lymphatic system disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Lymphadenopathy	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Gastrointestinal disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Oral disorder	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
General disorders and administration site conditions	2 (16.7)	(2.1, 48.4)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Injection site pain	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site erythema	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Infections and infestations	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Urinary tract infection	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Injury, poisoning and procedural complications	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Fall	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Ligament sprain	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Tendon injury	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Musculoskeletal and connective tissue disorders	2 (16.7)	(2.1, 48.4)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Muscle spasms	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Myalgia	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Ageusia	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Dizziness	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Migraine	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Taste disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Psychiatric disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Sleep disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Renal and urinary disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nephrolithiasis	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Respiratory, thoracic and mediastinal disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

14.145. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rhinorrhoea	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Skin and subcutaneous tissue disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Rash papular	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (02:05)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adae s150 1md2 soc 18 b2 p1

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	3 (25.0)	(5.5, 57.2)	2 (22.2)	(2.8, 60.0)
Gastrointestinal disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nausea	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Injury, poisoning and procedural complications	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Contusion	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Fall	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Musculoskeletal and connective tissue disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Muscle spasms	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Radiculopathy	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Sciatica	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Surgical and medical procedures	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Tooth extraction	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Vascular disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Hypertension	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (02:04)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adae s150 1md2 soc 65 b2 p1

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 1 – 18-55 Years of Age – BNT162b2 (30 µg) – Safety Population

	Vaccine Group (as Administered)			
	30 µg (N[a]=12)		Placebo (N[a]=3)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6 (50.0)	(21.1, 78.9)	0	(0.0, 70.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Lymphadenopathy	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Injection site pain	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Fall	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Tendon injury	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Pain in extremity	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
NERVOUS SYSTEM DISORDERS	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)
Dizziness	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Migraine	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Neuritis	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:04)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc 18 p1 saf

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 1 – 65-85 Years of Age – BNT162b2 (30 µg) – Safety Population

	Vaccine Group (as Administered)			
	30 µg (N[a]=12)		Placebo (N[a]=3)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Muscle spasms	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
NERVOUS SYSTEM DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Sciatica	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
VASCULAR DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Hypertension	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:04)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc 65 p1 saf

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (25.0)	(5.5, 57.2)	4 (33.3)	(9.9, 65.1)	6 (50.0)	(21.1, 78.9)	1 (11.1)	(0.3, 48.2)
Cardiac disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Tachycardia	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Gastrointestinal disorders	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Diarrhoea	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nausea	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
General disorders and administration site conditions	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Injection site pain	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Pyrexia	0	(0.0, 26.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Chills	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Fatigue	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site swelling	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injury, poisoning and procedural complications	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Contusion	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Metabolism and nutrition disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Decreased appetite	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Musculoskeletal and connective tissue disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Arthralgia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Back pain	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Musculoskeletal pain	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Myalgia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	3 (25.0)	(5.5, 57.2)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Headache	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Paraesthesia	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 26.5)	0	(0.0, 33.6)
Disturbance in attention	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Psychiatric disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Insomnia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Sleep disorder	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Respiratory, thoracic and mediastinal disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Cough	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:49)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_rel_vax2_18_b1_p1

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 3 Weeks After Dose 1, by System Organ Class and Preferred Term – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

	Vaccine Group (as Administered)			
	100 µg (N[a]=12)		Placebo (N[a]=3)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6 (50.0)	(21.1, 78.9)	1 (33.3)	(0.8, 90.6)
Cardiac disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Tachycardia	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Gastrointestinal disorders	2 (16.7)	(2.1, 48.4)	1 (33.3)	(0.8, 90.6)
Nausea	2 (16.7)	(2.1, 48.4)	0	(0.0, 70.8)
Paraesthesia oral	0	(0.0, 26.5)	1 (33.3)	(0.8, 90.6)
General disorders and administration site conditions	2 (16.7)	(2.1, 48.4)	0	(0.0, 70.8)
Injection site erythema	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Injection site pain	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Metabolism and nutrition disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Decreased appetite	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Musculoskeletal and connective tissue disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Myalgia	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Psychiatric disorders	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)
Sleep disorder	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)
Respiratory, thoracic and mediastinal disorders	0	(0.0, 26.5)	1 (33.3)	(0.8, 90.6)
Pharyngeal paraesthesia	0	(0.0, 26.5)	1 (33.3)	(0.8, 90.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 19SEP2020 (00:13)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adae_rel_vax2_18_b1_100_p1

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (25.0)	(5.5, 57.2)	4 (33.3)	(9.9, 65.1)	2 (16.7)	(2.1, 48.4)	1 (11.1)	(0.3, 48.2)
Eye disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Eye paraesthesia	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Gastrointestinal disorders	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Abdominal discomfort	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Aphthous ulcer	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nausea	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
General disorders and administration site conditions	1 (8.3)	(0.2, 38.5)	2 (16.7)	(2.1, 48.4)	2 (16.7)	(2.1, 48.4)	0	(0.0, 33.6)
Fatigue	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site bruising	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site pain	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Peripheral swelling	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Metabolism and nutrition disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Decreased appetite	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Musculoskeletal and connective tissue disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Myalgia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Psychiatric disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Irritability	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Sleep disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Skin and subcutaneous tissue disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Hyperhidrosis	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:50)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adae rel vax2 65 b1 p1

14.152. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (16.7)	(2.1, 48.4)	4 (33.3)	(9.9, 65.1)	3 (25.0)	(5.5, 57.2)	1 (11.1)	(0.3, 48.2)
Blood and lymphatic system disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Lymphadenopathy	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
General disorders and administration site conditions	2 (16.7)	(2.1, 48.4)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Injection site pain	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site erythema	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Nervous system disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Ageusia	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Dizziness	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Taste disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Psychiatric disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Sleep disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Skin and subcutaneous tissue disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Rash papular	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:50)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adae rel vax2 18 b2 p1

14.153. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Gastrointestinal disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nausea	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:50)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adae rel vax2 65 b2 p1

14.154. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Paraesthesia	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (06:18)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_s150_immd1_vax_18_b1_p1

14.155. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Eye disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Eye paraesthesia	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (06:20)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_s150_immd1_vax_65_b1_p1

14.156. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
General disorders and administration site conditions	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Injection site erythema	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Injection site pain	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Ageusia	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (08:33)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adae s150 immd1 vax 18 b2 p1

14.157. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Taste disorder	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (08:36)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adae s150 immd2 vax 18 b2 p1

14.158. Number (%) of Subjects Reporting at Least 1 Severe or Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18–55 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
General disorders and administration site conditions	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Pyrexia	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:50)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_sev_vax2_18_b1_p1

14.159. Number (%) of Subjects Reporting at Least 1 Severe or Life-Threatening Adverse Event From Dose 1 to 3 Weeks After Dose 1, by System Organ Class and Preferred Term – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

	Vaccine Group (as Administered)			
	100 µg (N[a]=12)		Placebo (N[a]=3)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Psychiatric disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Sleep disorder	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 19SEP2020 (00:14)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adae_sev_vax2_18_b1_100_p1

14.160. Number (%) of Subjects Reporting at Least 1 Severe or Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65–85 Years of Age – BNT162b1 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
General disorders and administration site conditions	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Fatigue	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Infections and infestations	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)
Herpes zoster	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 26.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:50)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_sev_vax2_65_b1_p1

14.161. Number (%) of Subjects Reporting at Least 1 Severe or Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N[a]=12)		20 µg (N[a]=12)		30 µg (N[a]=12)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Migraine	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:50)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_sev_vax2_18_b2_p1

14.162. Number (%) of Subjects Reporting at Least 1 Severe or Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

	Vaccine Group (as Administered)							
	10 µg (N^a=12)		20 µg (N^a=12)		30 µg (N^a=12)		Placebo (N^a=9)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Any event	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	1 (11.1)	(0.3, 48.2)
Musculoskeletal and connective tissue disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Muscle spasms	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (8.3)	(0.2, 38.5)	0	(0.0, 33.6)
Nervous system disorders	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)
Radiculopathy	0	(0.0, 26.5)	0	(0.0, 26.5)	0	(0.0, 26.5)	1 (11.1)	(0.3, 48.2)

Note: MedDRA (v23.0) 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 adverse event. For "any event", n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 01SEP2020 (08:50)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_sev_vax2_65_b2_p1

Clinical Laboratory Evaluations

14.163. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
Hemoglobin (g/L)	1/1-3 days	<0.8x LLN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Hematocrit (L/L)	1/1-3 days	<0.8x LLN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Erythrocytes (10^12/L)	1/1-3 days	<0.8x LLN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Volume (fL)	1/1-3 days	<0.9x LLN	12	0	12	0	11	0	9	0
		>1.1x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Hemoglobin (pg)	1/1-3 days	<0.9x LLN	12	0	12	0	11	0	9	0
		>1.1x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular HGB Concentration (g/L)	1/1-3 days	<0.9x LLN	12	0	12	0	11	0	9	0
		>1.1x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0

14.163. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Platelets (10^9/L)	1/1-3 days	<0.5x LLN	12	0	12	0	11	0	9	0
		>1.75x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
Leukocytes (10^9/L)	1/1-3 days	<0.6x LLN	12	0	12	0	11	0	9	0
		>1.5x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
Lymphocytes (10^9/L)	1/1-3 days	<0.8x LLN	12	1 (8.3)	12	4 (33.3)	11	6 (54.5)	9	0
		>1.2x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
Neutrophils (10^9/L)	1/1-3 days	<0.8x LLN	12	1 (8.3)	12	0	11	0	9	0
		>1.2x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	1 (11.1)
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	1 (8.3)	12	0	12	1 (8.3)	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
Basophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	11	0	9	0

14.163. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Eosinophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Monocytes (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Bilirubin (umol/L)	1/1-3 days	>1.5x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	0
Aspartate Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	11	0	9	0
	1/6-8 days	>3.0x ULN	12	0	11	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	11	0	11	0	9	0
	2/6-8 days	>3.0x ULN	12	0	11	0	12	0	8	0
Alanine Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Alkaline Phosphatase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Urea Nitrogen (mmol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
Creatinine (umol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0

14.163. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0

Abbreviations: LLN = lower limit of normal; ULN = upper limit of normal.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. The primary criteria for laboratory test abnormalities are a set of criteria used for pharmaceutical studies. The criteria are more than just a comparison against the normal range or baseline values. They are a percentage of the baseline values or normal range (ie, within 10% of the normal range).
b. N = total number of subjects with at least one result for the given laboratory test after study vaccination. These values are the denominator for the percentage calculations.
c. n = Number of subjects with a laboratory abnormality meeting the primary criteria after study vaccination.
d. Percentages are displayed for the laboratory tests with ≥1 subject meeting the specified criterion.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adlb s302 abn 18 b1 p1

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Alanine Aminotransferase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Alkaline Phosphatase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Aspartate Aminotransferase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	11	Normal	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
				Total	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
		30 µg	11	Normal	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
				Total	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	11	Normal	10 (90.9)	0	0	0	0	10 (90.9)
				Grade 1	1 (9.1)	0	0	0	0	1 (9.1)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	8	Normal	8 (100.0)	0	0	0	0	8 (100.0)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
Bilirubin	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Creatinine Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Eosinophils	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Hemoglobin	1/1-3 days	10 µg	12	Normal	9 (75.0)	1 (8.3)	0	0	0	10 (83.3)
				Grade 1	2 (16.7)	0	0	0	0	2 (16.7)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	9 (75.0)	1 (8.3)	0	0	0	10 (83.3)
				Grade 1	0	1 (8.3)	1 (8.3)	0	0	2 (16.7)
				Total	9 (75.0)	2 (16.7)	1 (8.3)	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	10 (83.3)	0	0	0	0	10 (83.3)
				Grade 1	2 (16.7)	0	0	0	0	2 (16.7)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	9 (75.0)	1 (8.3)	0	0	0	10 (83.3)
				Grade 1	0	2 (16.7)	0	0	0	2 (16.7)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	6 (50.0)	4 (33.3)	0	0	0	10 (83.3)
				Grade 1	2 (16.7)	0	0	0	0	2 (16.7)
				Total	8 (66.7)	4 (33.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	9 (75.0)	1 (8.3)	0	0	0	10 (83.3)
				Grade 1	0	2 (16.7)	0	0	0	2 (16.7)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	7 (58.3)	1 (8.3)	0	0	0	8 (66.7)
				Grade 1	3 (25.0)	1 (8.3)	0	0	0	4 (33.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	8 (66.7)	1 (8.3)	0	0	0	9 (75.0)
				Grade 1	0	3 (25.0)	0	0	0	3 (25.0)
				Total	8 (66.7)	4 (33.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
Lymphocytes	1/1-3 days	10 µg	12	Normal	8 (66.7)	2 (16.7)	1 (8.3)	1 (8.3)	0	12 (100.0)
				Total	8 (66.7)	2 (16.7)	1 (8.3)	1 (8.3)	0	12 (100.0)
		20 µg	12	Normal	3 (25.0)	5 (41.7)	2 (16.7)	2 (16.7)	0	12 (100.0)
				Total	3 (25.0)	5 (41.7)	2 (16.7)	2 (16.7)	0	12 (100.0)
		30 µg	11	Normal	2 (18.2)	3 (27.3)	5 (45.5)	1 (9.1)	0	11 (100.0)
				Total	2 (18.2)	3 (27.3)	5 (45.5)	1 (9.1)	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	0	0	0	0	10 (83.3)
				Grade 1	0	2 (16.7)	0	0	0	2 (16.7)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
Neutrophil Decrease	1/1-3 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	2 (22.2)	0	0	0	9 (100.0)
				Total	7 (77.8)	2 (22.2)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	9 (75.0)	2 (16.7)	0	0	0	11 (91.7)
				Grade 1	0	0	1 (8.3)	0	0	1 (8.3)
				Total	9 (75.0)	2 (16.7)	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	0	0	0	0	7 (77.8)
				Grade 1	2 (22.2)	0	0	0	0	2 (22.2)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Platelets Decrease	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
Urea Nitrogen	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
WBC Decrease	1/1-3 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
WBC Increase	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)

14.164. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

Abbreviations: FDA = Food and Drug Administration; LLN = lower limit of normal.
Note: Laboratory reference grades are based on the FDA toxicity grading scale for healthy adult volunteers enrolled in preventive vaccine clinical trials.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. N = total number of subjects with at least 1 result for the given laboratory test for both baseline and postvaccination visits. These values are the denominator for the percentage calculations.
b. n = Number of subjects with a laboratory abnormality meeting specified criteria for both baseline and postvaccination visits.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adlb_s502_shift_18_b1_p1

14.165. Percentage of Laboratory Test Abnormalities – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

			Vaccine Group (as Administered)			
			100 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
Hemoglobin (g/L)	1/1-3 days	<0.8x LLN	12	0	3	0
	1/6-8 days	<0.8x LLN	12	0	3	0
	1/19-23 days	<0.8x LLN	12	0	3	0
	1/25-31 days	<0.8x LLN	12	0	3	0
	1/85-105 days	<0.8x LLN	11	0	3	0
Hematocrit (L/L)	1/1-3 days	<0.8x LLN	12	0	3	0
	1/6-8 days	<0.8x LLN	12	0	3	0
	1/19-23 days	<0.8x LLN	12	0	3	0
	1/25-31 days	<0.8x LLN	12	0	3	0
	1/85-105 days	<0.8x LLN	11	0	3	0
Erythrocytes (10^12/L)	1/1-3 days	<0.8x LLN	12	0	3	0
	1/6-8 days	<0.8x LLN	12	0	3	0
	1/19-23 days	<0.8x LLN	12	0	3	0
	1/25-31 days	<0.8x LLN	12	0	3	0
	1/85-105 days	<0.8x LLN	11	0	3	0
Ery. Mean Corpuscular Volume (fL)	1/1-3 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/6-8 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/19-23 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/25-31 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/85-105 days	<0.9x LLN	11	0	3	0
		>1.1x ULN	11	0	3	0
Ery. Mean Corpuscular Hemoglobin (pg)	1/1-3 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/6-8 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/19-23 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/25-31 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0

14.165. Percentage of Laboratory Test Abnormalities – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

			Vaccine Group (as Administered)			
			100 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	1/85-105 days	<0.9x LLN	11	0	3	0
		>1.1x ULN	11	0	3	0
Ery. Mean Corpuscular HGB Concentration (g/L)	1/1-3 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/6-8 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/19-23 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/25-31 days	<0.9x LLN	12	0	3	0
		>1.1x ULN	12	0	3	0
	1/85-105 days	<0.9x LLN	11	0	3	0
		>1.1x ULN	11	0	3	0
Platelets (10^9/L)	1/1-3 days	<0.5x LLN	12	0	3	0
		>1.75x ULN	12	0	3	0
	1/6-8 days	<0.5x LLN	12	0	3	0
		>1.75x ULN	12	0	3	0
	1/19-23 days	<0.5x LLN	12	0	3	0
		>1.75x ULN	12	0	3	0
	1/25-31 days	<0.5x LLN	12	0	3	0
		>1.75x ULN	12	0	3	0
	1/85-105 days	<0.5x LLN	11	0	3	0
		>1.75x ULN	11	0	3	0
Leukocytes (10^9/L)	1/1-3 days	<0.6x LLN	12	0	3	0
		>1.5x ULN	12	0	3	0
	1/6-8 days	<0.6x LLN	12	0	3	0
		>1.5x ULN	12	0	3	0
	1/19-23 days	<0.6x LLN	12	0	3	0
		>1.5x ULN	12	0	3	0
	1/25-31 days	<0.6x LLN	12	0	3	0
		>1.5x ULN	12	0	3	0
	1/85-105 days	<0.6x LLN	11	0	3	0
		>1.5x ULN	11	0	3	0
Lymphocytes (10^9/L)	1/1-3 days	<0.8x LLN	12	9 (75.0)	3	0
		>1.2x ULN	12	0	3	0
	1/6-8 days	<0.8x LLN	12	0	3	0
		>1.2x ULN	12	0	3	0
	1/19-23 days	<0.8x LLN	12	0	3	0

14.165. Percentage of Laboratory Test Abnormalities – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

			Vaccine Group (as Administered)			
			100 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
		>1.2x ULN	12	0	3	0
	1/25-31 days	<0.8x LLN	12	0	3	0
		>1.2x ULN	12	0	3	0
	1/85-105 days	<0.8x LLN	11	0	3	0
		>1.2x ULN	11	0	3	0
Neutrophils (10^9/L)	1/1-3 days	<0.8x LLN	12	0	3	0
		>1.2x ULN	12	0	3	0
	1/6-8 days	<0.8x LLN	12	0	3	0
		>1.2x ULN	12	0	3	0
	1/19-23 days	<0.8x LLN	12	0	3	0
		>1.2x ULN	12	0	3	0
	1/25-31 days	<0.8x LLN	12	0	3	0
		>1.2x ULN	12	0	3	0
	1/85-105 days	<0.8x LLN	11	0	3	0
		>1.2x ULN	11	0	3	0
Basophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	3	0
	1/6-8 days	>1.2x ULN	12	0	3	0
	1/19-23 days	>1.2x ULN	12	0	3	0
	1/25-31 days	>1.2x ULN	12	0	3	0
	1/85-105 days	>1.2x ULN	11	0	3	0
Eosinophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	3	0
	1/6-8 days	>1.2x ULN	12	0	3	0
	1/19-23 days	>1.2x ULN	12	0	3	0
	1/25-31 days	>1.2x ULN	12	0	3	0
	1/85-105 days	>1.2x ULN	11	0	3	0
Monocytes (10^9/L)	1/1-3 days	>1.2x ULN	12	0	3	0
	1/6-8 days	>1.2x ULN	12	0	3	0
	1/19-23 days	>1.2x ULN	12	0	3	0
	1/25-31 days	>1.2x ULN	12	0	3	0
	1/85-105 days	>1.2x ULN	11	0	3	0
Bilirubin (umol/L)	1/1-3 days	>1.5x ULN	12	0	3	0
	1/6-8 days	>1.5x ULN	12	0	3	0
	1/19-23 days	>1.5x ULN	12	0	3	0
	1/25-31 days	>1.5x ULN	12	0	3	0
	1/85-105 days	>1.5x ULN	11	0	3	0
Aspartate Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	11	0	3	0
	1/6-8 days	>3.0x ULN	12	0	3	0

14.165. Percentage of Laboratory Test Abnormalities – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

			Vaccine Group (as Administered)			
			100 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	1/19-23 days	>3.0x ULN	12	0	3	0
	1/25-31 days	>3.0x ULN	12	0	3	0
	1/85-105 days	>3.0x ULN	11	0	3	0
Alanine Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	11	0	3	0
	1/6-8 days	>3.0x ULN	12	0	3	0
	1/19-23 days	>3.0x ULN	12	0	3	0
	1/25-31 days	>3.0x ULN	12	0	3	0
	1/85-105 days	>3.0x ULN	11	0	3	0
Alkaline Phosphatase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	3	0
	1/6-8 days	>3.0x ULN	12	0	3	0
	1/19-23 days	>3.0x ULN	12	0	3	0
	1/25-31 days	>3.0x ULN	12	0	3	0
	1/85-105 days	>3.0x ULN	11	0	3	0
Urea Nitrogen (mmol/L)	1/1-3 days	>1.3x ULN	12	0	3	0
	1/6-8 days	>1.3x ULN	12	0	3	0
	1/19-23 days	>1.3x ULN	12	0	3	0
	1/25-31 days	>1.3x ULN	12	0	3	0
	1/85-105 days	>1.3x ULN	11	0	3	0
Creatinine (umol/L)	1/1-3 days	>1.3x ULN	12	0	3	0
	1/6-8 days	>1.3x ULN	12	0	3	0
	1/19-23 days	>1.3x ULN	12	0	3	0
	1/25-31 days	>1.3x ULN	12	0	3	0
	1/85-105 days	>1.3x ULN	11	0	3	0

Abbreviations: LLN = lower limit of normal; ULN = upper limit of normal.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. The primary criteria for laboratory test abnormalities are a set of criteria used for pharmaceutical studies. The criteria are more than just a comparison against the normal range or baseline values. They are a percentage of the baseline values or normal range (ie, within 10% of the normal range).
b. N = total number of subjects with at least one result for the given laboratory test after study vaccination. These values are the denominator for the percentage calculations.
c. n = Number of subjects with a laboratory abnormality meeting the primary criteria after study vaccination.
d. Percentages are displayed for the laboratory tests with ≥1 subject meeting the specified criterion.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 21SEP2020 (14:31)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
./nda3/C4591001 IA P1 100/adlb s302 abn 18 b1 100 p1

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Alanine Aminotransferase Increased	1/1-3 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Alkaline Phosphatase Increased	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Aspartate Aminotransferase Increased	1/1-3 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Bilirubin	1/1-3 days	100 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
				Total	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Creatinine Increased	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Eosinophils	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Hemoglobin	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Lymphocytes	1/1-3 days	100 µg	12	Normal	0	2 (16.7)	6 (50.0)	4 (33.3)	0	12 (100.0)
				Total	0	2 (16.7)	6 (50.0)	4 (33.3)	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Neutrophil Decrease	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Platelets Decrease	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
Urea Nitrogen	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
WBC Decrease	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
WBC Increase	1/1-3 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	2 (66.7)	1 (33.3)	0	0	0	3 (100.0)
				Total	2 (66.7)	1 (33.3)	0	0	0	3 (100.0)
	1/6-8 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)

14.166. Shift Summary of Laboratory Results by Grade – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
	1/19-23 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/25-31 days	100 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)
	1/85-105 days	100 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	3	Normal	3 (100.0)	0	0	0	0	3 (100.0)
				Total	3 (100.0)	0	0	0	0	3 (100.0)

Abbreviations: FDA = Food and Drug Administration; LLN = lower limit of normal.
Note: Laboratory reference grades are based on the FDA toxicity grading scale for healthy adult volunteers enrolled in preventive vaccine clinical trials.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. N = total number of subjects with at least 1 result for the given laboratory test for both baseline and postvaccination visits. These values are the denominator for the percentage calculations.
b. n = Number of subjects with a laboratory abnormality meeting specified criteria for both baseline and postvaccination visits.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 21SEP2020 (15:07)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adlb_s502_shift_18_b1_100_p1

14.167. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
Hemoglobin (g/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Hematocrit (L/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Erythrocytes (10^12/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Volume (fL)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Hemoglobin (pg)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular HGB Concentration (g/L)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0

14.167. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Platelets (10^9/L)	1/1-3 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.5x LLN	12	0	12	0	11	0	9	0
		>1.75x ULN	12	0	12	0	11	0	9	0
	1/19-23 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
Leukocytes (10^9/L)	1/1-3 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
Lymphocytes (10^9/L)	1/1-3 days	<0.8x LLN	12	1 (8.3)	12	3 (25.0)	12	2 (16.7)	9	0
		>1.2x ULN	12	0	12	0	12	0	9	1 (11.1)
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	1 (11.1)
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	1 (11.1)
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
Neutrophils (10^9/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	9	1 (11.1)
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	2 (16.7)	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	1 (8.3)	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
Basophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0

14.167. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Eosinophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	1 (8.3)	9	0
	2/6-8 days	>1.2x ULN	12	0	12	1 (8.3)	12	0	9	0
Monocytes (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Bilirubin (umol/L)	1/1-3 days	>1.5x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	0
Aspartate Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	11	0	11	0	12	0	8	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	10	0	10	0	11	0	7	0
	2/6-8 days	>3.0x ULN	11	0	12	0	12	0	7	0
Alanine Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	11	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Alkaline Phosphatase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Urea Nitrogen (mmol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
Creatinine (umol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0

14.167. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]

Abbreviations: LLN = lower limit of normal; ULN = upper limit of normal.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. The primary criteria for laboratory test abnormalities are a set of criteria used for pharmaceutical studies. The criteria are more than just a comparison against the normal range or baseline values. They are a percentage of the baseline values or normal range (ie, within 10% of the normal range).
b. N = total number of subjects with at least one result for the given laboratory test after study vaccination. These values are the denominator for the percentage calculations.
c. n = Number of subjects with a laboratory abnormality meeting the primary criteria after study vaccination.
d. Percentages are displayed for the laboratory tests with ≥1 subject meeting the specified criterion.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adlb_s302_abn_65_b1_p1

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Alanine Aminotransferase Increased	1/1-3 days	10 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Alkaline Phosphatase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
Aspartate Aminotransferase Increased	1/1-3 days	10 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		20 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	8	Normal	8 (100.0)	0	0	0	0	8 (100.0)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	10	Normal	10 (100.0)	0	0	0	0	10 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	10 (100.0)	0	0	0	0	10 (100.0)
		20 µg	10	Normal	10 (100.0)	0	0	0	0	10 (100.0)
				Total	10 (100.0)	0	0	0	0	10 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	7	Normal	6 (85.7)	1 (14.3)	0	0	0	7 (100.0)
				Total	6 (85.7)	1 (14.3)	0	0	0	7 (100.0)
	2/6-8 days	10 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	7	Normal	6 (85.7)	0	0	0	0	6 (85.7)
				Grade 1	1 (14.3)	0	0	0	0	1 (14.3)
				Total	7 (100.0)	0	0	0	0	7 (100.0)
Bilirubin	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Creatinine Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Eosinophils	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Hemoglobin	1/1-3 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	0	1 (8.3)	0	0	1 (8.3)
				Total	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	0	1 (8.3)	0	0	1 (8.3)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	0	1 (8.3)	0	0	1 (8.3)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	0	0	0	0	10 (83.3)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Grade 2	0	0	1 (8.3)	0	0	1 (8.3)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
Lymphocytes	1/1-3 days	10 µg	12	Normal	4 (33.3)	6 (50.0)	1 (8.3)	0	1 (8.3)	12 (100.0)
				Total	4 (33.3)	6 (50.0)	1 (8.3)	0	1 (8.3)	12 (100.0)
		20 µg	12	Normal	2 (16.7)	2 (16.7)	8 (66.7)	0	0	12 (100.0)
				Total	2 (16.7)	2 (16.7)	8 (66.7)	0	0	12 (100.0)
		30 µg	12	Normal	5 (41.7)	4 (33.3)	2 (16.7)	1 (8.3)	0	12 (100.0)
				Total	5 (41.7)	4 (33.3)	2 (16.7)	1 (8.3)	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	0	0	0	0	10 (83.3)
				Grade 1	2 (16.7)	0	0	0	0	2 (16.7)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Neutrophil Decrease	1/1-3 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	9 (75.0)	2 (16.7)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	9 (75.0)	1 (8.3)	0	0	0	10 (83.3)
				Grade 1	1 (8.3)	1 (8.3)	0	0	0	2 (16.7)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	0	1 (8.3)	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
Platelets Decrease	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
				Total	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	11	Normal	10 (90.9)	0	0	0	0	10 (90.9)
				Grade 1	1 (9.1)	0	0	0	0	1 (9.1)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Urea Nitrogen	1/1-3 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
				Total	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	2 (22.2)	0	0	0	9 (100.0)
				Total	7 (77.8)	2 (22.2)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 2	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
				Total	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	0	0	0	0	7 (77.8)
				Grade 1	1 (11.1)	0	1 (11.1)	0	0	2 (22.2)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
WBC Decrease	1/1-3 days	10 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
WBC Increase	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

14.168. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Safety Population

					Maximum FDA Toxicity Grade					
					Normal	Grade 1	Grade 2	Grade 3	Grade 4	Total
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)

Abbreviations: FDA = Food and Drug Administration; LLN = lower limit of normal.
Note: Laboratory reference grades are based on the FDA toxicity grading scale for healthy adult volunteers enrolled in preventive vaccine clinical trials.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. N = total number of subjects with at least 1 result for the given laboratory test for both baseline and postvaccination visits. These values are the denominator for the percentage calculations.
b. n = Number of subjects with a laboratory abnormality meeting specified criteria for both baseline and postvaccination visits.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adlb_s502_shift_65_b1_p1

14.169. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
Hemoglobin (g/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Hematocrit (L/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Erythrocytes (10^12/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Volume (fL)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	8	0
		>1.1x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Hemoglobin (pg)	1/1-3 days	<0.9x LLN	12	0	12	0	12	1 (8.3)	8	0
		>1.1x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	1 (8.3)	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	1 (8.3)	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	1 (8.3)	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular HGB Concentration (g/L)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	8	0
		>1.1x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0

14.169. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Platelets (10^9/L)	1/1-3 days	<0.5x LLN	12	0	12	0	12	0	8	0
		>1.75x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.5x LLN	12	0	12	0	11	0	9	0
		>1.75x ULN	12	0	12	0	11	0	9	0
Leukocytes (10^9/L)	1/1-3 days	<0.6x LLN	12	0	12	0	12	0	8	0
		>1.5x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
Lymphocytes (10^9/L)	1/1-3 days	<0.8x LLN	12	0	12	1 (8.3)	12	1 (8.3)	8	0
		>1.2x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
Neutrophils (10^9/L)	1/1-3 days	<0.8x LLN	12	1 (8.3)	12	0	12	0	8	0
		>1.2x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	1 (8.3)	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
Basophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0

14.169. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Eosinophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Monocytes (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	8	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	1 (11.1)
Bilirubin (umol/L)	1/1-3 days	>1.5x ULN	12	1 (8.3)	12	0	12	0	9	0
	1/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	1 (11.1)
	1/19-23 days	>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	1 (11.1)
Aspartate Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	11	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	11	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	11	0	9	0
Alanine Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Alkaline Phosphatase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Urea Nitrogen (mmol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
Creatinine (umol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0

14.169. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]

Abbreviations: LLN = lower limit of normal; ULN = upper limit of normal.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. The primary criteria for laboratory test abnormalities are a set of criteria used for pharmaceutical studies. The criteria are more than just a comparison against the normal range or baseline values. They are a percentage of the baseline values or normal range (ie, within 10% of the normal range).
b. N = total number of subjects with at least one result for the given laboratory test after study vaccination. These values are the denominator for the percentage calculations.
c. n = Number of subjects with a laboratory abnormality meeting the primary criteria after study vaccination.
d. Percentages are displayed for the laboratory tests with ≥1 subject meeting the specified criterion.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adlb_s302_abn_18_b2_p1

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Alanine Aminotransferase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Alkaline Phosphatase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Aspartate Aminotransferase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	11	Normal	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
				Total	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Bilirubin	1/1-3 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 2	0	0	0	1 (8.3)	0	1 (8.3)
				Total	11 (91.7)	0	0	1 (8.3)	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
	1/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 2	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	0	1 (11.1)	0	0	1 (11.1)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 2	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	0	1 (11.1)	0	0	1 (11.1)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
Creatinine Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Eosinophils	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	8	Normal	8 (100.0)	0	0	0	0	8 (100.0)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Hemoglobin	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		Placebo	8	Normal	7 (87.5)	0	0	0	0	7 (87.5)
				Grade 1	1 (12.5)	0	0	0	0	1 (12.5)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	8 (66.7)	2 (16.7)	0	0	0	10 (83.3)
				Grade 1	2 (16.7)	0	0	0	0	2 (16.7)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
Lymphocytes	1/1-3 days	10 µg	12	Normal	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		20 µg	12	Normal	9 (75.0)	2 (16.7)	1 (8.3)	0	0	12 (100.0)
				Total	9 (75.0)	2 (16.7)	1 (8.3)	0	0	12 (100.0)
		30 µg	12	Normal	7 (58.3)	4 (33.3)	1 (8.3)	0	0	12 (100.0)
				Total	7 (58.3)	4 (33.3)	1 (8.3)	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	8	Normal	8 (100.0)	0	0	0	0	8 (100.0)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	1 (11.1)	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	1 (11.1)	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
Neutrophil Decrease	1/1-3 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	8	Normal	7 (87.5)	0	0	0	0	7 (87.5)
				Grade 1	1 (12.5)	0	0	0	0	1 (12.5)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	1 (11.1)	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	10 (83.3)	0	0	0	0	10 (83.3)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Grade 2	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Platelets Decrease	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	8	Normal	7 (87.5)	1 (12.5)	0	0	0	8 (100.0)
				Total	7 (87.5)	1 (12.5)	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Urea Nitrogen	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Grade 1	0	0	1 (11.1)	0	0	1 (11.1)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	0	1 (11.1)	0	0	1 (11.1)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 2	0	0	1 (11.1)	0	0	1 (11.1)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
WBC Decrease	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	8	Normal	8 (100.0)	0	0	0	0	8 (100.0)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	2 (22.2)	0	0	0	9 (100.0)
				Total	7 (77.8)	2 (22.2)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	0	0	0	0	7 (77.8)
				Grade 1	2 (22.2)	0	0	0	0	2 (22.2)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
WBC Increase	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	8	Normal	8 (100.0)	0	0	0	0	8 (100.0)
				Total	8 (100.0)	0	0	0	0	8 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

14.170. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
					Normal	Grade 1	Grade 2	Grade 3	Grade 4	Total
Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)

Abbreviations: FDA = Food and Drug Administration; LLN = lower limit of normal.
Note: Laboratory reference grades are based on the FDA toxicity grading scale for healthy adult volunteers enrolled in preventive vaccine clinical trials.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. N = total number of subjects with at least 1 result for the given laboratory test for both baseline and postvaccination visits. These values are the denominator for the percentage calculations.
b. n = Number of subjects with a laboratory abnormality meeting specified criteria for both baseline and postvaccination visits.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adlb_s502_shift_18_b2_p1

14.171. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
Hemoglobin (g/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Hematocrit (L/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Erythrocytes (10^12/L)	1/1-3 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Volume (fL)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular Hemoglobin (pg)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Ery. Mean Corpuscular HGB Concentration (g/L)	1/1-3 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.9x LLN	12	0	12	0	12	0	9	0

14.171. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
		>1.1x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.9x LLN	12	0	12	0	12	0	9	0
		>1.1x ULN	12	0	12	0	12	0	9	0
Platelets (10^9/L)	1/1-3 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.5x LLN	11	0	12	0	12	0	9	0
		>1.75x ULN	11	0	12	0	12	0	9	0
	1/19-23 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.5x LLN	12	0	12	0	12	0	9	0
		>1.75x ULN	12	0	12	0	12	0	9	0
Leukocytes (10^9/L)	1/1-3 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.6x LLN	12	0	12	0	12	0	9	0
		>1.5x ULN	12	0	12	0	12	0	9	0
Lymphocytes (10^9/L)	1/1-3 days	<0.8x LLN	12	1 (8.3)	12	1 (8.3)	12	1 (8.3)	9	0
		>1.2x ULN	12	1 (8.3)	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	1 (8.3)	12	0	12	1 (8.3)	9	0
	1/19-23 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	1 (8.3)	12	0	12	1 (8.3)	9	0
	2/6-8 days	<0.8x LLN	12	0	12	0	12	0	9	0
		>1.2x ULN	12	1 (8.3)	12	0	12	1 (8.3)	9	0
Neutrophils (10^9/L)	1/1-3 days	<0.8x LLN	12	0	12	2 (16.7)	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	<0.8x LLN	12	1 (8.3)	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	<0.8x LLN	12	1 (8.3)	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	<0.8x LLN	12	1 (8.3)	12	0	12	0	9	0
		>1.2x ULN	12	0	12	0	12	0	9	0
Basophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0

14.171. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Eosinophils (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Monocytes (10^9/L)	1/1-3 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.2x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.2x ULN	12	0	12	0	12	0	9	0
Bilirubin (umol/L)	1/1-3 days	>1.5x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.5x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.5x ULN	12	0	12	0	12	0	9	0
Aspartate Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	10	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	11	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	11	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Alanine Aminotransferase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Alkaline Phosphatase (ukat/L)	1/1-3 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>3.0x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>3.0x ULN	12	0	12	0	12	0	9	0
Urea Nitrogen (mmol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
Creatinine (umol/L)	1/1-3 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0
	1/19-23 days	>1.3x ULN	12	0	12	0	12	0	9	0
	2/6-8 days	>1.3x ULN	12	0	12	0	12	0	9	0

14.171. Percentage of Laboratory Test Abnormalities – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

			Vaccine Group (as Administered)							
			10 µg		20 µg		30 µg		Placebo	
Laboratory Test (Units)	Dose/Visit Window	Primary Criteria[a]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]	N[b]	n[c] (%)[d]

Abbreviations: LLN = lower limit of normal; ULN = upper limit of normal.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. The primary criteria for laboratory test abnormalities are a set of criteria used for pharmaceutical studies. The criteria are more than just a comparison against the normal range or baseline values. They are a percentage of the baseline values or normal range (ie, within 10% of the normal range).
b. N = total number of subjects with at least one result for the given laboratory test after study vaccination. These values are the denominator for the percentage calculations.
c. n = Number of subjects with a laboratory abnormality meeting the primary criteria after study vaccination.
d. Percentages are displayed for the laboratory tests with ≥1 subject meeting the specified criterion.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File:
(CDISC)/C4591001 IA P1/adlb s302 abn 65 b2 p1

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade					
					Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Alanine Aminotransferase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Alkaline Phosphatase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Aspartate Aminotransferase Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	10	Normal	10 (100.0)	0	0	0	0	10 (100.0)
				Total	10 (100.0)	0	0	0	0	10 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	11	Normal	11 (100.0)	0	0	0	0	11 (100.0)
				Total	11 (100.0)	0	0	0	0	11 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Bilirubin	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Creatinine Increased	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Eosinophils	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Hemoglobin	1/1-3 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
Lymphocytes	1/1-3 days	10 µg	12	Normal	9 (75.0)	2 (16.7)	0	1 (8.3)	0	12 (100.0)
				Total	9 (75.0)	2 (16.7)	0	1 (8.3)	0	12 (100.0)
		20 µg	12	Normal	4 (33.3)	6 (50.0)	2 (16.7)	0	0	12 (100.0)
				Total	4 (33.3)	6 (50.0)	2 (16.7)	0	0	12 (100.0)
		30 µg	12	Normal	8 (66.7)	3 (25.0)	0	0	0	11 (91.7)
				Grade 1	0	0	0	1 (8.3)	0	1 (8.3)
				Total	8 (66.7)	3 (25.0)	0	1 (8.3)	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	1 (11.1)	0	0	0	0	1 (11.1)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	0	1 (8.3)	0	0	1 (8.3)
				Total	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	0	1 (11.1)	0	0	1 (11.1)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
Neutrophil Decrease	1/1-3 days	10 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	8 (66.7)	1 (8.3)	2 (16.7)	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	9 (75.0)	1 (8.3)	2 (16.7)	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	7 (58.3)	4 (33.3)	0	0	0	11 (91.7)
				Grade 1	0	0	1 (8.3)	0	0	1 (8.3)
				Total	7 (58.3)	4 (33.3)	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
Platelets Decrease	1/1-3 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	1 (11.1)	0	0	0	8 (88.9)
				Grade 1	0	1 (11.1)	0	0	0	1 (11.1)
				Total	7 (77.8)	2 (22.2)	0	0	0	9 (100.0)
	1/6-8 days	10 µg	11	Normal	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
				Total	10 (90.9)	1 (9.1)	0	0	0	11 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	7 (77.8)	1 (11.1)	0	0	0	8 (88.9)
				Grade 1	0	0	1 (11.1)	0	0	1 (11.1)
				Total	7 (77.8)	1 (11.1)	1 (11.1)	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
				Total	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 1	0	0	1 (11.1)	0	0	1 (11.1)
				Total	8 (88.9)	0	1 (11.1)	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 2	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	0	0	0	0	8 (88.9)
				Grade 2	0	1 (11.1)	0	0	0	1 (11.1)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
Urea Nitrogen	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
				Total	11 (91.7)	0	1 (8.3)	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	0	2 (16.7)	0	0	12 (100.0)
				Total	10 (83.3)	0	2 (16.7)	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		20 µg	12	Normal	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		30 µg	12	Normal	9 (75.0)	1 (8.3)	0	0	0	10 (83.3)
				Grade 1	0	2 (16.7)	0	0	0	2 (16.7)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
				Total	9 (100.0)	0	0	0	0	9 (100.0)
WBC Decrease	1/1-3 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	0	1 (8.3)	0	0	1 (8.3)
				Total	10 (83.3)	1 (8.3)	1 (8.3)	0	0	12 (100.0)
		20 µg	12	Normal	9 (75.0)	1 (8.3)	2 (16.7)	0	0	12 (100.0)
				Total	9 (75.0)	1 (8.3)	2 (16.7)	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	10 (83.3)	1 (8.3)	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
				Total	8 (88.9)	1 (11.1)	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	9 (75.0)	2 (16.7)	0	0	0	11 (91.7)
				Grade 1	1 (8.3)	0	0	0	0	1 (8.3)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	10 (83.3)	2 (16.7)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	9 (75.0)	1 (8.3)	0	0	0	10 (83.3)
				Grade 1	0	2 (16.7)	0	0	0	2 (16.7)
				Total	9 (75.0)	3 (25.0)	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	11 (91.7)	0	0	0	0	11 (91.7)
				Grade 1	0	1 (8.3)	0	0	0	1 (8.3)
				Total	11 (91.7)	1 (8.3)	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
WBC Increase	1/1-3 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

Laboratory Test	Dose/Visit Window	Vaccine Group (as Administered)	N[a]	Baseline Grade	Maximum FDA Toxicity Grade: Normal n[b] (%)	Grade 1 n[b] (%)	Grade 2 n[b] (%)	Grade 3 n[b] (%)	Grade 4 n[b] (%)	Total n[b] (%)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	1/19-23 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)
	2/6-8 days	10 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		20 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)

14.172. Shift Summary of Laboratory Results by Grade – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Safety Population

					Maximum FDA Toxicity Grade					
Laboratory Test	**Dose/Visit Window**	**Vaccine Group (as Administered)**	**N[a]**	**Baseline Grade**	**Normal n[b] (%)**	**Grade 1 n[b] (%)**	**Grade 2 n[b] (%)**	**Grade 3 n[b] (%)**	**Grade 4 n[b] (%)**	**Total n[b] (%)**
		30 µg	12	Normal	12 (100.0)	0	0	0	0	12 (100.0)
				Total	12 (100.0)	0	0	0	0	12 (100.0)
		Placebo	9	Normal	9 (100.0)	0	0	0	0	9 (100.0)
				Total	9 (100.0)	0	0	0	0	9 (100.0)

Abbreviations: FDA = Food and Drug Administration; LLN = lower limit of normal.
Note: Laboratory reference grades are based on the FDA toxicity grading scale for healthy adult volunteers enrolled in preventive vaccine clinical trials.
Note: Bilirubin values reported as "<0.2" mg/dL (<3.4 µM/L) are imputed as 0.5 × LLN for analysis.
a. N = total number of subjects with at least 1 result for the given laboratory test for both baseline and postvaccination visits. These values are the denominator for the percentage calculations.
b. n = Number of subjects with a laboratory abnormality meeting specified criteria for both baseline and postvaccination visits.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:32) Source Data: adlb Table Generation: 29AUG2020 (08:09)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adlb s502 shift 65 b2 p1

Physical Examinations

14.173. Physical Examination Findings at Baseline – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	0	0	0	0	0
Abdomen					
Normal	12 (100.0)	11 (91.7)	12 (100.0)	9 (100.0)	44 (97.8)
Not done	0	1 (8.3)	0	0	1 (2.2)
Ears					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Extremities					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Eyes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
General appearance					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Head					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Heart					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Lungs					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Lymph nodes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Musculoskeletal					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Neurological					
Normal	12 (100.0)	10 (83.3)	12 (100.0)	9 (100.0)	43 (95.6)
Not done	0	2 (16.7)	0	0	2 (4.4)
Nose					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Skin					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Throat					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)

14.173. Physical Examination Findings at Baseline – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (12:00)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adpe_s001_18_b1_p1

14.174. Abnormal Physical Examination Findings After Randomization – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – All Randomized Subjects

		Vaccine Group (as Randomized)				
		10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**Dose/Visit Window**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	1/1-3 days	2 (16.7)	1 (8.3)	6 (50.0)	0	9 (20.0)
	1/6-8 days	0	0	0	1 (11.1)	1 (2.2)
	1/19-23 days	1 (8.3)	2 (16.7)	1 (8.3)	0	4 (8.9)
	2/6-8 days	3 (25.0)	0	3 (25.0)	1 (11.1)	7 (15.6)
	2/12-16 days	2 (16.7)	0	0	0	2 (4.4)
Abdomen						
Abnormal	2/12-16 days	1 (8.3)	0	0	0	1 (2.2)
Extremities						
Abnormal	1/1-3 days	0	0	4 (33.3)	0	4 (8.9)
	1/6-8 days	0	0	0	1 (11.1)	1 (2.2)
	2/6-8 days	2 (16.7)	0	2 (16.7)	0	4 (8.9)
Eyes						
Abnormal	2/12-16 days	1 (8.3)	0	0	0	1 (2.2)
Heart						
Abnormal	1/1-3 days	0	0	1 (8.3)	0	1 (2.2)
Lymph nodes						
Abnormal	1/19-23 days	0	0	1 (8.3)	0	1 (2.2)
Musculoskeletal						
Abnormal	1/1-3 days	2 (16.7)	1 (8.3)	1 (8.3)	0	4 (8.9)
	2/6-8 days	0	0	1 (8.3)	0	1 (2.2)
Skin						
Abnormal	1/1-3 days	0	1 (8.3)	2 (16.7)	0	3 (6.7)
	1/6-8 days	0	0	0	1 (11.1)	1 (2.2)
	1/19-23 days	1 (8.3)	1 (8.3)	0	0	2 (4.4)
	2/6-8 days	1 (8.3)	0	0	1 (11.1)	2 (4.4)
Throat						
Abnormal	1/19-23 days	0	1 (8.3)	0	0	1 (2.2)

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (11:58)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adpe_s002_18_b1_p1

14.175. Physical Examination Findings at Baseline – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All Randomized Subjects

	Vaccine Group (as Randomized)		
	100 µg (N^a=12)	Placebo (N^a=3)	Total (N^a=15)
Body System	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	1 (8.3)	0	1 (6.7)
Abdomen			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Ears			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Extremities			
Normal	11 (91.7)	3 (100.0)	14 (93.3)
Abnormal	1 (8.3)	0	1 (6.7)
Not done	0	0	0
Eyes			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
General appearance			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Head			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Heart			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Lungs			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0

14.175. Physical Examination Findings at Baseline – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All Randomized Subjects

	Vaccine Group (as Randomized)		
	100 µg (N^a=12)	Placebo (N^a=3)	Total (N^a=15)
Body System	**n^b (%)**	**n^b (%)**	**n^b (%)**
Lymph nodes			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Musculoskeletal			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Neurological			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Nose			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Skin			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0
Throat			
Normal	12 (100.0)	3 (100.0)	15 (100.0)
Abnormal	0	0	0
Not done	0	0	0

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 21SEP2020 (22:37)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adpe_s001_18_b1_100_p1

14.176. Abnormal Physical Examination Findings From Dose 1 to 3 Weeks After Dose 1 – Phase 1 – 18-55 Years of Age – BNT162b1 (100 µg) – All Randomized Subjects

		Vaccine Group (as Randomized)		
		100 µg (N^a=12)	Placebo (N^a=3)	Total (N^a=15)
Body System	**Dose/Visit Window**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	1/1-3 days	9 (75.0)	0	9 (60.0)
Extremities				
Abnormal	1/1-3 days	7 (58.3)	0	7 (46.7)
Musculoskeletal				
Abnormal	1/1-3 days	2 (16.7)	0	2 (13.3)

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 19SEP2020 (08:12)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adpe s002 18 b1 100 p1

14.177. Physical Examination Findings at Baseline – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	2 (16.7)	0	2 (16.7)	1 (11.1)	5 (11.1)
Abdomen					
Normal	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Not done	1 (8.3)	0	0	0	1 (2.2)
Ears					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Extremities					
Normal	12 (100.0)	12 (100.0)	11 (91.7)	8 (88.9)	43 (95.6)
Abnormal	0	0	0	1 (11.1)	1 (2.2)
Not done	0	0	1 (8.3)	0	1 (2.2)
Eyes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
General appearance					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Head					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Heart					
Normal	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Abnormal	0	0	1 (8.3)	0	1 (2.2)
Lungs					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Lymph nodes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Musculoskeletal					
Normal	10 (83.3)	12 (100.0)	11 (91.7)	9 (100.0)	42 (93.3)
Abnormal	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Not done	1 (8.3)	0	0	0	1 (2.2)
Neurological					
Normal	11 (91.7)	12 (100.0)	12 (100.0)	9 (100.0)	44 (97.8)
Not done	1 (8.3)	0	0	0	1 (2.2)
Nose					
Normal	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Not done	0	0	1 (8.3)	0	1 (2.2)
Skin					
Normal	11 (91.7)	12 (100.0)	11 (91.7)	9 (100.0)	43 (95.6)

14.177. Physical Examination Findings at Baseline – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Abnormal	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Throat					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (12:01)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adpe s001 65 b1 p1

14.178. Abnormal Physical Examination Findings After Randomization – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – All Randomized Subjects

		Vaccine Group (as Randomized)				
		10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
Body System	Dose/Visit Window	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Any abnormality[c]	1/1-3 days	3 (25.0)	6 (50.0)	4 (33.3)	2 (22.2)	15 (33.3)
	1/6-8 days	1 (8.3)	1 (8.3)	1 (8.3)	1 (11.1)	4 (8.9)
	1/19-23 days	0	1 (8.3)	1 (8.3)	0	2 (4.4)
	2/6-8 days	1 (8.3)	1 (8.3)	2 (16.7)	0	4 (8.9)
	2/12-16 days	1 (8.3)	0	1 (8.3)	0	2 (4.4)
Extremities						
Abnormal	1/1-3 days	2 (16.7)	2 (16.7)	2 (16.7)	0	6 (13.3)
	1/6-8 days	1 (8.3)	0	0	0	1 (2.2)
	1/19-23 days	0	1 (8.3)	0	0	1 (2.2)
	2/6-8 days	0	1 (8.3)	1 (8.3)	0	2 (4.4)
	2/12-16 days	0	0	1 (8.3)	0	1 (2.2)
Heart						
Abnormal	1/1-3 days	1 (8.3)	0	0	0	1 (2.2)
Lymph nodes						
Abnormal	1/19-23 days	0	0	1 (8.3)	0	1 (2.2)
Musculoskeletal						
Abnormal	1/1-3 days	0	4 (33.3)	2 (16.7)	0	6 (13.3)
	1/6-8 days	0	0	1 (8.3)	0	1 (2.2)
	2/6-8 days	1 (8.3)	0	0	0	1 (2.2)
	2/12-16 days	1 (8.3)	0	0	0	1 (2.2)
Skin						
Abnormal	1/1-3 days	0	0	0	2 (22.2)	2 (4.4)
	1/6-8 days	0	1 (8.3)	1 (8.3)	1 (11.1)	3 (6.7)
	2/6-8 days	0	0	1 (8.3)	0	1 (2.2)
	2/12-16 days	0	0	1 (8.3)	0	1 (2.2)

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (11:59)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adpe s002 65 b1 p1

14.179. Physical Examination Findings at Baseline – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	0	1 (8.3)	2 (16.7)	2 (22.2)	5 (11.1)
Abdomen					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Ears					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Extremities					
Normal	12 (100.0)	11 (91.7)	12 (100.0)	8 (88.9)	43 (95.6)
Abnormal	0	1 (8.3)	0	1 (11.1)	2 (4.4)
Eyes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
General appearance					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Head					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Heart					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Lungs					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Lymph nodes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Musculoskeletal					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Neurological					
Normal	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Abnormal	0	0	1 (8.3)	0	1 (2.2)
Nose					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Skin					
Normal	12 (100.0)	12 (100.0)	11 (91.7)	8 (88.9)	43 (95.6)
Abnormal	0	0	1 (8.3)	1 (11.1)	2 (4.4)
Throat					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)

14.179. Physical Examination Findings at Baseline – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
Body System	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**	**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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (12:01)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adpe_s001_18_b2_p1

14.180. Abnormal Physical Examination Findings After Randomization – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – All Randomized Subjects

		Vaccine Group (as Randomized)				
		10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**Dose/Visit Window**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	1/1-3 days	2 (16.7)	1 (8.3)	2 (16.7)	0	5 (11.1)
	1/19-23 days	0	0	0	1 (11.1)	1 (2.2)
	2/6-8 days	1 (8.3)	2 (16.7)	1 (8.3)	0	4 (8.9)
Extremities						
Abnormal	1/1-3 days	2 (16.7)	1 (8.3)	1 (8.3)	0	4 (8.9)
Lymph nodes						
Abnormal	2/6-8 days	0	0	1 (8.3)	0	1 (2.2)
Nose						
Abnormal	2/6-8 days	1 (8.3)	0	0	0	1 (2.2)
Skin						
Abnormal	1/1-3 days	0	0	1 (8.3)	0	1 (2.2)
	1/19-23 days	0	0	0	1 (11.1)	1 (2.2)
	2/6-8 days	0	2 (16.7)	0	0	2 (4.4)
Throat						
Abnormal	2/6-8 days	1 (8.3)	0	0	0	1 (2.2)

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (11:59)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adpe_s002_18_b2_p1

14.181. Physical Examination Findings at Baseline – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All Randomized Subjects

	Vaccine Group (as Randomized)				
	10 µg (N[a]=12)	20 µg (N[a]=12)	30 µg (N[a]=12)	Placebo (N[a]=9)	Total (N[a]=45)
Body System	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**
Any abnormality[c]	0	0	1 (8.3)	0	1 (2.2)
Abdomen					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Ears					
Normal	10 (83.3)	12 (100.0)	12 (100.0)	9 (100.0)	43 (95.6)
Not done	2 (16.7)	0	0	0	2 (4.4)
Extremities					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Eyes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
General appearance					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Head					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Heart					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Lungs					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Lymph nodes					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Musculoskeletal					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Neurological					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Nose					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Skin					
Normal	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Throat					
Normal	12 (100.0)	12 (100.0)	11 (91.7)	9 (100.0)	44 (97.8)
Abnormal	0	0	1 (8.3)	0	1 (2.2)

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (12:02)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adpe_s001_65_b2_p1

14.182. Abnormal Physical Examination Findings After Randomization – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – All Randomized Subjects

		Vaccine Group (as Randomized)				
		10 µg (N^a=12)	20 µg (N^a=12)	30 µg (N^a=12)	Placebo (N^a=9)	Total (N^a=45)
Body System	**Dose/Visit Window**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**	**n^b (%)**
Any abnormality[c]	1/1-3 days	0	2 (16.7)	0	0	2 (4.4)
	1/6-8 days	0	0	0	1 (11.1)	1 (2.2)
	1/19-23 days	0	0	1 (8.3)	1 (11.1)	2 (4.4)
	2/6-8 days	1 (8.3)	0	0	0	1 (2.2)
	2/12-16 days	0	1 (8.3)	0	0	1 (2.2)
Extremities						
Abnormal	1/1-3 days	0	1 (8.3)	0	0	1 (2.2)
	1/19-23 days	0	0	1 (8.3)	0	1 (2.2)
Lymph nodes						
Abnormal	1/19-23 days	0	0	0	1 (11.1)	1 (2.2)
	2/6-8 days	1 (8.3)	0	0	0	1 (2.2)
	2/12-16 days	0	1 (8.3)	0	0	1 (2.2)
Musculoskeletal						
Abnormal	1/1-3 days	0	1 (8.3)	0	0	1 (2.2)
	1/6-8 days	0	0	0	1 (11.1)	1 (2.2)
	1/19-23 days	0	0	1 (8.3)	0	1 (2.2)

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. "Any abnormality" is defined as having at least 1 abnormal result for any of the examined body sites.
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (11:59)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adpe s002 65 b2 p1

Phase 2

Conduct of Study

14.183. Disposition of All Randomized Subjects, by Age Group – Phase 2 Age Group: 18-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=88) n[b] (%)	Placebo (N[a]=90) n[b] (%)	Total (N[a]=178) n[b] (%)
Randomized	88 (100.0)	90 (100.0)	178 (100.0)
Not vaccinated	0	0	0
Vaccinated			
Dose 1	88 (100.0)	90 (100.0)	178 (100.0)
Dose 2	87 (98.9)	90 (100.0)	177 (99.4)
Withdrawn after Dose 1 and before Dose 2	1 (1.1)	0	1 (0.6)
Withdrawn after Dose 2	0	0	0
Reason for withdrawal			
Adverse event	1 (1.1)	0	1 (0.6)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:11) Source Data: adds Table Generation: 28OCT2020 (23:31)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adds_s002_age_p2o_rand

14.184. Disposition of All Randomized Subjects, by Age Group – Phase 2 Age Group: 56-85 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=92) n^b (%)	Placebo (N^a=90) n^b (%)	Total (N^a=182) n^b (%)
Randomized	92 (100.0)	90 (100.0)	182 (100.0)
Not vaccinated	0	0	0
Vaccinated			
Dose 1	92 (100.0)	90 (100.0)	182 (100.0)
Dose 2	92 (100.0)	89 (98.9)	181 (99.5)
Withdrawn after Dose 1 and before Dose 2	0	0	0
Withdrawn after Dose 2	0	0	0

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:11) Source Data: adds Table Generation: 28OCT2020 (23:31)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adds_s002_age_p2o_rand

14.185. Vaccine as Administered by Vaccine Group – Phase 2 – All Randomized Subjects

Vaccine Group (as Administered)	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)
Vaccinated	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)
Not vaccinated	0	0	0	0
Dose 1				
BNT162b2 (30 µg)	88 (100.0)	92 (100.0)	180 (100.0)	0
Placebo	0	0	0	180 (100.0)
Dose 2				
BNT162b2 (30 µg)	87 (98.9)	92 (100.0)	179 (99.4)	0
Placebo	0	0	0	179 (99.4)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 12SEP2020 (21:51) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/advx_s002_adm_p2_rand

14.186. Vaccine Administration Timing – Phase 2 – All Randomized Subjects

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Randomized	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)
Not vaccinated	0	0	0	0
Dose 1	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)
Dose 2[c]	87 (98.9)	92 (100.0)	179 (99.4)	179 (99.4)
<19 Days	0	1 (1.1)	1 (0.6)	3 (1.7)
19 to 23 Days[d]	84 (95.5)	91 (98.9)	175 (97.2)	174 (96.7)
>23 Days	3 (3.4)	0	3 (1.7)	2 (1.1)

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.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 12SEP2020 (21:52) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2 unblinded/C4591001 IA P2/advx s002 time p2 rand

14.187. Immunogenicity Populations – Phase 2

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years n[a] (%)	56-85 Years n[a] (%)	18-85 Years n[a] (%)	18-85 Years n[a] (%)	Total n[a] (%)
Randomized[b]	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)	360 (100.0)
Dose 2 all-available immunogenicity population	85 (96.6)	91 (98.9)	176 (97.8)	176 (97.8)	352 (97.8)
Subjects excluded from Dose 2 all-available immunogenicity population	3 (3.4)	1 (1.1)	4 (2.2)	4 (2.2)	8 (2.2)
Reason for exclusion					
Did not receive Dose 2	1 (1.1)	0	1 (0.6)	0	1 (0.3)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	2 (2.3)	1 (1.1)	3 (1.7)	4 (2.2)	7 (1.9)
Dose 2 evaluable immunogenicity population	80 (90.9)	89 (96.7)	169 (93.9)	167 (92.8)	336 (93.3)
Subjects excluded from Dose 2 evaluable immunogenicity population	8 (9.1)	3 (3.3)	11 (6.1)	13 (7.2)	24 (6.7)
Reason for exclusion[c]					
Did not receive 2 doses of the vaccine to which they are randomly assigned	1 (1.1)	0	1 (0.6)	0	1 (0.3)
Did not receive Dose 2 within 19-42 days after Dose 1	0	1 (1.1)	1 (0.6)	4 (2.2)	5 (1.4)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	2 (2.3)	1 (1.1)	3 (1.7)	4 (2.2)	7 (1.9)
Did not have blood collection within 28-42 days after Dose 2	5 (5.7)	2 (2.2)	7 (3.9)	7 (3.9)	14 (3.9)
Had important protocol deviation(s) as determined by the clinician	0	0	0	1 (0.6)	1 (0.3)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.

PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adsl Table Generation: 12NOV2020 (02:19)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s008 imm pop p2

14.188. Demographic Characteristics, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=88) n[b] (%)	Placebo (N[a]=90) n[b] (%)	Total (N[a]=178) n[b] (%)
Sex			
Male	46 (52.3)	48 (53.3)	94 (52.8)
Female	42 (47.7)	42 (46.7)	84 (47.2)
Race			
White	72 (81.8)	71 (78.9)	143 (80.3)
Black or African American	9 (10.2)	12 (13.3)	21 (11.8)
American Indian or Alaska native	0	1 (1.1)	1 (0.6)
Asian	5 (5.7)	4 (4.4)	9 (5.1)
Multiracial	1 (1.1)	1 (1.1)	2 (1.1)
Not reported	1 (1.1)	1 (1.1)	2 (1.1)
Ethnicity			
Hispanic/Latino	13 (14.8)	19 (21.1)	32 (18.0)
Non-Hispanic/non-Latino	74 (84.1)	70 (77.8)	144 (80.9)
Not reported	1 (1.1)	1 (1.1)	2 (1.1)
Age at vaccination (years)			
Mean (SD)	41.4 (10.30)	37.9 (10.47)	39.6 (10.50)
Median	44.0	38.0	42.0
Min, max	(18, 55)	(20, 55)	(18, 55)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 28OCT2020 (23:20)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2/adsl s005 demo age p2 saf

14.189. Demographic Characteristics, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=92) n[b] (%)	Placebo (N[a]=90) n[b] (%)	Total (N[a]=182) n[b] (%)
Sex			
Male	50 (54.3)	46 (51.1)	96 (52.7)
Female	42 (45.7)	44 (48.9)	86 (47.3)
Race			
White	85 (92.4)	81 (90.0)	166 (91.2)
Black or African American	3 (3.3)	9 (10.0)	12 (6.6)
American Indian or Alaska native	1 (1.1)	0	1 (0.5)
Asian	0	0	0
Multiracial	1 (1.1)	0	1 (0.5)
Not reported	2 (2.2)	0	2 (1.1)
Ethnicity			
Hispanic/Latino	3 (3.3)	1 (1.1)	4 (2.2)
Non-Hispanic/non-Latino	88 (95.7)	88 (97.8)	176 (96.7)
Not reported	1 (1.1)	1 (1.1)	2 (1.1)
Age at vaccination (years)			
Mean (SD)	65.9 (6.53)	64.7 (6.01)	65.3 (6.29)
Median	65.0	64.0	64.0
Min, max	(56, 85)	(56, 83)	(56, 85)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 28OCT2020 (23:20)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2/adsl s005 demo age p2 saf

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Any medical history	78 (88.6)	86 (93.5)	164 (91.1)	160 (88.9)
Blood and lymphatic system disorders	0	2 (2.2)	2 (1.1)	6 (3.3)
Anaemia	0	0	0	6 (3.3)
Immune thrombocytopenia	0	1 (1.1)	1 (0.6)	0
Leukopenia	0	1 (1.1)	1 (0.6)	0
Cardiac disorders	2 (2.3)	13 (14.1)	15 (8.3)	11 (6.1)
Angina pectoris	0	0	0	2 (1.1)
Aortic valve stenosis	0	1 (1.1)	1 (0.6)	0
Arrhythmia	0	0	0	1 (0.6)
Atrial fibrillation	0	2 (2.2)	2 (1.1)	3 (1.7)
Bundle branch block right	1 (1.1)	0	1 (0.6)	0
Coronary artery disease	0	4 (4.3)	4 (2.2)	2 (1.1)
Coronary artery dissection	0	1 (1.1)	1 (0.6)	0
Coronary artery occlusion	0	2 (2.2)	2 (1.1)	0
Extrasystoles	0	0	0	1 (0.6)
Mitral valve prolapse	0	1 (1.1)	1 (0.6)	1 (0.6)
Myocardial infarction	0	3 (3.3)	3 (1.7)	2 (1.1)
Palpitations	1 (1.1)	0	1 (0.6)	1 (0.6)
Sinus arrhythmia	0	1 (1.1)	1 (0.6)	0
Congenital, familial and genetic disorders	2 (2.3)	2 (2.2)	4 (2.2)	7 (3.9)
Congenital cystic kidney disease	0	0	0	1 (0.6)
Corneal dystrophy	0	1 (1.1)	1 (0.6)	2 (1.1)
Factor V Leiden mutation	0	0	0	2 (1.1)
Gilbert's syndrome	0	0	0	1 (0.6)
Hydrocele	1 (1.1)	0	1 (0.6)	0
Pectus excavatum	0	1 (1.1)	1 (0.6)	0
Sickle cell trait	1 (1.1)	0	1 (0.6)	0
Thalassaemia alpha	0	0	0	1 (0.6)
Ear and labyrinth disorders	0	8 (8.7)	8 (4.4)	13 (7.2)
Cerumen impaction	0	1 (1.1)	1 (0.6)	1 (0.6)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Deafness	0	1 (1.1)	1 (0.6)	2 (1.1)
Deafness bilateral	0	1 (1.1)	1 (0.6)	2 (1.1)
Deafness unilateral	0	1 (1.1)	1 (0.6)	0
Ear pain	0	0	0	1 (0.6)
Hypoacusis	0	1 (1.1)	1 (0.6)	0
Meniere's disease	0	0	0	1 (0.6)
Tinnitus	0	2 (2.2)	2 (1.1)	4 (2.2)
Vertigo	0	1 (1.1)	1 (0.6)	2 (1.1)
Vertigo positional	0	0	0	1 (0.6)
Endocrine disorders	2 (2.3)	12 (13.0)	14 (7.8)	15 (8.3)
Goitre	0	0	0	1 (0.6)
Hyperthyroidism	0	0	0	1 (0.6)
Hypogonadism	1 (1.1)	0	1 (0.6)	0
Hypogonadism male	0	1 (1.1)	1 (0.6)	0
Hypothyroidism	1 (1.1)	10 (10.9)	11 (6.1)	14 (7.8)
Thyroid mass	0	1 (1.1)	1 (0.6)	0
Eye disorders	16 (18.2)	26 (28.3)	42 (23.3)	41 (22.8)
Amblyopia	1 (1.1)	0	1 (0.6)	1 (0.6)
Astigmatism	1 (1.1)	3 (3.3)	4 (2.2)	5 (2.8)
Blindness unilateral	0	0	0	2 (1.1)
Borderline glaucoma	0	1 (1.1)	1 (0.6)	0
Cataract	1 (1.1)	8 (8.7)	9 (5.0)	7 (3.9)
Cataract cortical	0	0	0	1 (0.6)
Dry eye	0	2 (2.2)	2 (1.1)	3 (1.7)
Eye allergy	1 (1.1)	0	1 (0.6)	0
Glaucoma	1 (1.1)	2 (2.2)	3 (1.7)	4 (2.2)
Hypermetropia	2 (2.3)	10 (10.9)	12 (6.7)	5 (2.8)
Maculopathy	1 (1.1)	0	1 (0.6)	0
Meibomian gland dysfunction	1 (1.1)	0	1 (0.6)	0
Myopia	12 (13.6)	7 (7.6)	19 (10.6)	21 (11.7)
Myopic chorioretinal degeneration	0	1 (1.1)	1 (0.6)	0
Presbyopia	2 (2.3)	4 (4.3)	6 (3.3)	4 (2.2)
Pupils unequal	0	0	0	1 (0.6)
Retinal detachment	0	0	0	2 (1.1)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Retinal scar	0	1 (1.1)	1 (0.6)	0
Retinal tear	1 (1.1)	1 (1.1)	2 (1.1)	0
Retinal vein thrombosis	0	0	0	1 (0.6)
Strabismus	0	0	0	1 (0.6)
Gastrointestinal disorders	19 (21.6)	23 (25.0)	42 (23.3)	32 (17.8)
Abdominal hernia	0	1 (1.1)	1 (0.6)	0
Constipation	2 (2.3)	2 (2.2)	4 (2.2)	3 (1.7)
Crohn's disease	0	2 (2.2)	2 (1.1)	0
Diarrhoea	1 (1.1)	0	1 (0.6)	0
Diverticulum	0	0	0	2 (1.1)
Duodenogastric reflux	0	0	0	1 (0.6)
Dyspepsia	2 (2.3)	1 (1.1)	3 (1.7)	4 (2.2)
Gastric ulcer	0	0	0	1 (0.6)
Gastric ulcer haemorrhage	0	1 (1.1)	1 (0.6)	0
Gastrooesophageal reflux disease	13 (14.8)	10 (10.9)	23 (12.8)	14 (7.8)
Haemorrhoids	1 (1.1)	1 (1.1)	2 (1.1)	4 (2.2)
Hiatus hernia	0	0	0	1 (0.6)
Inguinal hernia	0	2 (2.2)	2 (1.1)	1 (0.6)
Intestinal polyp	0	1 (1.1)	1 (0.6)	0
Irritable bowel syndrome	2 (2.3)	2 (2.2)	4 (2.2)	4 (2.2)
Large intestine polyp	0	2 (2.2)	2 (1.1)	2 (1.1)
Mouth ulceration	0	0	0	1 (0.6)
Nausea	0	0	0	1 (0.6)
Pancreatic cyst	0	2 (2.2)	2 (1.1)	0
Pancreatitis	0	1 (1.1)	1 (0.6)	0
Proctitis	0	0	0	1 (0.6)
Reflux gastritis	1 (1.1)	0	1 (0.6)	0
Tooth impacted	1 (1.1)	0	1 (0.6)	0
Umbilical hernia	0	0	0	1 (0.6)
General disorders and administration site conditions	4 (4.5)	3 (3.3)	7 (3.9)	6 (3.3)
Asthenia	0	0	0	1 (0.6)
Chronic fatigue syndrome	1 (1.1)	0	1 (0.6)	0
Fatigue	0	1 (1.1)	1 (0.6)	1 (0.6)
Hernia	2 (2.3)	1 (1.1)	3 (1.7)	1 (0.6)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Malaise	0	0	0	1 (0.6)
Oedema	0	1 (1.1)	1 (0.6)	1 (0.6)
Pain	0	0	0	1 (0.6)
Peripheral swelling	1 (1.1)	0	1 (0.6)	2 (1.1)
Hepatobiliary disorders	5 (5.7)	7 (7.6)	12 (6.7)	9 (5.0)
Cholecystitis	2 (2.3)	3 (3.3)	5 (2.8)	2 (1.1)
Cholelithiasis	1 (1.1)	3 (3.3)	4 (2.2)	5 (2.8)
Gallbladder disorder	0	1 (1.1)	1 (0.6)	0
Hepatic steatosis	2 (2.3)	0	2 (1.1)	1 (0.6)
Nonalcoholic fatty liver disease	0	0	0	1 (0.6)
Immune system disorders	30 (34.1)	33 (35.9)	63 (35.0)	72 (40.0)
Allergy to animal	1 (1.1)	0	1 (0.6)	4 (2.2)
Allergy to arthropod sting	0	0	0	1 (0.6)
Allergy to chemicals	0	0	0	1 (0.6)
Drug hypersensitivity	12 (13.6)	13 (14.1)	25 (13.9)	19 (10.6)
Dust allergy	0	0	0	1 (0.6)
Food allergy	1 (1.1)	2 (2.2)	3 (1.7)	6 (3.3)
Hypersensitivity	0	1 (1.1)	1 (0.6)	3 (1.7)
Iodine allergy	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Milk allergy	0	0	0	1 (0.6)
Mycotic allergy	0	0	0	1 (0.6)
Rubber sensitivity	0	2 (2.2)	2 (1.1)	2 (1.1)
Seasonal allergy	21 (23.9)	21 (22.8)	42 (23.3)	53 (29.4)
Infections and infestations	18 (20.5)	18 (19.6)	36 (20.0)	25 (13.9)
Adenoiditis	1 (1.1)	0	1 (0.6)	0
Appendicitis	5 (5.7)	8 (8.7)	13 (7.2)	7 (3.9)
Bacterial tracheitis	1 (1.1)	0	1 (0.6)	0
Bacterial vaginosis	1 (1.1)	0	1 (0.6)	0
Chronic sinusitis	0	1 (1.1)	1 (0.6)	0
Diverticulitis	0	1 (1.1)	1 (0.6)	1 (0.6)
Ear infection	0	1 (1.1)	1 (0.6)	0
Epididymitis	1 (1.1)	0	1 (0.6)	0
Fungal skin infection	1 (1.1)	0	1 (0.6)	1 (0.6)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)
Gastroenteritis	0	0	0	1 (0.6)
Herpes simplex	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Herpes virus infection	1 (1.1)	0	1 (0.6)	0
Herpes zoster	0	0	0	2 (1.1)
Hordeolum	1 (1.1)	0	1 (0.6)	0
Measles	0	0	0	1 (0.6)
Onychomycosis	0	0	0	4 (2.2)
Oral herpes	0	0	0	1 (0.6)
Otitis media	1 (1.1)	0	1 (0.6)	0
Pneumonia	0	0	0	1 (0.6)
Postoperative wound infection	0	0	0	1 (0.6)
Rhinitis	0	2 (2.2)	2 (1.1)	0
Sinusitis	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Staphylococcal infection	0	0	0	1 (0.6)
Tinea pedis	1 (1.1)	0	1 (0.6)	0
Tonsillitis	4 (4.5)	5 (5.4)	9 (5.0)	6 (3.3)
Tuberculosis	1 (1.1)	0	1 (0.6)	0
Upper respiratory tract infection	0	1 (1.1)	1 (0.6)	0
Urinary tract infection	0	1 (1.1)	1 (0.6)	1 (0.6)
Varicella	0	1 (1.1)	1 (0.6)	1 (0.6)
Injury, poisoning and procedural complications	7 (8.0)	16 (17.4)	23 (12.8)	17 (9.4)
Ankle fracture	0	2 (2.2)	2 (1.1)	1 (0.6)
Back injury	0	0	0	1 (0.6)
Craniocerebral injury	0	1 (1.1)	1 (0.6)	1 (0.6)
Epicondylitis	0	0	0	1 (0.6)
Eye injury	0	0	0	1 (0.6)
Femur fracture	0	0	0	1 (0.6)
Foot fracture	3 (3.4)	1 (1.1)	4 (2.2)	1 (0.6)
Glaucoma traumatic	0	1 (1.1)	1 (0.6)	0
Hand fracture	0	1 (1.1)	1 (0.6)	1 (0.6)
Head injury	0	0	0	1 (0.6)
Hip fracture	0	1 (1.1)	1 (0.6)	0
Humerus fracture	0	0	0	1 (0.6)
Ligament rupture	1 (1.1)	1 (1.1)	2 (1.1)	0
Limb injury	0	1 (1.1)	1 (0.6)	0

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Limb traumatic amputation	0	0	0	1 (0.6)
Lower limb fracture	0	1 (1.1)	1 (0.6)	0
Meniscus injury	1 (1.1)	1 (1.1)	2 (1.1)	3 (1.7)
Nerve injury	0	1 (1.1)	1 (0.6)	0
Radius fracture	0	0	0	1 (0.6)
Skeletal injury	0	1 (1.1)	1 (0.6)	2 (1.1)
Skin laceration	1 (1.1)	0	1 (0.6)	0
Spinal compression fracture	0	0	0	1 (0.6)
Tendon injury	0	1 (1.1)	1 (0.6)	1 (0.6)
Tendon rupture	0	1 (1.1)	1 (0.6)	0
Upper limb fracture	1 (1.1)	2 (2.2)	3 (1.7)	2 (1.1)
Wrist fracture	0	2 (2.2)	2 (1.1)	1 (0.6)
Investigations	6 (6.8)	18 (19.6)	24 (13.3)	26 (14.4)
Arthroscopy	0	0	0	3 (1.7)
Biopsy breast	0	0	0	1 (0.6)
Biopsy prostate	0	1 (1.1)	1 (0.6)	0
Blood cholesterol increased	2 (2.3)	9 (9.8)	11 (6.1)	14 (7.8)
Blood testosterone decreased	1 (1.1)	2 (2.2)	3 (1.7)	0
Blood triglycerides increased	0	2 (2.2)	2 (1.1)	2 (1.1)
Cardiac murmur	1 (1.1)	2 (2.2)	3 (1.7)	1 (0.6)
Cardiac murmur functional	0	1 (1.1)	1 (0.6)	0
Colonoscopy	2 (2.3)	0	2 (1.1)	2 (1.1)
Electrocardiogram ST segment depression	1 (1.1)	0	1 (0.6)	0
Electrocardiogram abnormal	0	1 (1.1)	1 (0.6)	0
Endoscopy	1 (1.1)	0	1 (0.6)	1 (0.6)
Endoscopy gastrointestinal	0	0	0	1 (0.6)
Heart rate increased	0	0	0	1 (0.6)
Heart rate irregular	0	2 (2.2)	2 (1.1)	0
Hepatic enzyme increased	0	0	0	1 (0.6)
Staphylococcus test positive	0	0	0	1 (0.6)
Stool analysis abnormal	0	1 (1.1)	1 (0.6)	0
Vitamin D decreased	0	1 (1.1)	1 (0.6)	1 (0.6)
Metabolism and nutrition disorders	22 (25.0)	39 (42.4)	61 (33.9)	51 (28.3)
Dyslipidaemia	0	2 (2.2)	2 (1.1)	1 (0.6)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Glucose tolerance impaired	0	2 (2.2)	2 (1.1)	2 (1.1)
Gout	0	2 (2.2)	2 (1.1)	1 (0.6)
Hypercholesterolaemia	4 (4.5)	14 (15.2)	18 (10.0)	18 (10.0)
Hyperlipidaemia	4 (4.5)	10 (10.9)	14 (7.8)	8 (4.4)
Hypoglycaemia	0	0	0	1 (0.6)
Hypokalaemia	0	1 (1.1)	1 (0.6)	0
Hypolipidaemia	0	0	0	1 (0.6)
Lactose intolerance	1 (1.1)	3 (3.3)	4 (2.2)	0
Magnesium deficiency	0	1 (1.1)	1 (0.6)	0
Obesity	7 (8.0)	1 (1.1)	8 (4.4)	8 (4.4)
Overweight	2 (2.3)	2 (2.2)	4 (2.2)	4 (2.2)
Type 2 diabetes mellitus	4 (4.5)	14 (15.2)	18 (10.0)	17 (9.4)
Vitamin B12 deficiency	2 (2.3)	0	2 (1.1)	3 (1.7)
Vitamin D deficiency	4 (4.5)	3 (3.3)	7 (3.9)	3 (1.7)
Musculoskeletal and connective tissue disorders	17 (19.3)	40 (43.5)	57 (31.7)	54 (30.0)
Arthralgia	0	1 (1.1)	1 (0.6)	4 (2.2)
Arthritis	2 (2.3)	4 (4.3)	6 (3.3)	4 (2.2)
Back pain	7 (8.0)	4 (4.3)	11 (6.1)	14 (7.8)
Diastasis recti abdominis	0	1 (1.1)	1 (0.6)	0
Exostosis	0	1 (1.1)	1 (0.6)	3 (1.7)
Femoroacetabular impingement	1 (1.1)	0	1 (0.6)	0
Fibromyalgia	3 (3.4)	0	3 (1.7)	2 (1.1)
Foot deformity	1 (1.1)	1 (1.1)	2 (1.1)	0
Intervertebral disc compression	0	1 (1.1)	1 (0.6)	0
Intervertebral disc degeneration	2 (2.3)	1 (1.1)	3 (1.7)	1 (0.6)
Intervertebral disc protrusion	1 (1.1)	1 (1.1)	2 (1.1)	4 (2.2)
Joint range of motion decreased	0	0	0	1 (0.6)
Muscle spasms	0	1 (1.1)	1 (0.6)	2 (1.1)
Musculoskeletal pain	1 (1.1)	1 (1.1)	2 (1.1)	3 (1.7)
Myalgia	1 (1.1)	1 (1.1)	2 (1.1)	0
Neck pain	2 (2.3)	1 (1.1)	3 (1.7)	2 (1.1)
Osteoarthritis	4 (4.5)	16 (17.4)	20 (11.1)	22 (12.2)
Osteopenia	0	4 (4.3)	4 (2.2)	5 (2.8)
Osteoporosis	0	6 (6.5)	6 (3.3)	4 (2.2)
Pain in extremity	0	0	0	1 (0.6)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Plantar fasciitis	0	1 (1.1)	1 (0.6)	0
Rheumatoid arthritis	0	1 (1.1)	1 (0.6)	0
Rotator cuff syndrome	0	3 (3.3)	3 (1.7)	6 (3.3)
Scoliosis	1 (1.1)	0	1 (0.6)	1 (0.6)
Spinal disorder	1 (1.1)	0	1 (0.6)	0
Spinal osteoarthritis	0	0	0	2 (1.1)
Spinal stenosis	0	0	0	1 (0.6)
Spondylitis	0	1 (1.1)	1 (0.6)	1 (0.6)
Spondylolisthesis	1 (1.1)	0	1 (0.6)	0
Synovial cyst	0	1 (1.1)	1 (0.6)	1 (0.6)
Temporomandibular joint syndrome	0	0	0	2 (1.1)
Tendonitis	0	1 (1.1)	1 (0.6)	1 (0.6)
Trigger finger	1 (1.1)	0	1 (0.6)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (3.4)	18 (19.6)	21 (11.7)	22 (12.2)
Acoustic neuroma	0	1 (1.1)	1 (0.6)	0
Basal cell carcinoma	0	5 (5.4)	5 (2.8)	4 (2.2)
Benign breast neoplasm	0	0	0	1 (0.6)
Bladder cancer	0	0	0	1 (0.6)
Breast cancer	0	2 (2.2)	2 (1.1)	1 (0.6)
Colon cancer	0	2 (2.2)	2 (1.1)	0
Gastrointestinal stromal tumour	0	0	0	1 (0.6)
Lipoma	0	1 (1.1)	1 (0.6)	0
Malignant melanoma	0	1 (1.1)	1 (0.6)	2 (1.1)
Meningioma benign	0	1 (1.1)	1 (0.6)	0
Ovarian cancer	0	1 (1.1)	1 (0.6)	0
Ovarian neoplasm	0	0	0	1 (0.6)
Phyllodes tumour	1 (1.1)	0	1 (0.6)	0
Prostate cancer	0	1 (1.1)	1 (0.6)	1 (0.6)
Seborrhoeic keratosis	0	0	0	1 (0.6)
Skin cancer	0	0	0	1 (0.6)
Skin papilloma	0	1 (1.1)	1 (0.6)	1 (0.6)
Squamous cell carcinoma of skin	0	2 (2.2)	2 (1.1)	1 (0.6)
Testis cancer	0	0	0	1 (0.6)
Uterine cancer	0	1 (1.1)	1 (0.6)	1 (0.6)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Uterine leiomyoma	3 (3.4)	3 (3.3)	6 (3.3)	5 (2.8)
Nervous system disorders	17 (19.3)	19 (20.7)	36 (20.0)	31 (17.2)
Amnesia	0	0	0	1 (0.6)
Carotid artery occlusion	0	1 (1.1)	1 (0.6)	0
Carpal tunnel syndrome	2 (2.3)	2 (2.2)	4 (2.2)	1 (0.6)
Central auditory processing disorder	1 (1.1)	0	1 (0.6)	0
Cerebrovascular accident	2 (2.3)	1 (1.1)	3 (1.7)	0
Cluster headache	0	0	0	1 (0.6)
Complex regional pain syndrome	0	1 (1.1)	1 (0.6)	0
Diabetic neuropathy	1 (1.1)	1 (1.1)	2 (1.1)	2 (1.1)
Epilepsy	0	1 (1.1)	1 (0.6)	1 (0.6)
Essential tremor	0	1 (1.1)	1 (0.6)	0
Facial paralysis	0	0	0	2 (1.1)
Headache	2 (2.3)	1 (1.1)	3 (1.7)	6 (3.3)
Hypersomnia	0	1 (1.1)	1 (0.6)	0
Hypoaesthesia	1 (1.1)	1 (1.1)	2 (1.1)	0
Hypoxic-ischaemic encephalopathy	0	0	0	1 (0.6)
Migraine	10 (11.4)	4 (4.3)	14 (7.8)	13 (7.2)
Nerve compression	1 (1.1)	0	1 (0.6)	1 (0.6)
Neuralgia	1 (1.1)	0	1 (0.6)	0
Neuropathy peripheral	0	1 (1.1)	1 (0.6)	4 (2.2)
Paraesthesia	0	1 (1.1)	1 (0.6)	0
Restless legs syndrome	0	0	0	2 (1.1)
Seizure	0	2 (2.2)	2 (1.1)	0
Syncope	1 (1.1)	0	1 (0.6)	0
Tension headache	1 (1.1)	1 (1.1)	2 (1.1)	0
Tremor	0	0	0	1 (0.6)
Writer's cramp	0	1 (1.1)	1 (0.6)	0
Pregnancy, puerperium and perinatal conditions	0	0	0	1 (0.6)
Ectopic pregnancy	0	0	0	1 (0.6)
Psychiatric disorders	29 (33.0)	20 (21.7)	49 (27.2)	43 (23.9)
Adjustment disorder with depressed mood	0	1 (1.1)	1 (0.6)	0
Alcoholism	1 (1.1)	1 (1.1)	2 (1.1)	0

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Anxiety	17 (19.3)	3 (3.3)	20 (11.1)	19 (10.6)
Attention deficit hyperactivity disorder	6 (6.8)	2 (2.2)	8 (4.4)	3 (1.7)
Bipolar disorder	2 (2.3)	0	2 (1.1)	2 (1.1)
Depression	8 (9.1)	9 (9.8)	17 (9.4)	17 (9.4)
Generalised anxiety disorder	0	0	0	1 (0.6)
Insomnia	9 (10.2)	11 (12.0)	20 (11.1)	14 (7.8)
Libido decreased	1 (1.1)	0	1 (0.6)	2 (1.1)
Major depression	1 (1.1)	0	1 (0.6)	2 (1.1)
Obsessive-compulsive disorder	0	0	0	1 (0.6)
Panic attack	1 (1.1)	0	1 (0.6)	1 (0.6)
Panic disorder	1 (1.1)	0	1 (0.6)	0
Perinatal depression	1 (1.1)	0	1 (0.6)	0
Persistent depressive disorder	0	0	0	1 (0.6)
Post-traumatic stress disorder	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Premature ejaculation	0	0	0	1 (0.6)
Renal and urinary disorders	7 (8.0)	8 (8.7)	15 (8.3)	8 (4.4)
Bladder perforation	0	0	0	1 (0.6)
Bladder prolapse	1 (1.1)	0	1 (0.6)	0
Chronic kidney disease	0	0	0	1 (0.6)
Dysuria	1 (1.1)	0	1 (0.6)	0
Hydronephrosis	1 (1.1)	0	1 (0.6)	0
Hypertonic bladder	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Micturition disorder	0	0	0	2 (1.1)
Nephrolithiasis	2 (2.3)	6 (6.5)	8 (4.4)	4 (2.2)
Nocturia	1 (1.1)	0	1 (0.6)	1 (0.6)
Renal cyst	0	1 (1.1)	1 (0.6)	0
Stress urinary incontinence	0	1 (1.1)	1 (0.6)	0
Reproductive system and breast disorders	10 (11.4)	16 (17.4)	26 (14.4)	18 (10.0)
Amenorrhoea	1 (1.1)	0	1 (0.6)	0
Benign prostatic hyperplasia	0	8 (8.7)	8 (4.4)	5 (2.8)
Colpocele	0	0	0	1 (0.6)
Endometriosis	1 (1.1)	1 (1.1)	2 (1.1)	2 (1.1)
Erectile dysfunction	2 (2.3)	4 (4.3)	6 (3.3)	4 (2.2)
Fibrocystic breast disease	1 (1.1)	0	1 (0.6)	0

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Infertility	0	0	0	1 (0.6)
Menopausal symptoms	0	1 (1.1)	1 (0.6)	0
Menorrhagia	0	1 (1.1)	1 (0.6)	1 (0.6)
Ovarian cyst	3 (3.4)	0	3 (1.7)	2 (1.1)
Premenstrual syndrome	1 (1.1)	0	1 (0.6)	0
Prostatitis	0	0	0	1 (0.6)
Prostatomegaly	0	4 (4.3)	4 (2.2)	1 (0.6)
Uterine cyst	0	0	0	1 (0.6)
Uterine prolapse	0	0	0	1 (0.6)
Vulvovaginal dryness	1 (1.1)	0	1 (0.6)	1 (0.6)
Respiratory, thoracic and mediastinal disorders	17 (19.3)	10 (10.9)	27 (15.0)	27 (15.0)
Asthma	5 (5.7)	4 (4.3)	9 (5.0)	14 (7.8)
Asthma exercise induced	4 (4.5)	0	4 (2.2)	0
Bronchial hyperreactivity	0	0	0	1 (0.6)
Bronchiectasis	0	0	0	1 (0.6)
Bronchitis chronic	0	0	0	1 (0.6)
Childhood asthma	1 (1.1)	0	1 (0.6)	0
Chronic obstructive pulmonary disease	0	2 (2.2)	2 (1.1)	1 (0.6)
Nasal septum deviation	2 (2.3)	1 (1.1)	3 (1.7)	0
Pneumonia aspiration	0	0	0	1 (0.6)
Rhinitis allergic	0	2 (2.2)	2 (1.1)	2 (1.1)
Rhinitis perennial	0	0	0	1 (0.6)
Sinus congestion	1 (1.1)	0	1 (0.6)	0
Sleep apnoea syndrome	4 (4.5)	2 (2.2)	6 (3.3)	8 (4.4)
Skin and subcutaneous tissue disorders	11 (12.5)	7 (7.6)	18 (10.0)	17 (9.4)
Acne	3 (3.4)	0	3 (1.7)	3 (1.7)
Alopecia	1 (1.1)	0	1 (0.6)	2 (1.1)
Androgenetic alopecia	0	0	0	1 (0.6)
Dermatitis	1 (1.1)	0	1 (0.6)	0
Dermatitis contact	0	0	0	1 (0.6)
Dry skin	0	1 (1.1)	1 (0.6)	0
Eczema	4 (4.5)	1 (1.1)	5 (2.8)	5 (2.8)
Lipodystrophy acquired	0	1 (1.1)	1 (0.6)	0
Palmoplantar keratoderma	1 (1.1)	0	1 (0.6)	0

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Panniculitis	0	1 (1.1)	1 (0.6)	0
Pruritus	0	1 (1.1)	1 (0.6)	0
Psoriasis	0	0	0	1 (0.6)
Rash	0	1 (1.1)	1 (0.6)	0
Rosacea	1 (1.1)	1 (1.1)	2 (1.1)	2 (1.1)
Scab	0	0	0	1 (0.6)
Urticaria	0	0	0	1 (0.6)
Vitiligo	0	1 (1.1)	1 (0.6)	0
Social circumstances	9 (10.2)	24 (26.1)	33 (18.3)	28 (15.6)
Corrective lens user	3 (3.4)	3 (3.3)	6 (3.3)	7 (3.9)
Ex-tobacco user	0	2 (2.2)	2 (1.1)	3 (1.7)
Menopause	1 (1.1)	0	1 (0.6)	2 (1.1)
Postmenopause	4 (4.5)	20 (21.7)	24 (13.3)	18 (10.0)
Tobacco user	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Surgical and medical procedures	41 (46.6)	48 (52.2)	89 (49.4)	76 (42.2)
Abdominal hernia repair	0	1 (1.1)	1 (0.6)	0
Acoustic neuroma removal	0	1 (1.1)	1 (0.6)	0
Adenoidectomy	4 (4.5)	0	4 (2.2)	1 (0.6)
Adenotonsillectomy	0	0	0	1 (0.6)
Ankle operation	1 (1.1)	2 (2.2)	3 (1.7)	0
Aortic valve replacement	0	1 (1.1)	1 (0.6)	0
Appendicectomy	5 (5.7)	6 (6.5)	11 (6.1)	8 (4.4)
Arterial repair	0	1 (1.1)	1 (0.6)	0
Bladder repair	1 (1.1)	0	1 (0.6)	1 (0.6)
Bone lesion excision	0	1 (1.1)	1 (0.6)	1 (0.6)
Bone operation	0	1 (1.1)	1 (0.6)	0
Breast conserving surgery	0	2 (2.2)	2 (1.1)	0
Breast tumour excision	1 (1.1)	0	1 (0.6)	0
Bunion operation	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Caesarean section	2 (2.3)	1 (1.1)	3 (1.7)	3 (1.7)
Carpal tunnel decompression	1 (1.1)	2 (2.2)	3 (1.7)	1 (0.6)
Cataract operation	0	1 (1.1)	1 (0.6)	0
Cheilectomy	0	0	0	1 (0.6)
Cholecystectomy	4 (4.5)	9 (9.8)	13 (7.2)	9 (5.0)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Chondroplasty	0	0	0	1 (0.6)
Colectomy	0	1 (1.1)	1 (0.6)	0
Colostomy	0	1 (1.1)	1 (0.6)	0
Corneal operation	0	1 (1.1)	1 (0.6)	0
Coronary arterial stent insertion	0	4 (4.3)	4 (2.2)	5 (2.8)
Coronary artery bypass	0	2 (2.2)	2 (1.1)	1 (0.6)
Dupuytren's contracture operation	0	0	0	1 (0.6)
Ear tube insertion	1 (1.1)	0	1 (0.6)	0
Ear tube removal	1 (1.1)	0	1 (0.6)	1 (0.6)
Elbow operation	0	0	0	2 (1.1)
Endometrial ablation	0	1 (1.1)	1 (0.6)	0
External fixation of fracture	1 (1.1)	0	1 (0.6)	0
Eyelid operation	0	0	0	1 (0.6)
Female sterilisation	4 (4.5)	1 (1.1)	5 (2.8)	6 (3.3)
Fracture treatment	1 (1.1)	1 (1.1)	2 (1.1)	3 (1.7)
Gallbladder operation	0	0	0	1 (0.6)
Gastrectomy	1 (1.1)	1 (1.1)	2 (1.1)	2 (1.1)
Gastric banding	1 (1.1)	0	1 (0.6)	0
Gastric bypass	1 (1.1)	1 (1.1)	2 (1.1)	2 (1.1)
Gastroplasty	0	0	0	1 (0.6)
Glaucoma surgery	0	1 (1.1)	1 (0.6)	0
Haemorrhoid operation	0	0	0	1 (0.6)
Hernia hiatus repair	0	0	0	1 (0.6)
Hernia repair	2 (2.3)	1 (1.1)	3 (1.7)	5 (2.8)
Hip arthroplasty	0	0	0	2 (1.1)
Hip surgery	0	1 (1.1)	1 (0.6)	0
Hysterectomy	5 (5.7)	7 (7.6)	12 (6.7)	15 (8.3)
Inguinal hernia repair	0	1 (1.1)	1 (0.6)	1 (0.6)
Intervertebral disc operation	1 (1.1)	0	1 (0.6)	2 (1.1)
Intra-uterine contraceptive device insertion	0	0	0	1 (0.6)
Jaw operation	0	0	0	1 (0.6)
Keratomileusis	1 (1.1)	2 (2.2)	3 (1.7)	1 (0.6)
Knee arthroplasty	0	3 (3.3)	3 (1.7)	4 (2.2)
Lens extraction	0	1 (1.1)	1 (0.6)	0
Ligament operation	1 (1.1)	0	1 (0.6)	2 (1.1)
Limb operation	1 (1.1)	0	1 (0.6)	2 (1.1)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N^a=88) n^b (%)	56-85 Years (N^a=92) n^b (%)	18-85 Years (N^a=180) n^b (%)	18-85 Years (N^a=180) n^b (%)
Lipoma excision	0	1 (1.1)	1 (0.6)	0
Liposuction	0	0	0	1 (0.6)
Lithotomy position	0	0	0	1 (0.6)
Lithotripsy	0	1 (1.1)	1 (0.6)	0
Lymphadenectomy	0	0	0	1 (0.6)
Mammoplasty	0	1 (1.1)	1 (0.6)	2 (1.1)
Meniscus operation	1 (1.1)	0	1 (0.6)	0
Muscle operation	0	0	0	1 (0.6)
Myomectomy	0	0	0	1 (0.6)
Myopia correction	1 (1.1)	0	1 (0.6)	1 (0.6)
Nasal septal operation	3 (3.4)	1 (1.1)	4 (2.2)	0
Neck surgery	0	1 (1.1)	1 (0.6)	0
Neurectomy	0	0	0	1 (0.6)
Oophorectomy	1 (1.1)	1 (1.1)	2 (1.1)	0
Oophorectomy bilateral	0	1 (1.1)	1 (0.6)	1 (0.6)
Orthognathic surgery	1 (1.1)	0	1 (0.6)	0
Ovarian cystectomy	0	0	0	1 (0.6)
Pancreaticoduodenectomy	0	1 (1.1)	1 (0.6)	0
Peripheral nerve decompression	0	0	0	1 (0.6)
Phlebectomy	0	0	0	1 (0.6)
Pilonidal sinus repair	1 (1.1)	0	1 (0.6)	0
Polypectomy	0	1 (1.1)	1 (0.6)	0
Prophylaxis against HIV infection	0	0	0	1 (0.6)
Prostatectomy	0	1 (1.1)	1 (0.6)	0
Rectocele repair	0	0	0	1 (0.6)
Renal stone removal	0	0	0	1 (0.6)
Retinal operation	1 (1.1)	0	1 (0.6)	0
Rhinoplasty	1 (1.1)	0	1 (0.6)	0
Rotator cuff repair	0	1 (1.1)	1 (0.6)	4 (2.2)
Salpingectomy	0	1 (1.1)	1 (0.6)	0
Shoulder operation	0	1 (1.1)	1 (0.6)	2 (1.1)
Sinus operation	1 (1.1)	0	1 (0.6)	0
Skin lesion removal	0	0	0	1 (0.6)
Skin neoplasm excision	0	0	0	2 (1.1)
Spinal fusion surgery	1 (1.1)	1 (1.1)	2 (1.1)	1 (0.6)
Spinal laminectomy	0	0	0	2 (1.1)

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)
Spinal operation	0	0	0	2 (1.1)
Splenectomy	0	1 (1.1)	1 (0.6)	1 (0.6)
Strabismus correction	1 (1.1)	0	1 (0.6)	0
Surgery	0	0	0	2 (1.1)
Synovial cyst removal	0	1 (1.1)	1 (0.6)	1 (0.6)
Temporomandibular joint surgery	0	0	0	1 (0.6)
Tendon sheath incision	0	0	0	1 (0.6)
Tenoplasty	0	0	0	2 (1.1)
Tenotomy	0	0	0	1 (0.6)
Therapeutic embolisation	0	1 (1.1)	1 (0.6)	0
Thyroidectomy	0	1 (1.1)	1 (0.6)	1 (0.6)
Tonsillectomy	7 (8.0)	5 (5.4)	12 (6.7)	11 (6.1)
Trabeculectomy	0	1 (1.1)	1 (0.6)	2 (1.1)
Transurethral prostatectomy	0	1 (1.1)	1 (0.6)	1 (0.6)
Tumour excision	0	0	0	1 (0.6)
Umbilical hernia repair	0	0	0	1 (0.6)
Ureteral stent insertion	0	1 (1.1)	1 (0.6)	0
Ureteral stent removal	0	1 (1.1)	1 (0.6)	0
Varicocele repair	0	0	0	1 (0.6)
Vascular graft	0	1 (1.1)	1 (0.6)	0
Vasectomy	7 (8.0)	4 (4.3)	11 (6.1)	5 (2.8)
Vascular disorders	14 (15.9)	39 (42.4)	53 (29.4)	43 (23.9)
Arterial occlusive disease	0	1 (1.1)	1 (0.6)	0
Arteriosclerosis	0	0	0	1 (0.6)
Deep vein thrombosis	0	1 (1.1)	1 (0.6)	1 (0.6)
Essential hypertension	0	1 (1.1)	1 (0.6)	0
Hot flush	1 (1.1)	1 (1.1)	2 (1.1)	4 (2.2)
Hypertension	12 (13.6)	37 (40.2)	49 (27.2)	37 (20.6)
Hypotension	0	1 (1.1)	1 (0.6)	0
Varicose vein	0	0	0	2 (1.1)
White coat hypertension	1 (1.1)	0	1 (0.6)	0

14.190. Medical History – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:10) Source Data: admh Table Generation: 09SEP2020 (23:32)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2/admh s002 p2 saf

14.191. Demographic Characteristics – Phase 2 – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years (N^a=80) n^b (%)	56-85 Years (N^a=89) n^b (%)	18-85 Years (N^a=169) n^b (%)	18-85 Years (N^a=167) n^b (%)	Total (N^a=336) n^b (%)
Sex					
Male	41 (51.3)	49 (55.1)	90 (53.3)	85 (50.9)	175 (52.1)
Female	39 (48.8)	40 (44.9)	79 (46.7)	82 (49.1)	161 (47.9)
Race					
White	64 (80.0)	83 (93.3)	147 (87.0)	138 (82.6)	285 (84.8)
Black or African American	9 (11.3)	3 (3.4)	12 (7.1)	22 (13.2)	34 (10.1)
American Indian or Alaska native	0	1 (1.1)	1 (0.6)	1 (0.6)	2 (0.6)
Asian	5 (6.3)	0	5 (3.0)	4 (2.4)	9 (2.7)
Multiracial	1 (1.3)	1 (1.1)	2 (1.2)	1 (0.6)	3 (0.9)
Not reported	1 (1.3)	1 (1.1)	2 (1.2)	1 (0.6)	3 (0.9)
Ethnicity					
Hispanic/Latino	13 (16.3)	3 (3.4)	16 (9.5)	20 (12.0)	36 (10.7)
Non-Hispanic/non-Latino	66 (82.5)	85 (95.5)	151 (89.3)	145 (86.8)	296 (88.1)
Not reported	1 (1.3)	1 (1.1)	2 (1.2)	2 (1.2)	4 (1.2)
Age at vaccination (years)					
Mean (SD)	41.0 (10.47)	65.9 (6.64)	54.1 (15.18)	51.6 (15.92)	52.8 (15.58)
Median	43.5	65.0	56.0	56.0	56.0
Min, max	(18, 55)	(56, 85)	(18, 85)	(20, 83)	(18, 85)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adsl Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adsl_s005_demo_p2_d2_eval

14.192. Demographic Characteristics – Phase 2 – Dose 2 All-Available Immunogenicity Population

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years (N[a]=85) n[b] (%)	56-85 Years (N[a]=91) n[b] (%)	18-85 Years (N[a]=176) n[b] (%)	18-85 Years (N[a]=176) n[b] (%)	Total (N[a]=352) n[b] (%)
Sex					
Male	44 (51.8)	50 (54.9)	94 (53.4)	92 (52.3)	186 (52.8)
Female	41 (48.2)	41 (45.1)	82 (46.6)	84 (47.7)	166 (47.2)
Race					
White	69 (81.2)	85 (93.4)	154 (87.5)	147 (83.5)	301 (85.5)
Black or African American	9 (10.6)	3 (3.3)	12 (6.8)	22 (12.5)	34 (9.7)
American Indian or Alaska native	0	1 (1.1)	1 (0.6)	1 (0.6)	2 (0.6)
Asian	5 (5.9)	0	5 (2.8)	4 (2.3)	9 (2.6)
Multiracial	1 (1.2)	1 (1.1)	2 (1.1)	1 (0.6)	3 (0.9)
Not reported	1 (1.2)	1 (1.1)	2 (1.1)	1 (0.6)	3 (0.9)
Ethnicity					
Hispanic/Latino	13 (15.3)	3 (3.3)	16 (9.1)	20 (11.4)	36 (10.2)
Non-Hispanic/non-Latino	71 (83.5)	87 (95.6)	158 (89.8)	154 (87.5)	312 (88.6)
Not reported	1 (1.2)	1 (1.1)	2 (1.1)	2 (1.1)	4 (1.1)
Age at vaccination (years)					
Mean (SD)	41.2 (10.42)	65.9 (6.57)	54.0 (15.10)	51.5 (15.76)	52.7 (15.46)
Median	44.0	65.0	56.0	55.5	56.0
Min, max	(18, 55)	(56, 85)	(18, 85)	(20, 83)	(18, 85)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adsl Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adsl_s005_demo_p2_d2_aai

14.193. Immunogenicity Blood Samples Drawn – Phase 2 – All Randomized Subjects

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)
Randomized	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)
Not vaccinated	0	0	0	0
Blood sample drawn	0	0	0	0
Vaccinated at Dose 1	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)
Blood sample drawn before Dose 1[c]	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)
Vaccinated at Dose 2	87 (98.9)	92 (100.0)	179 (99.4)	180 (100.0)
Blood sample drawn 1 month after Dose 2[c]				
<28 Days	4 (4.5)	1 (1.1)	5 (2.8)	2 (1.1)
28 to 35 Days	80 (90.9)	88 (95.7)	168 (93.3)	170 (94.4)
>35 Days	3 (3.4)	2 (2.2)	5 (2.8)	5 (2.8)
Not obtained	0	1 (1.1)	1 (0.6)	3 (1.7)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adsl Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adsl_s001_imm_bld_p2_rand

14.194. E-Diary Transmission – Phase 2 – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)
Vaccinated at Dose 1	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)
E-diary				
Not transmitted[c]	0	0	0	0
Transmitted[d]				
Day 1	86 (97.7)	90 (97.8)	176 (97.8)	170 (94.4)
Day 2	83 (94.3)	90 (97.8)	173 (96.1)	171 (95.0)
Day 3	81 (92.0)	89 (96.7)	170 (94.4)	175 (97.2)
Day 4	77 (87.5)	88 (95.7)	165 (91.7)	168 (93.3)
Day 5	80 (90.9)	86 (93.5)	166 (92.2)	171 (95.0)
Day 6	84 (95.5)	89 (96.7)	173 (96.1)	169 (93.9)
Day 7	83 (94.3)	89 (96.7)	172 (95.6)	171 (95.0)
All 7 days[e]	59 (67.0)	76 (82.6)	135 (75.0)	135 (75.0)
Vaccinated at Dose 2	87 (98.9)	92 (100.0)	179 (99.4)	179 (99.4)
E-diary				
Not transmitted[c]	1 (1.1)	1 (1.1)	2 (1.1)	3 (1.7)
Transmitted[d]				
Day 1	66 (75.0)	79 (85.9)	145 (80.6)	138 (76.7)
Day 2	80 (90.9)	85 (92.4)	165 (91.7)	162 (90.0)
Day 3	76 (86.4)	85 (92.4)	161 (89.4)	166 (92.2)
Day 4	80 (90.9)	85 (92.4)	165 (91.7)	161 (89.4)
Day 5	80 (90.9)	85 (92.4)	165 (91.7)	166 (92.2)
Day 6	79 (89.8)	81 (88.0)	160 (88.9)	157 (87.2)
Day 7	78 (88.6)	84 (91.3)	162 (90.0)	167 (92.8)
All 7 days[e]	45 (51.1)	58 (63.0)	103 (57.2)	101 (56.1)

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. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 to Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie,"all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 to Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 11SEP2020 (11:50)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_s200_trns_p2_saf

Immunogenicity

14.195. Summary of Geometric Mean Titers/Concentrations – Phase 2 – Dose 2 Evaluable Immunogenicity Population

Assay	Dose/ Sampling Time Point[a]	Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
		n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	80	10.1 (9.9, 10.4)	88	10.3 (9.9, 10.7)	168	10.2 (10.0, 10.5)	167	10.4 (10.0, 10.9)
	2/1 Month	80	399.4 (342.1, 466.2)	87	255.0 (205.7, 316.0)	167	316.1 (275.6, 362.6)	167	10.6 (10.0, 11.3)
S1-binding IgG level assay (U/mL)	1/Prevax	80	0.8 (0.6, 0.9)	88	0.8 (0.7, 1.1)	168	0.8 (0.7, 0.9)	167	0.8 (0.7, 0.9)
	2/1 Month	80	7122.8 (6217.4, 8160.2)	87	3960.7 (3007.2, 5216.6)	167	5246.5 (4460.3, 6171.4)	167	1.0 (0.8, 1.2)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gm p2 eval

14.196. Summary of Geometric Mean Titers – NT90 – Phase 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	80	10.0 (10.0, 10.0)	88	10.0 (10.0, 10.0)	168	10.0 (10.0, 10.0)	167	10.1 (9.9, 10.3)
	2/1 Month	80	117.3 (100.5, 136.9)	87	77.6 (62.4, 96.6)	167	94.6 (82.4, 108.6)	167	10.5 (10.0, 11.0)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gm nt90 p2 eval

14.197. Summary of Geometric Mean Titers/Concentrations – Phase 2 – Dose 2 All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	85	10.1 (9.9, 10.4)	90	10.3 (9.9, 10.7)	175	10.2 (10.0, 10.4)	176	10.4 (10.0, 10.8)
	2/1 Month	85	389.3 (334.1, 453.7)	91	266.9 (215.3, 330.8)	176	320.3 (279.8, 366.6)	176	10.6 (10.0, 11.3)
S1-binding IgG level assay (U/mL)	1/Prevax	85	0.8 (0.6, 0.9)	90	0.8 (0.7, 1.0)	175	0.8 (0.7, 0.9)	176	0.8 (0.7, 0.9)
	2/1 Month	85	6940.9 (6089.1, 7911.7)	91	4077.4 (3123.9, 5321.8)	176	5271.8 (4513.7, 6157.3)	176	0.9 (0.8, 1.1)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gm p2 aai

14.198. Summary of Geometric Mean Titers – NT90 – Phase 2 – Dose 2 All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	85	10.0 (10.0, 10.0)	90	10.0 (10.0, 10.0)	175	10.0 (10.0, 10.0)	176	10.1 (9.9, 10.3)
	2/1 Month	85	114.1 (97.9, 132.9)	91	81.0 (65.1, 100.8)	176	95.5 (83.4, 109.5)	176	10.5 (10.0, 10.9)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gm nt90 p2 aai

14.199. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	80	39.4 (34.0, 45.6)	86	24.9 (20.2, 30.9)	166	31.1 (27.2, 35.5)	167	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	80	9167.2 (7452.8, 11276.0)	86	4975.5 (3655.9, 6771.4)	166	6679.4 (5511.6, 8094.7)	167	1.2 (1.0, 1.4)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gmfr p2 eval

14.200. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – NT90 – Phase 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer)	2/1 Month	80	11.7 (10.1, 13.7)	86	7.7 (6.2, 9.6)	166	9.4 (8.2, 10.9)	167	1.0 (1.0, 1.1)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gmfr nt90 p2 eval

14.201. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 2 – Dose 2 All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	85	38.4 (33.2, 44.4)	90	25.9 (21.0, 31.9)	175	31.4 (27.5, 35.7)	176	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	85	8956.9 (7347.2, 10919.3)	90	4855.7 (3567.2, 6609.6)	175	6537.4 (5409.8, 7900.0)	176	1.2 (1.0, 1.3)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gmfr p2 aai

14.202. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – NT90 – Phase 2 – Dose 2 All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT90 (titer)	2/1 Month	85	11.4 (9.8, 13.3)	90	8.1 (6.5, 10.1)	175	9.5 (8.3, 10.9)	176	1.0 (1.0, 1.1)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gmfr nt90 p2 aai

14.203. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	POS	1	31.0 (NE, NE)	4	18.1 (5.6, 58.2)	5	20.2 (8.7, 46.9)	4	38.4 (5.2, 282.5)
		NEG	79	10.0 (10.0, 10.0)	83	10.0 (10.0, 10.0)	162	10.0 (10.0, 10.0)	162	10.1 (9.9, 10.2)
	2/1 Month	POS	1	4233.0 (NE, NE)	2	3469.9 (0.1, 9.247E7)	3	3707.6 (495.5, 27743.3)	4	53.2 (5.5, 515.3)
		NEG	79	387.6 (335.4, 448.0)	84	237.7 (194.4, 290.7)	163	301.3 (264.7, 342.9)	162	10.2 (9.8, 10.7)
S1-binding IgG level assay (U/mL)	1/Prevax	POS	1	246.1 (NE, NE)	4	36.9 (0.5, 2848.7)	5	53.9 (2.4, 1222.0)	4	153.0 (12.7, 1844.4)
		NEG	79	0.7 (0.6, 0.8)	83	0.7 (0.6, 0.8)	162	0.7 (0.7, 0.8)	162	0.7 (0.7, 0.8)
	2/1 Month	POS	1	45474.1 (NE, NE)	2	23255.3 (106.2, 5.092E6)	3	29080.6 (6983.3, 121100.2)	4	144.4 (9.5, 2189.7)
		NEG	79	6957.6 (6113.5, 7918.3)	84	3759.2 (2847.3, 4963.2)	163	5066.1 (4308.9, 5956.5)	162	0.8 (0.7, 1.0)

14.203. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (04:18)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gm lt p2 eval

14.204. Summary of Geometric Mean Titers by Baseline SARS-CoV-2 Status – NT90 – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	POS	1	10.0 (NE, NE)	4	10.0 (10.0, 10.0)	5	10.0 (10.0, 10.0)	4	15.5 (3.8, 62.8)
		NEG	79	10.0 (10.0, 10.0)	83	10.0 (10.0, 10.0)	162	10.0 (10.0, 10.0)	162	10.0 (10.0, 10.0)
	2/1 Month	POS	1	1411.0 (NE, NE)	2	1515.4 (0.1, 4.079E7)	3	1479.8 (200.9, 10900.1)	4	21.4 (4.1, 113.5)
		NEG	79	113.7 (98.5, 131.1)	84	71.8 (58.8, 87.7)	163	89.7 (79.0, 102.0)	162	10.3 (9.9, 10.7)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable;
NEG = negative; NT90 = 90% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s001_gm_lt_nt90_p2_eval

14.205. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 All-Available Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	POS	1	31.0 (NE, NE)	4	18.1 (5.6, 58.2)	5	20.2 (8.7, 46.9)	4	38.4 (5.2, 282.5)
		NEG	84	10.0 (10.0, 10.0)	85	10.0 (10.0, 10.0)	169	10.0 (10.0, 10.0)	171	10.1 (9.9, 10.2)
	2/1 Month	POS	1	4233.0 (NE, NE)	4	2286.2 (383.3, 13634.8)	5	2585.9 (737.7, 9064.8)	4	53.2 (5.5, 515.3)
		NEG	84	378.4 (327.7, 437.0)	86	239.8 (196.8, 292.1)	170	300.4 (264.8, 340.8)	171	10.2 (9.8, 10.6)
S1-binding IgG level assay (U/mL)	1/Prevax	POS	1	246.1 (NE, NE)	4	36.9 (0.5, 2848.7)	5	53.9 (2.4, 1222.0)	4	153.0 (12.7, 1844.4)
		NEG	84	0.7 (0.6, 0.8)	85	0.7 (0.6, 0.8)	169	0.7 (0.7, 0.8)	171	0.7 (0.7, 0.8)
	2/1 Month	POS	1	45474.1 (NE, NE)	4	16935.0 (6311.2, 45441.6)	5	20633.8 (8700.3, 48935.9)	4	144.4 (9.5, 2189.7)
		NEG	84	6787.3 (5992.0, 7688.1)	86	3780.0 (2879.8, 4961.5)	170	5047.8 (4319.9, 5898.2)	171	0.8 (0.7, 1.0)

14.205. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 All-Available Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (04:13)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gm lt p2 aai

14.206. Summary of Geometric Mean Titers by Baseline SARS-CoV-2 Status – NT90 – Phase 2 – Dose 2 All-Available Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT90 (titer)	1/Prevax	POS	1	10.0 (NE, NE)	4	10.0 (10.0, 10.0)	5	10.0 (10.0, 10.0)	4	15.5 (3.8, 62.8)
		NEG	84	10.0 (10.0, 10.0)	85	10.0 (10.0, 10.0)	169	10.0 (10.0, 10.0)	171	10.0 (10.0, 10.0)
	2/1 Month	POS	1	1411.0 (NE, NE)	4	841.0 (113.8, 6214.8)	5	932.7 (234.2, 3714.2)	4	21.4 (4.1, 113.5)
		NEG	84	110.7 (96.0, 127.7)	86	72.1 (59.3, 87.8)	170	89.1 (78.7, 101.0)	171	10.3 (9.9, 10.7)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable;
NEG = negative; NT90 = 90% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s001_gm_lt_nt90_p2_aai

14.207. Summary of Geometric Mean Titers/Concentrations – Positive SARS-CoV-2 Prior to 1 Month After Dose 2 – Phase 2 – Dose 2 All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	1	31.0 (NE, NE)	4	18.1 (5.6, 58.2)	5	20.2 (8.7, 46.9)	4	38.4 (5.2, 282.5)
	2/1 Month	1	4233.0 (NE, NE)	4	2286.2 (383.3, 13634.8)	5	2585.9 (737.7, 9064.8)	4	53.2 (5.5, 515.3)
S1-binding IgG level assay (U/mL)	1/Prevax	1	246.1 (NE, NE)	4	36.9 (0.5, 2848.7)	5	53.9 (2.4, 1222.0)	4	153.0 (12.7, 1844.4)
	2/1 Month	1	45474.1 (NE, NE)	4	16935.0 (6311.2, 45441.6)	5	20633.8 (8700.3, 48935.9)	4	144.4 (9.5, 2189.7)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NE = not estimable; NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 14NOV2020 (07:17)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology 2/adva s001 gm po p2 aai

14.208. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	POS	1	136.5 (NE, NE)	2	163.6 (0.0, 6.156E10)	3	154.0 (3.2, 7377.7)	4	1.4 (0.9, 2.0)
		NEG	79	38.8 (33.5, 44.8)	83	23.6 (19.3, 29.0)	162	30.1 (26.4, 34.3)	162	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	POS	1	184.7 (NE, NE)	2	191.8 (0.0, 1.993E6)	3	189.4 (31.0, 1156.2)	4	0.9 (0.6, 1.5)
		NEG	79	9631.6 (8008.6, 11583.6)	83	5312.3 (3946.8, 7150.4)	162	7100.7 (5925.1, 8509.7)	162	1.2 (1.0, 1.4)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test;
NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s002 gmfr lt p2 eval

14.209. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point by Baseline SARS-CoV-2 Status – NT90 – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT90 (titer)	2/1 Month	POS	1	141.1 (NE, NE)	2	151.5 (0.0, 4.079E6)	3	148.0 (20.1, 1090.0)	4	1.4 (0.7, 2.6)
		NEG	79	11.4 (9.9, 13.1)	83	7.1 (5.8, 8.7)	162	9.0 (7.9, 10.2)	162	1.0 (1.0, 1.1)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable;
NEG = negative; NT90 = 90% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s002 gmfr nt90 lt p2 eval

14.210. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 All-Available Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	POS	1	136.5 (NE, NE)	4	126.1 (14.3, 1113.4)	5	128.1 (29.4, 558.7)	4	1.4 (0.9, 2.0)
		NEG	84	37.8 (32.8, 43.7)	85	23.9 (19.5, 29.1)	169	30.0 (26.4, 34.1)	171	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	POS	1	184.7 (NE, NE)	4	458.9 (11.7, 17975.3)	5	382.6 (30.5, 4800.8)	4	0.9 (0.6, 1.5)
		NEG	84	9380.5 (7853.7, 11204.1)	85	5356.1 (4004.4, 7163.9)	169	7076.4 (5943.9, 8424.8)	171	1.2 (1.0, 1.3)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test;
NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s002 gmfr lt p2 aai

14.211. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point by Baseline SARS-CoV-2 Status – NT90 – Phase 2 – Dose 2 All-Available Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT90 (titer)	2/1 Month	POS	1	141.1 (NE, NE)	4	84.1 (11.4, 621.5)	5	93.3 (23.4, 371.4)	4	1.4 (0.7, 2.6)
		NEG	84	11.1 (9.6, 12.8)	85	7.2 (5.9, 8.7)	169	8.9 (7.8, 10.1)	171	1.0 (1.0, 1.1)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable;
NEG = negative; NT90 = 90% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s002 gmfr nt90 lt p2 aai

14.212. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Positive SARS-CoV-2 Prior to 1 Month After Dose 2 – Phase 2 – Dose 2 All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	1	136.5 (NE, NE)	4	126.1 (14.3, 1113.4)	5	128.1 (29.4, 558.7)	4	1.4 (0.9, 2.0)
S1-binding IgG level assay (U/mL)	2/1 Month	1	184.7 (NE, NE)	4	458.9 (11.7, 17975.3)	5	382.6 (30.5, 4800.8)	4	0.9 (0.6, 1.5)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 14NOV2020 (07:18)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology 2/adva s001 gmfr po p2 aai

Local Reactions

14.213. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]												
	Any	88	3 (3.4)	(0.7, 9.6)	92	4 (4.3)	(1.2, 10.8)	180	7 (3.9)	(1.6, 7.8)	180	1 (0.6)	(0.0, 3.1)
	Mild	88	1 (1.1)	(0.0, 6.2)	92	2 (2.2)	(0.3, 7.6)	180	3 (1.7)	(0.3, 4.8)	180	1 (0.6)	(0.0, 3.1)
	Moderate	88	2 (2.3)	(0.3, 8.0)	92	2 (2.2)	(0.3, 7.6)	180	4 (2.2)	(0.6, 5.6)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Swelling[d]												
	Any	88	6 (6.8)	(2.5, 14.3)	92	6 (6.5)	(2.4, 13.7)	180	12 (6.7)	(3.5, 11.4)	180	0	(0.0, 2.0)
	Mild	88	2 (2.3)	(0.3, 8.0)	92	2 (2.2)	(0.3, 7.6)	180	4 (2.2)	(0.6, 5.6)	180	0	(0.0, 2.0)
	Moderate	88	4 (4.5)	(1.3, 11.2)	92	4 (4.3)	(1.2, 10.8)	180	8 (4.4)	(1.9, 8.6)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Pain at the injection site[e]												
	Any	88	75 (85.2)	(76.1, 91.9)	92	65 (70.7)	(60.2, 79.7)	180	140 (77.8)	(71.0, 83.6)	180	16 (8.9)	(5.2, 14.0)
	Mild	88	50 (56.8)	(45.8, 67.3)	92	49 (53.3)	(42.6, 63.7)	180	99 (55.0)	(47.4, 62.4)	180	16 (8.9)	(5.2, 14.0)
	Moderate	88	25 (28.4)	(19.3, 39.0)	92	15 (16.3)	(9.4, 25.5)	180	40 (22.2)	(16.4, 29.0)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	1 (1.1)	(0.0, 5.9)	180	1 (0.6)	(0.0, 3.1)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)

14.213. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any local reaction[f]	88	75 (85.2)	(76.1, 91.9)	92	66 (71.7)	(61.4, 80.6)	180	141 (78.3)	(71.6, 84.1)	180	16 (8.9)	(5.2, 14.0)
2	Redness[d]												
	Any	86	3 (3.5)	(0.7, 9.9)	91	7 (7.7)	(3.1, 15.2)	177	10 (5.6)	(2.7, 10.1)	176	0	(0.0, 2.1)
	Mild	86	2 (2.3)	(0.3, 8.1)	91	2 (2.2)	(0.3, 7.7)	177	4 (2.3)	(0.6, 5.7)	176	0	(0.0, 2.1)
	Moderate	86	1 (1.2)	(0.0, 6.3)	91	4 (4.4)	(1.2, 10.9)	177	5 (2.8)	(0.9, 6.5)	176	0	(0.0, 2.1)
	Severe	86	0	(0.0, 4.2)	91	1 (1.1)	(0.0, 6.0)	177	1 (0.6)	(0.0, 3.1)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Swelling[d]												
	Any	86	3 (3.5)	(0.7, 9.9)	91	11 (12.1)	(6.2, 20.6)	177	14 (7.9)	(4.4, 12.9)	176	0	(0.0, 2.1)
	Mild	86	3 (3.5)	(0.7, 9.9)	91	5 (5.5)	(1.8, 12.4)	177	8 (4.5)	(2.0, 8.7)	176	0	(0.0, 2.1)
	Moderate	86	0	(0.0, 4.2)	91	6 (6.6)	(2.5, 13.8)	177	6 (3.4)	(1.3, 7.2)	176	0	(0.0, 2.1)
	Severe	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Pain at the injection site[e]												
	Any	86	69 (80.2)	(70.2, 88.0)	91	66 (72.5)	(62.2, 81.4)	177	135 (76.3)	(69.3, 82.3)	176	17 (9.7)	(5.7, 15.0)
	Mild	86	46 (53.5)	(42.4, 64.3)	91	50 (54.9)	(44.2, 65.4)	177	96 (54.2)	(46.6, 61.7)	176	15 (8.5)	(4.8, 13.7)
	Moderate	86	22 (25.6)	(16.8, 36.1)	91	16 (17.6)	(10.4, 27.0)	177	38 (21.5)	(15.7, 28.3)	176	2 (1.1)	(0.1, 4.0)
	Severe	86	1 (1.2)	(0.0, 6.3)	91	0	(0.0, 4.0)	177	1 (0.6)	(0.0, 3.1)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Any local reaction[f]	86	69 (80.2)	(70.2, 88.0)	91	66 (72.5)	(62.2, 81.4)	177	135 (76.3)	(69.3, 82.3)	176	17 (9.7)	(5.7, 15.0)
Any dose	Redness[d]												

14.213. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	88	6 (6.8)	(2.5, 14.3)	92	8 (8.7)	(3.8, 16.4)	180	14 (7.8)	(4.3, 12.7)	180	1 (0.6)	(0.0, 3.1)
	Mild	88	3 (3.4)	(0.7, 9.6)	92	3 (3.3)	(0.7, 9.2)	180	6 (3.3)	(1.2, 7.1)	180	1 (0.6)	(0.0, 3.1)
	Moderate	88	3 (3.4)	(0.7, 9.6)	92	4 (4.3)	(1.2, 10.8)	180	7 (3.9)	(1.6, 7.8)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	1 (1.1)	(0.0, 5.9)	180	1 (0.6)	(0.0, 3.1)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Swelling[d]												
	Any	88	8 (9.1)	(4.0, 17.1)	92	13 (14.1)	(7.7, 23.0)	180	21 (11.7)	(7.4, 17.3)	180	0	(0.0, 2.0)
	Mild	88	4 (4.5)	(1.3, 11.2)	92	5 (5.4)	(1.8, 12.2)	180	9 (5.0)	(2.3, 9.3)	180	0	(0.0, 2.0)
	Moderate	88	4 (4.5)	(1.3, 11.2)	92	8 (8.7)	(3.8, 16.4)	180	12 (6.7)	(3.5, 11.4)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Pain at the injection site[e]												
	Any	88	83 (94.3)	(87.2, 98.1)	92	73 (79.3)	(69.6, 87.1)	180	156 (86.7)	(80.8, 91.3)	180	26 (14.4)	(9.7, 20.4)
	Mild	88	48 (54.5)	(43.6, 65.2)	92	46 (50.0)	(39.4, 60.6)	180	94 (52.2)	(44.7, 59.7)	180	24 (13.3)	(8.7, 19.2)
	Moderate	88	34 (38.6)	(28.4, 49.6)	92	26 (28.3)	(19.4, 38.6)	180	60 (33.3)	(26.5, 40.7)	180	2 (1.1)	(0.1, 4.0)
	Severe	88	1 (1.1)	(0.0, 6.2)	92	1 (1.1)	(0.0, 5.9)	180	2 (1.1)	(0.1, 4.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Any local reaction[f]	88	83 (94.3)	(87.2, 98.1)	92	73 (79.3)	(69.6, 87.1)	180	156 (86.7)	(80.8, 91.3)	180	26 (14.4)	(9.7, 20.4)

14.213. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 12SEP2020 (19:59)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2 unblinded/C4591001 IA P2/adce s010 lr p2 saf

14.214. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
18-55 Years	1	Redness[d]						
		Any	88	3 (3.4)	(0.7, 9.6)	90	0	(0.0, 4.0)
		Mild	88	1 (1.1)	(0.0, 6.2)	90	0	(0.0, 4.0)
		Moderate	88	2 (2.3)	(0.3, 8.0)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Swelling[d]						
		Any	88	6 (6.8)	(2.5, 14.3)	90	0	(0.0, 4.0)
		Mild	88	2 (2.3)	(0.3, 8.0)	90	0	(0.0, 4.0)
		Moderate	88	4 (4.5)	(1.3, 11.2)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Pain at the injection site[e]						
		Any	88	75 (85.2)	(76.1, 91.9)	90	7 (7.8)	(3.2, 15.4)
		Mild	88	50 (56.8)	(45.8, 67.3)	90	7 (7.8)	(3.2, 15.4)
		Moderate	88	25 (28.4)	(19.3, 39.0)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Any local reaction[f]	88	75 (85.2)	(76.1, 91.9)	90	7 (7.8)	(3.2, 15.4)
	2	Redness[d]						

14.214. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	86	3 (3.5)	(0.7, 9.9)	88	0	(0.0, 4.1)
		Mild	86	2 (2.3)	(0.3, 8.1)	88	0	(0.0, 4.1)
		Moderate	86	1 (1.2)	(0.0, 6.3)	88	0	(0.0, 4.1)
		Severe	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Swelling[d]						
		Any	86	3 (3.5)	(0.7, 9.9)	88	0	(0.0, 4.1)
		Mild	86	3 (3.5)	(0.7, 9.9)	88	0	(0.0, 4.1)
		Moderate	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Severe	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Pain at the injection site[e]						
		Any	86	69 (80.2)	(70.2, 88.0)	88	8 (9.1)	(4.0, 17.1)
		Mild	86	46 (53.5)	(42.4, 64.3)	88	6 (6.8)	(2.5, 14.3)
		Moderate	86	22 (25.6)	(16.8, 36.1)	88	2 (2.3)	(0.3, 8.0)
		Severe	86	1 (1.2)	(0.0, 6.3)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Any local reaction[f]	86	69 (80.2)	(70.2, 88.0)	88	8 (9.1)	(4.0, 17.1)
	Any dose	Redness[d]						
		Any	88	6 (6.8)	(2.5, 14.3)	90	0	(0.0, 4.0)
		Mild	88	3 (3.4)	(0.7, 9.6)	90	0	(0.0, 4.0)
		Moderate	88	3 (3.4)	(0.7, 9.6)	90	0	(0.0, 4.0)

14.214. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Swelling[d]						
		Any	88	8 (9.1)	(4.0, 17.1)	90	0	(0.0, 4.0)
		Mild	88	4 (4.5)	(1.3, 11.2)	90	0	(0.0, 4.0)
		Moderate	88	4 (4.5)	(1.3, 11.2)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Pain at the injection site[e]						
		Any	88	83 (94.3)	(87.2, 98.1)	90	11 (12.2)	(6.3, 20.8)
		Mild	88	48 (54.5)	(43.6, 65.2)	90	9 (10.0)	(4.7, 18.1)
		Moderate	88	34 (38.6)	(28.4, 49.6)	90	2 (2.2)	(0.3, 7.8)
		Severe	88	1 (1.1)	(0.0, 6.2)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Any local reaction[f]	88	83 (94.3)	(87.2, 98.1)	90	11 (12.2)	(6.3, 20.8)
56-85 Years	1	Redness[d]						
		Any	92	4 (4.3)	(1.2, 10.8)	90	1 (1.1)	(0.0, 6.0)
		Mild	92	2 (2.2)	(0.3, 7.6)	90	1 (1.1)	(0.0, 6.0)
		Moderate	92	2 (2.2)	(0.3, 7.6)	90	0	(0.0, 4.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Swelling[d]						

14.214. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	92	6 (6.5)	(2.4, 13.7)	90	0	(0.0, 4.0)
		Mild	92	2 (2.2)	(0.3, 7.6)	90	0	(0.0, 4.0)
		Moderate	92	4 (4.3)	(1.2, 10.8)	90	0	(0.0, 4.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Pain at the injection site[e]						
		Any	92	65 (70.7)	(60.2, 79.7)	90	9 (10.0)	(4.7, 18.1)
		Mild	92	49 (53.3)	(42.6, 63.7)	90	9 (10.0)	(4.7, 18.1)
		Moderate	92	15 (16.3)	(9.4, 25.5)	90	0	(0.0, 4.0)
		Severe	92	1 (1.1)	(0.0, 5.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Any local reaction[f]	92	66 (71.7)	(61.4, 80.6)	90	9 (10.0)	(4.7, 18.1)
	2	Redness[d]						
		Any	91	7 (7.7)	(3.1, 15.2)	88	0	(0.0, 4.1)
		Mild	91	2 (2.2)	(0.3, 7.7)	88	0	(0.0, 4.1)
		Moderate	91	4 (4.4)	(1.2, 10.9)	88	0	(0.0, 4.1)
		Severe	91	1 (1.1)	(0.0, 6.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Swelling[d]						
		Any	91	11 (12.1)	(6.2, 20.6)	88	0	(0.0, 4.1)
		Mild	91	5 (5.5)	(1.8, 12.4)	88	0	(0.0, 4.1)
		Moderate	91	6 (6.6)	(2.5, 13.8)	88	0	(0.0, 4.1)

14.214. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Pain at the injection site[e]						
		Any	91	66 (72.5)	(62.2, 81.4)	88	9 (10.2)	(4.8, 18.5)
		Mild	91	50 (54.9)	(44.2, 65.4)	88	9 (10.2)	(4.8, 18.5)
		Moderate	91	16 (17.6)	(10.4, 27.0)	88	0	(0.0, 4.1)
		Severe	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Any local reaction[f]	91	66 (72.5)	(62.2, 81.4)	88	9 (10.2)	(4.8, 18.5)
	Any dose	Redness[d]						
		Any	92	8 (8.7)	(3.8, 16.4)	90	1 (1.1)	(0.0, 6.0)
		Mild	92	3 (3.3)	(0.7, 9.2)	90	1 (1.1)	(0.0, 6.0)
		Moderate	92	4 (4.3)	(1.2, 10.8)	90	0	(0.0, 4.0)
		Severe	92	1 (1.1)	(0.0, 5.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Swelling[d]						
		Any	92	13 (14.1)	(7.7, 23.0)	90	0	(0.0, 4.0)
		Mild	92	5 (5.4)	(1.8, 12.2)	90	0	(0.0, 4.0)
		Moderate	92	8 (8.7)	(3.8, 16.4)	90	0	(0.0, 4.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Pain at the injection site[e]						

14.214. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	92	73 (79.3)	(69.6, 87.1)	90	15 (16.7)	(9.6, 26.0)
		Mild	92	46 (50.0)	(39.4, 60.6)	90	15 (16.7)	(9.6, 26.0)
		Moderate	92	26 (28.3)	(19.4, 38.6)	90	0	(0.0, 4.0)
		Severe	92	1 (1.1)	(0.0, 5.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Any local reaction[f]	92	73 (79.3)	(69.6, 87.1)	90	15 (16.7)	(9.6, 26.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:23)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2 unblinded/C4591001 IA P2 2/adce s010 lr age p2 saf

14.215. Onset Days for Local Reactions – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Local Reaction	18-55 Years	56-85 Years	18-85 Years	18-85 Years
1	Redness				
	n[a]	3	4	7	1
	Mean (SD)	3.7 (2.89)	3.3 (0.50)	3.4 (1.72)	2.0 (NE)
	Median	2.0	3.0	3.0	2.0
	Min, max	(2, 7)	(3, 4)	(2, 7)	(2, 2)
	Swelling				
	n[a]	6	6	12	0
	Mean (SD)	2.0 (0.63)	1.7 (0.52)	1.8 (0.58)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(1, 3)	(1, 2)	(1, 3)	(NE, NE)
	Pain at the injection site				
	n[a]	75	65	140	16
	Mean (SD)	1.5 (0.81)	1.7 (0.47)	1.6 (0.68)	2.1 (1.77)
	Median	1.0	2.0	2.0	1.0
	Min, max	(1, 7)	(1, 2)	(1, 7)	(1, 7)
	Any local reaction[b]				
	n[a]	75	66	141	16
	Mean (SD)	1.5 (0.53)	1.7 (0.47)	1.6 (0.51)	2.1 (1.77)
	Median	1.0	2.0	2.0	1.0
	Min, max	(1, 3)	(1, 2)	(1, 3)	(1, 7)
2	Redness				
	n[a]	3	7	10	0
	Mean (SD)	1.7 (0.58)	2.6 (0.79)	2.3 (0.82)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(1, 2)	(2, 4)	(1, 4)	(NE, NE)
	Swelling				
	n[a]	3	11	14	0
	Mean (SD)	1.3 (0.58)	2.2 (0.40)	2.0 (0.55)	NE (NE)
	Median	1.0	2.0	2.0	NE
	Min, max	(1, 2)	(2, 3)	(1, 3)	(NE, NE)
	Pain at the injection site				
	n[a]	69	66	135	17
	Mean (SD)	1.6 (0.70)	1.5 (0.56)	1.5 (0.63)	1.9 (1.17)
	Median	1.0	1.0	1.0	1.0

14.215. Onset Days for Local Reactions – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Local Reaction	18-55 Years	56-85 Years	18-85 Years	18-85 Years
	Min, max	(1, 4)	(1, 3)	(1, 4)	(1, 5)
	Any local reaction[b]				
	n[a]	69	66	135	17
	Mean (SD)	1.6 (0.70)	1.5 (0.53)	1.5 (0.62)	1.9 (1.17)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 4)	(1, 3)	(1, 4)	(1, 5)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 12SEP2020 (19:59)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2/adce s050 lr onset p2 saf

14.216. Onset Days for Local Reactions, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
18-55 Years	1	Redness		
		n[a]	3	0
		Mean (SD)	3.7 (2.89)	NE (NE)
		Median	2.0	NE
		Min, max	(2, 7)	(NE, NE)
		Swelling		
		n[a]	6	0
		Mean (SD)	2.0 (0.63)	NE (NE)
		Median	2.0	NE
		Min, max	(1, 3)	(NE, NE)
		Pain at the injection site		
		n[a]	75	7
		Mean (SD)	1.5 (0.81)	1.9 (1.46)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 5)
		Any local reaction[b]		
		n[a]	75	7
		Mean (SD)	1.5 (0.53)	1.9 (1.46)
		Median	1.0	1.0
		Min, max	(1, 3)	(1, 5)
	2	Redness		
		n[a]	3	0
		Mean (SD)	1.7 (0.58)	NE (NE)
		Median	2.0	NE
		Min, max	(1, 2)	(NE, NE)
		Swelling		
		n[a]	3	0
		Mean (SD)	1.3 (0.58)	NE (NE)
		Median	1.0	NE
		Min, max	(1, 2)	(NE, NE)
		Pain at the injection site		
		n[a]	69	8
		Mean (SD)	1.6 (0.70)	1.6 (0.92)
		Median	1.0	1.0
		Min, max	(1, 4)	(1, 3)

14.216. Onset Days for Local Reactions, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Any local reaction[b]		
		n[a]	69	8
		Mean (SD)	1.6 (0.70)	1.6 (0.92)
		Median	1.0	1.0
		Min, max	(1, 4)	(1, 3)
56-85 Years	1	Redness		
		n[a]	4	1
		Mean (SD)	3.3 (0.50)	2.0 (NE)
		Median	3.0	2.0
		Min, max	(3, 4)	(2, 2)
		Swelling		
		n[a]	6	0
		Mean (SD)	1.7 (0.52)	NE (NE)
		Median	2.0	NE
		Min, max	(1, 2)	(NE, NE)
		Pain at the injection site		
		n[a]	65	9
		Mean (SD)	1.7 (0.47)	2.2 (2.05)
		Median	2.0	1.0
		Min, max	(1, 2)	(1, 7)
		Any local reaction[b]		
		n[a]	66	9
		Mean (SD)	1.7 (0.47)	2.2 (2.05)
		Median	2.0	1.0
		Min, max	(1, 2)	(1, 7)
	2	Redness		
		n[a]	7	0
		Mean (SD)	2.6 (0.79)	NE (NE)
		Median	2.0	NE
		Min, max	(2, 4)	(NE, NE)
		Swelling		
		n[a]	11	0
		Mean (SD)	2.2 (0.40)	NE (NE)
		Median	2.0	NE
		Min, max	(2, 3)	(NE, NE)
		Pain at the injection site		
		n[a]	66	9

14.216. Onset Days for Local Reactions, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	1.5 (0.56)	2.1 (1.36)
		Median	1.0	2.0
		Min, max	(1, 3)	(1, 5)
		Any local reaction[b]		
		n[a]	66	9
		Mean (SD)	1.5 (0.53)	2.1 (1.36)
		Median	1.0	2.0
		Min, max	(1, 3)	(1, 5)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (19:09)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_s050_lr_onset_age_p2_saf

14.217. Duration (Days) From First to Last Day of Local Reactions – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Local Reaction	18-55 Years	56-85 Years	18-85 Years	18-85 Years
1	Redness				
	n[a]	3	4	7	1
	Mean (SD)	7.0 (6.08)	2.3 (0.96)	4.3 (4.39)	2.0 (NE)
	Median	4.0	2.5	3.0	2.0
	Min, max	(3, 14)	(1, 3)	(1, 14)	(2, 2)
	Swelling				
	n[a]	6	6	12	0
	Mean (SD)	2.0 (1.67)	2.0 (1.10)	2.0 (1.35)	NE (NE)
	Median	1.0	2.0	1.0	NE
	Min, max	(1, 5)	(1, 3)	(1, 5)	(NE, NE)
	Pain at the injection site				
	n[a]	75	65	140	16
	Mean (SD)	2.1 (1.45)	2.0 (1.36)	2.0 (1.40)	2.5 (4.46)
	Median	2.0	2.0	2.0	1.0
	Min, max	(1, 11)	(1, 8)	(1, 11)	(1, 19)
2	Redness				
	n[a]	3	7	10	0
	Mean (SD)	2.3 (1.53)	2.9 (1.21)	2.7 (1.25)	NE (NE)
	Median	2.0	3.0	3.0	NE
	Min, max	(1, 4)	(1, 5)	(1, 5)	(NE, NE)
	Swelling				
	n[a]	3	11	14	0
	Mean (SD)	1.3 (0.58)	1.9 (1.22)	1.8 (1.12)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 4)	(1, 4)	(NE, NE)
	Pain at the injection site				
	n[a]	69	66	135	17
	Mean (SD)	2.3 (1.23)	2.3 (1.43)	2.3 (1.33)	1.6 (1.06)
	Median	2.0	2.0	2.0	1.0
	Min, max	(1, 6)	(1, 6)	(1, 6)	(1, 4)
	Unknown[b]	1	0	1	0

14.217. Duration (Days) From First to Last Day of Local Reactions – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Local Reaction	18-55 Years	56-85 Years	18-85 Years	18-85 Years

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adcevd Table Generation: 12SEP2020 (19:59)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_s030_lr_dur_p2_saf

14.218. Duration (Days) From First to Last Day of Local Reactions, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
18-55 Years	1	Redness		
		n[a]	3	0
		Mean (SD)	7.0 (6.08)	NE (NE)
		Median	4.0	NE
		Min, max	(3, 14)	(NE, NE)
		Swelling		
		n[a]	6	0
		Mean (SD)	2.0 (1.67)	NE (NE)
		Median	1.0	NE
		Min, max	(1, 5)	(NE, NE)
		Pain at the injection site		
		n[a]	75	7
		Mean (SD)	2.1 (1.45)	1.7 (0.95)
		Median	2.0	1.0
		Min, max	(1, 11)	(1, 3)
	2	Redness		
		n[a]	3	0
		Mean (SD)	2.3 (1.53)	NE (NE)
		Median	2.0	NE
		Min, max	(1, 4)	(NE, NE)
		Swelling		
		n[a]	3	0
		Mean (SD)	1.3 (0.58)	NE (NE)
		Median	1.0	NE
		Min, max	(1, 2)	(NE, NE)
		Pain at the injection site		
		n[a]	69	8
		Mean (SD)	2.3 (1.23)	2.1 (1.36)
		Median	2.0	1.5
		Min, max	(1, 6)	(1, 4)
		Unknown[b]	1	0
56-85 Years	1	Redness		
		n[a]	4	1
		Mean (SD)	2.3 (0.96)	2.0 (NE)
		Median	2.5	2.0

14.218. Duration (Days) From First to Last Day of Local Reactions, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 3)	(2, 2)
		Swelling		
		n[a]	6	0
		Mean (SD)	2.0 (1.10)	NE (NE)
		Median	2.0	NE
		Min, max	(1, 3)	(NE, NE)
		Pain at the injection site		
		n[a]	65	9
		Mean (SD)	2.0 (1.36)	3.1 (5.97)
		Median	2.0	1.0
		Min, max	(1, 8)	(1, 19)
	2	Redness		
		n[a]	7	0
		Mean (SD)	2.9 (1.21)	NE (NE)
		Median	3.0	NE
		Min, max	(1, 5)	(NE, NE)
		Swelling		
		n[a]	11	0
		Mean (SD)	1.9 (1.22)	NE (NE)
		Median	1.0	NE
		Min, max	(1, 4)	(NE, NE)
		Pain at the injection site		
		n[a]	66	9
		Mean (SD)	2.3 (1.43)	1.1 (0.33)
		Median	2.0	1.0
		Min, max	(1, 6)	(1, 2)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. For symptoms that are ongoing at the time of next dose, stop date is computed as the next dose date.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adcevd Table Generation: 09OCT2020 (19:11)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2 2/adce s030 lr dur age p2 saf

Systemic Events

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever												
	≥38.0°C	88	3 (3.4)	(0.7, 9.6)	92	0	(0.0, 3.9)	180	3 (1.7)	(0.3, 4.8)	180	0	(0.0, 2.0)
	≥38.0°C to 38.4°C	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	>38.4°C to 38.9°C	88	3 (3.4)	(0.7, 9.6)	92	0	(0.0, 3.9)	180	3 (1.7)	(0.3, 4.8)	180	0	(0.0, 2.0)
	>38.9°C to 40.0°C	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	>40.0°C	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Fatigue[d]												
	Any	88	44 (50.0)	(39.1, 60.9)	92	33 (35.9)	(26.1, 46.5)	180	77 (42.8)	(35.4, 50.4)	180	49 (27.2)	(20.9, 34.3)
	Mild	88	26 (29.5)	(20.3, 40.2)	92	16 (17.4)	(10.3, 26.7)	180	42 (23.3)	(17.4, 30.2)	180	32 (17.8)	(12.5, 24.2)
	Moderate	88	18 (20.5)	(12.6, 30.4)	92	17 (18.5)	(11.1, 27.9)	180	35 (19.4)	(13.9, 26.0)	180	17 (9.4)	(5.6, 14.7)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Headache[d]												
	Any	88	28 (31.8)	(22.3, 42.6)	92	25 (27.2)	(18.4, 37.4)	180	53 (29.4)	(22.9, 36.7)	180	44 (24.4)	(18.4, 31.4)
	Mild	88	18 (20.5)	(12.6, 30.4)	92	21 (22.8)	(14.7, 32.8)	180	39 (21.7)	(15.9, 28.4)	180	28 (15.6)	(10.6, 21.7)
	Moderate	88	10 (11.4)	(5.6, 19.9)	92	4 (4.3)	(1.2, 10.8)	180	14 (7.8)	(4.3, 12.7)	180	15 (8.3)	(4.7, 13.4)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	1 (0.6)	(0.0, 3.1)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Chills[d]												
	Any	88	8 (9.1)	(4.0, 17.1)	92	7 (7.6)	(3.1, 15.1)	180	15 (8.3)	(4.7, 13.4)	180	7 (3.9)	(1.6, 7.8)
	Mild	88	6 (6.8)	(2.5, 14.3)	92	5 (5.4)	(1.8, 12.2)	180	11 (6.1)	(3.1, 10.7)	180	7 (3.9)	(1.6, 7.8)
	Moderate	88	2 (2.3)	(0.3, 8.0)	92	2 (2.2)	(0.3, 7.6)	180	4 (2.2)	(0.6, 5.6)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Vomiting[e]												
	Any	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	2 (1.1)	(0.1, 4.0)
	Mild	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	2 (1.1)	(0.1, 4.0)
	Moderate	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Diarrhea[f]												
	Any	88	15 (17.0)	(9.9, 26.6)	92	11 (12.0)	(6.1, 20.4)	180	26 (14.4)	(9.7, 20.4)	180	22 (12.2)	(7.8, 17.9)
	Mild	88	9 (10.2)	(4.8, 18.5)	92	9 (9.8)	(4.6, 17.8)	180	18 (10.0)	(6.0, 15.3)	180	19 (10.6)	(6.5, 16.0)
	Moderate	88	6 (6.8)	(2.5, 14.3)	92	2 (2.2)	(0.3, 7.6)	180	8 (4.4)	(1.9, 8.6)	180	3 (1.7)	(0.3, 4.8)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	New or worsened muscle pain[d]												
	Any	88	21 (23.9)	(15.4, 34.1)	92	13 (14.1)	(7.7, 23.0)	180	34 (18.9)	(13.5, 25.4)	180	11 (6.1)	(3.1, 10.7)
	Mild	88	12 (13.6)	(7.2, 22.6)	92	8 (8.7)	(3.8, 16.4)	180	20 (11.1)	(6.9, 16.6)	180	8 (4.4)	(1.9, 8.6)
	Moderate	88	9 (10.2)	(4.8, 18.5)	92	5 (5.4)	(1.8, 12.2)	180	14 (7.8)	(4.3, 12.7)	180	3 (1.7)	(0.3, 4.8)

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	New or worsened joint pain[d]												
	Any	88	8 (9.1)	(4.0, 17.1)	92	4 (4.3)	(1.2, 10.8)	180	12 (6.7)	(3.5, 11.4)	180	7 (3.9)	(1.6, 7.8)
	Mild	88	6 (6.8)	(2.5, 14.3)	92	3 (3.3)	(0.7, 9.2)	180	9 (5.0)	(2.3, 9.3)	180	4 (2.2)	(0.6, 5.6)
	Moderate	88	2 (2.3)	(0.3, 8.0)	92	1 (1.1)	(0.0, 5.9)	180	3 (1.7)	(0.3, 4.8)	180	3 (1.7)	(0.3, 4.8)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Any systemic event[g]	88	57 (64.8)	(53.9, 74.7)	92	47 (51.1)	(40.4, 61.7)	180	104 (57.8)	(50.2, 65.1)	180	78 (43.3)	(36.0, 50.9)
	Use of antipyretic or pain medication[h]	88	25 (28.4)	(19.3, 39.0)	92	18 (19.6)	(12.0, 29.1)	180	43 (23.9)	(17.9, 30.8)	180	20 (11.1)	(6.9, 16.6)
2	Fever												
	≥38.0°C	86	15 (17.4)	(10.1, 27.1)	91	10 (11.0)	(5.4, 19.3)	177	25 (14.1)	(9.4, 20.1)	176	0	(0.0, 2.1)
	≥38.0°C to 38.4°C	86	7 (8.1)	(3.3, 16.1)	91	7 (7.7)	(3.1, 15.2)	177	14 (7.9)	(4.4, 12.9)	176	0	(0.0, 2.1)
	>38.4°C to 38.9°C	86	6 (7.0)	(2.6, 14.6)	91	3 (3.3)	(0.7, 9.3)	177	9 (5.1)	(2.4, 9.4)	176	0	(0.0, 2.1)
	>38.9°C to 40.0°C	86	2 (2.3)	(0.3, 8.1)	91	0	(0.0, 4.0)	177	2 (1.1)	(0.1, 4.0)	176	0	(0.0, 2.1)
	>40.0°C	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Fatigue[d]												
	Any	86	51 (59.3)	(48.2, 69.8)	91	48 (52.7)	(42.0, 63.3)	177	99 (55.9)	(48.3, 63.4)	176	36 (20.5)	(14.8, 27.2)
	Mild	86	14 (16.3)	(9.2, 25.8)	91	22 (24.2)	(15.8, 34.3)	177	36 (20.3)	(14.7, 27.0)	176	21 (11.9)	(7.5, 17.7)
	Moderate	86	32 (37.2)	(27.0, 48.3)	91	24 (26.4)	(17.7, 36.7)	177	56 (31.6)	(24.9, 39.0)	176	15 (8.5)	(4.8, 13.7)
	Severe	86	5 (5.8)	(1.9, 13.0)	91	2 (2.2)	(0.3, 7.7)	177	7 (4.0)	(1.6, 8.0)	176	0	(0.0, 2.1)

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Headache[d]												
	Any	86	44 (51.2)	(40.1, 62.1)	91	33 (36.3)	(26.4, 47.0)	177	77 (43.5)	(36.1, 51.1)	176	29 (16.5)	(11.3, 22.8)
	Mild	86	19 (22.1)	(13.9, 32.3)	91	18 (19.8)	(12.2, 29.4)	177	37 (20.9)	(15.2, 27.6)	176	17 (9.7)	(5.7, 15.0)
	Moderate	86	21 (24.4)	(15.8, 34.9)	91	14 (15.4)	(8.7, 24.5)	177	35 (19.8)	(14.2, 26.4)	176	11 (6.3)	(3.2, 10.9)
	Severe	86	4 (4.7)	(1.3, 11.5)	91	1 (1.1)	(0.0, 6.0)	177	5 (2.8)	(0.9, 6.5)	176	1 (0.6)	(0.0, 3.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Chills[d]												
	Any	86	35 (40.7)	(30.2, 51.8)	91	19 (20.9)	(13.1, 30.7)	177	54 (30.5)	(23.8, 37.9)	176	4 (2.3)	(0.6, 5.7)
	Mild	86	19 (22.1)	(13.9, 32.3)	91	9 (9.9)	(4.6, 17.9)	177	28 (15.8)	(10.8, 22.0)	176	3 (1.7)	(0.4, 4.9)
	Moderate	86	13 (15.1)	(8.3, 24.5)	91	9 (9.9)	(4.6, 17.9)	177	22 (12.4)	(8.0, 18.2)	176	1 (0.6)	(0.0, 3.1)
	Severe	86	3 (3.5)	(0.7, 9.9)	91	1 (1.1)	(0.0, 6.0)	177	4 (2.3)	(0.6, 5.7)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Vomiting[e]												
	Any	86	2 (2.3)	(0.3, 8.1)	91	0	(0.0, 4.0)	177	2 (1.1)	(0.1, 4.0)	176	1 (0.6)	(0.0, 3.1)
	Mild	86	2 (2.3)	(0.3, 8.1)	91	0	(0.0, 4.0)	177	2 (1.1)	(0.1, 4.0)	176	1 (0.6)	(0.0, 3.1)
	Moderate	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Severe	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Diarrhea[f]												
	Any	86	17 (19.8)	(12.0, 29.8)	91	8 (8.8)	(3.9, 16.6)	177	25 (14.1)	(9.4, 20.1)	176	14 (8.0)	(4.4, 13.0)
	Mild	86	14 (16.3)	(9.2, 25.8)	91	6 (6.6)	(2.5, 13.8)	177	20 (11.3)	(7.0, 16.9)	176	12 (6.8)	(3.6, 11.6)

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	86	3 (3.5)	(0.7, 9.9)	91	2 (2.2)	(0.3, 7.7)	177	5 (2.8)	(0.9, 6.5)	176	2 (1.1)	(0.1, 4.0)
	Severe	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	New or worsened muscle pain[d]												
	Any	86	39 (45.3)	(34.6, 56.5)	91	26 (28.6)	(19.6, 39.0)	177	65 (36.7)	(29.6, 44.3)	176	6 (3.4)	(1.3, 7.3)
	Mild	86	18 (20.9)	(12.9, 31.0)	91	11 (12.1)	(6.2, 20.6)	177	29 (16.4)	(11.3, 22.7)	176	4 (2.3)	(0.6, 5.7)
	Moderate	86	19 (22.1)	(13.9, 32.3)	91	14 (15.4)	(8.7, 24.5)	177	33 (18.6)	(13.2, 25.2)	176	2 (1.1)	(0.1, 4.0)
	Severe	86	2 (2.3)	(0.3, 8.1)	91	1 (1.1)	(0.0, 6.0)	177	3 (1.7)	(0.4, 4.9)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	New or worsened joint pain[d]												
	Any	86	15 (17.4)	(10.1, 27.1)	91	15 (16.5)	(9.5, 25.7)	177	30 (16.9)	(11.7, 23.3)	176	8 (4.5)	(2.0, 8.8)
	Mild	86	8 (9.3)	(4.1, 17.5)	91	8 (8.8)	(3.9, 16.6)	177	16 (9.0)	(5.3, 14.3)	176	4 (2.3)	(0.6, 5.7)
	Moderate	86	7 (8.1)	(3.3, 16.1)	91	7 (7.7)	(3.1, 15.2)	177	14 (7.9)	(4.4, 12.9)	176	4 (2.3)	(0.6, 5.7)
	Severe	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Grade 4	86	0	(0.0, 4.2)	91	0	(0.0, 4.0)	177	0	(0.0, 2.1)	176	0	(0.0, 2.1)
	Any systemic event[g]	86	64 (74.4)	(63.9, 83.2)	91	59 (64.8)	(54.1, 74.6)	177	123 (69.5)	(62.1, 76.2)	176	54 (30.7)	(24.0, 38.1)
	Use of antipyretic or pain medication[h]	86	42 (48.8)	(37.9, 59.9)	91	32 (35.2)	(25.4, 45.9)	177	74 (41.8)	(34.5, 49.4)	176	15 (8.5)	(4.8, 13.7)
Any dose	Fever												
	≥38.0°C	88	17 (19.3)	(11.7, 29.1)	92	10 (10.9)	(5.3, 19.1)	180	27 (15.0)	(10.1, 21.1)	180	0	(0.0, 2.0)
	≥38.0°C to 38.4°C	88	7 (8.0)	(3.3, 15.7)	92	7 (7.6)	(3.1, 15.1)	180	14 (7.8)	(4.3, 12.7)	180	0	(0.0, 2.0)

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	>38.4°C to 38.9°C	88	8 (9.1)	(4.0, 17.1)	92	3 (3.3)	(0.7, 9.2)	180	11 (6.1)	(3.1, 10.7)	180	0	(0.0, 2.0)
	>38.9°C to 40.0°C	88	2 (2.3)	(0.3, 8.0)	92	0	(0.0, 3.9)	180	2 (1.1)	(0.1, 4.0)	180	0	(0.0, 2.0)
	>40.0°C	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Fatigue[d]												
	Any	88	62 (70.5)	(59.8, 79.7)	92	55 (59.8)	(49.0, 69.9)	180	117 (65.0)	(57.6, 71.9)	180	67 (37.2)	(30.1, 44.7)
	Mild	88	19 (21.6)	(13.5, 31.6)	92	21 (22.8)	(14.7, 32.8)	180	40 (22.2)	(16.4, 29.0)	180	39 (21.7)	(15.9, 28.4)
	Moderate	88	38 (43.2)	(32.7, 54.2)	92	32 (34.8)	(25.1, 45.4)	180	70 (38.9)	(31.7, 46.4)	180	28 (15.6)	(10.6, 21.7)
	Severe	88	5 (5.7)	(1.9, 12.8)	92	2 (2.2)	(0.3, 7.6)	180	7 (3.9)	(1.6, 7.8)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Headache[d]												
	Any	88	55 (62.5)	(51.5, 72.6)	92	40 (43.5)	(33.2, 54.2)	180	95 (52.8)	(45.2, 60.2)	180	54 (30.0)	(23.4, 37.3)
	Mild	88	25 (28.4)	(19.3, 39.0)	92	23 (25.0)	(16.6, 35.1)	180	48 (26.7)	(20.4, 33.8)	180	29 (16.1)	(11.1, 22.3)
	Moderate	88	26 (29.5)	(20.3, 40.2)	92	16 (17.4)	(10.3, 26.7)	180	42 (23.3)	(17.4, 30.2)	180	23 (12.8)	(8.3, 18.6)
	Severe	88	4 (4.5)	(1.3, 11.2)	92	1 (1.1)	(0.0, 5.9)	180	5 (2.8)	(0.9, 6.4)	180	2 (1.1)	(0.1, 4.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Chills[d]												
	Any	88	37 (42.0)	(31.6, 53.0)	92	24 (26.1)	(17.5, 36.3)	180	61 (33.9)	(27.0, 41.3)	180	9 (5.0)	(2.3, 9.3)
	Mild	88	20 (22.7)	(14.5, 32.9)	92	13 (14.1)	(7.7, 23.0)	180	33 (18.3)	(13.0, 24.8)	180	8 (4.4)	(1.9, 8.6)
	Moderate	88	14 (15.9)	(9.0, 25.2)	92	10 (10.9)	(5.3, 19.1)	180	24 (13.3)	(8.7, 19.2)	180	1 (0.6)	(0.0, 3.1)
	Severe	88	3 (3.4)	(0.7, 9.6)	92	1 (1.1)	(0.0, 5.9)	180	4 (2.2)	(0.6, 5.6)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Vomiting[e]												

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	88	2 (2.3)	(0.3, 8.0)	92	0	(0.0, 3.9)	180	2 (1.1)	(0.1, 4.0)	180	3 (1.7)	(0.3, 4.8)
	Mild	88	2 (2.3)	(0.3, 8.0)	92	0	(0.0, 3.9)	180	2 (1.1)	(0.1, 4.0)	180	3 (1.7)	(0.3, 4.8)
	Moderate	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Diarrhea[f]												
	Any	88	26 (29.5)	(20.3, 40.2)	92	15 (16.3)	(9.4, 25.5)	180	41 (22.8)	(16.9, 29.6)	180	29 (16.1)	(11.1, 22.3)
	Mild	88	18 (20.5)	(12.6, 30.4)	92	11 (12.0)	(6.1, 20.4)	180	29 (16.1)	(11.1, 22.3)	180	25 (13.9)	(9.2, 19.8)
	Moderate	88	8 (9.1)	(4.0, 17.1)	92	4 (4.3)	(1.2, 10.8)	180	12 (6.7)	(3.5, 11.4)	180	4 (2.2)	(0.6, 5.6)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	New or worsened muscle pain[d]												
	Any	88	45 (51.1)	(40.2, 61.9)	92	31 (33.7)	(24.2, 44.3)	180	76 (42.2)	(34.9, 49.8)	180	15 (8.3)	(4.7, 13.4)
	Mild	88	18 (20.5)	(12.6, 30.4)	92	14 (15.2)	(8.6, 24.2)	180	32 (17.8)	(12.5, 24.2)	180	10 (5.6)	(2.7, 10.0)
	Moderate	88	25 (28.4)	(19.3, 39.0)	92	16 (17.4)	(10.3, 26.7)	180	41 (22.8)	(16.9, 29.6)	180	5 (2.8)	(0.9, 6.4)
	Severe	88	2 (2.3)	(0.3, 8.0)	92	1 (1.1)	(0.0, 5.9)	180	3 (1.7)	(0.3, 4.8)	180	0	(0.0, 2.0)
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	New or worsened joint pain[d]												
	Any	88	18 (20.5)	(12.6, 30.4)	92	16 (17.4)	(10.3, 26.7)	180	34 (18.9)	(13.5, 25.4)	180	13 (7.2)	(3.9, 12.0)
	Mild	88	9 (10.2)	(4.8, 18.5)	92	9 (9.8)	(4.6, 17.8)	180	18 (10.0)	(6.0, 15.3)	180	6 (3.3)	(1.2, 7.1)
	Moderate	88	9 (10.2)	(4.8, 18.5)	92	7 (7.6)	(3.1, 15.1)	180	16 (8.9)	(5.2, 14.0)	180	7 (3.9)	(1.6, 7.8)
	Severe	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)

14.219. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)									Placebo		
		18-55 Years			56-85 Years			18-85 Years			18-85 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	88	0	(0.0, 4.1)	92	0	(0.0, 3.9)	180	0	(0.0, 2.0)	180	0	(0.0, 2.0)
	Any systemic event[g]	88	75 (85.2)	(76.1, 91.9)	92	65 (70.7)	(60.2, 79.7)	180	140 (77.8)	(71.0, 83.6)	180	95 (52.8)	(45.2, 60.2)
	Use of antipyretic or pain medication[h]	88	47 (53.4)	(42.5, 64.1)	92	38 (41.3)	(31.1, 52.1)	180	85 (47.2)	(39.8, 54.8)	180	31 (17.2)	(12.0, 23.5)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 12SEP2020 (20:57)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_s020_se_p2_saf

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
18-55 Years	1	Fever						
		≥38.0°C	88	3 (3.4)	(0.7, 9.6)	90	0	(0.0, 4.0)
		≥38.0°C to 38.4°C	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		>38.4°C to 38.9°C	88	3 (3.4)	(0.7, 9.6)	90	0	(0.0, 4.0)
		>38.9°C to 40.0°C	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		>40.0°C	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Fatigue[d]						
		Any	88	44 (50.0)	(39.1, 60.9)	90	32 (35.6)	(25.7, 46.3)
		Mild	88	26 (29.5)	(20.3, 40.2)	90	21 (23.3)	(15.1, 33.4)
		Moderate	88	18 (20.5)	(12.6, 30.4)	90	11 (12.2)	(6.3, 20.8)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Headache[d]						
		Any	88	28 (31.8)	(22.3, 42.6)	90	28 (31.1)	(21.8, 41.7)
		Mild	88	18 (20.5)	(12.6, 30.4)	90	15 (16.7)	(9.6, 26.0)
		Moderate	88	10 (11.4)	(5.6, 19.9)	90	12 (13.3)	(7.1, 22.1)
		Severe	88	0	(0.0, 4.1)	90	1 (1.1)	(0.0, 6.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Chills[d]						
		Any	88	8 (9.1)	(4.0, 17.1)	90	5 (5.6)	(1.8, 12.5)
		Mild	88	6 (6.8)	(2.5, 14.3)	90	5 (5.6)	(1.8, 12.5)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	88	2 (2.3)	(0.3, 8.0)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Vomiting[e]						
		Any	88	0	(0.0, 4.1)	90	1 (1.1)	(0.0, 6.0)
		Mild	88	0	(0.0, 4.1)	90	1 (1.1)	(0.0, 6.0)
		Moderate	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Diarrhea[f]						
		Any	88	15 (17.0)	(9.9, 26.6)	90	14 (15.6)	(8.8, 24.7)
		Mild	88	9 (10.2)	(4.8, 18.5)	90	12 (13.3)	(7.1, 22.1)
		Moderate	88	6 (6.8)	(2.5, 14.3)	90	2 (2.2)	(0.3, 7.8)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		New or worsened muscle pain[d]						
		Any	88	21 (23.9)	(15.4, 34.1)	90	3 (3.3)	(0.7, 9.4)
		Mild	88	12 (13.6)	(7.2, 22.6)	90	2 (2.2)	(0.3, 7.8)
		Moderate	88	9 (10.2)	(4.8, 18.5)	90	1 (1.1)	(0.0, 6.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		New or worsened joint pain[d]						

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	88	8 (9.1)	(4.0, 17.1)	90	1 (1.1)	(0.0, 6.0)
		Mild	88	6 (6.8)	(2.5, 14.3)	90	1 (1.1)	(0.0, 6.0)
		Moderate	88	2 (2.3)	(0.3, 8.0)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Any systemic event[g]	88	57 (64.8)	(53.9, 74.7)	90	45 (50.0)	(39.3, 60.7)
		Use of antipyretic or pain medication[h]	88	25 (28.4)	(19.3, 39.0)	90	11 (12.2)	(6.3, 20.8)
	2	Fever						
		≥38.0°C	86	15 (17.4)	(10.1, 27.1)	88	0	(0.0, 4.1)
		≥38.0°C to 38.4°C	86	7 (8.1)	(3.3, 16.1)	88	0	(0.0, 4.1)
		>38.4°C to 38.9°C	86	6 (7.0)	(2.6, 14.6)	88	0	(0.0, 4.1)
		>38.9°C to 40.0°C	86	2 (2.3)	(0.3, 8.1)	88	0	(0.0, 4.1)
		>40.0°C	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Fatigue[d]						
		Any	86	51 (59.3)	(48.2, 69.8)	88	21 (23.9)	(15.4, 34.1)
		Mild	86	14 (16.3)	(9.2, 25.8)	88	14 (15.9)	(9.0, 25.2)
		Moderate	86	32 (37.2)	(27.0, 48.3)	88	7 (8.0)	(3.3, 15.7)
		Severe	86	5 (5.8)	(1.9, 13.0)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Headache[d]						
		Any	86	44 (51.2)	(40.1, 62.1)	88	18 (20.5)	(12.6, 30.4)
		Mild	86	19 (22.1)	(13.9, 32.3)	88	9 (10.2)	(4.8, 18.5)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	86	21 (24.4)	(15.8, 34.9)	88	8 (9.1)	(4.0, 17.1)
		Severe	86	4 (4.7)	(1.3, 11.5)	88	1 (1.1)	(0.0, 6.2)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Chills[d]						
		Any	86	35 (40.7)	(30.2, 51.8)	88	2 (2.3)	(0.3, 8.0)
		Mild	86	19 (22.1)	(13.9, 32.3)	88	1 (1.1)	(0.0, 6.2)
		Moderate	86	13 (15.1)	(8.3, 24.5)	88	1 (1.1)	(0.0, 6.2)
		Severe	86	3 (3.5)	(0.7, 9.9)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Vomiting[e]						
		Any	86	2 (2.3)	(0.3, 8.1)	88	0	(0.0, 4.1)
		Mild	86	2 (2.3)	(0.3, 8.1)	88	0	(0.0, 4.1)
		Moderate	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Severe	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Diarrhea[f]						
		Any	86	17 (19.8)	(12.0, 29.8)	88	7 (8.0)	(3.3, 15.7)
		Mild	86	14 (16.3)	(9.2, 25.8)	88	5 (5.7)	(1.9, 12.8)
		Moderate	86	3 (3.5)	(0.7, 9.9)	88	2 (2.3)	(0.3, 8.0)
		Severe	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		New or worsened muscle pain[d]						

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	86	39 (45.3)	(34.6, 56.5)	88	2 (2.3)	(0.3, 8.0)
		Mild	86	18 (20.9)	(12.9, 31.0)	88	1 (1.1)	(0.0, 6.2)
		Moderate	86	19 (22.1)	(13.9, 32.3)	88	1 (1.1)	(0.0, 6.2)
		Severe	86	2 (2.3)	(0.3, 8.1)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		New or worsened joint pain[d]						
		Any	86	15 (17.4)	(10.1, 27.1)	88	3 (3.4)	(0.7, 9.6)
		Mild	86	8 (9.3)	(4.1, 17.5)	88	1 (1.1)	(0.0, 6.2)
		Moderate	86	7 (8.1)	(3.3, 16.1)	88	2 (2.3)	(0.3, 8.0)
		Severe	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Grade 4	86	0	(0.0, 4.2)	88	0	(0.0, 4.1)
		Any systemic event[g]	86	64 (74.4)	(63.9, 83.2)	88	30 (34.1)	(24.3, 45.0)
		Use of antipyretic or pain medication[h]	86	42 (48.8)	(37.9, 59.9)	88	6 (6.8)	(2.5, 14.3)
	Any dose	Fever						
		≥38.0°C	88	17 (19.3)	(11.7, 29.1)	90	0	(0.0, 4.0)
		≥38.0°C to 38.4°C	88	7 (8.0)	(3.3, 15.7)	90	0	(0.0, 4.0)
		>38.4°C to 38.9°C	88	8 (9.1)	(4.0, 17.1)	90	0	(0.0, 4.0)
		>38.9°C to 40.0°C	88	2 (2.3)	(0.3, 8.0)	90	0	(0.0, 4.0)
		>40.0°C	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Fatigue[d]						
		Any	88	62 (70.5)	(59.8, 79.7)	90	40 (44.4)	(34.0, 55.3)
		Mild	88	19 (21.6)	(13.5, 31.6)	90	25 (27.8)	(18.9, 38.2)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	88	38 (43.2)	(32.7, 54.2)	90	15 (16.7)	(9.6, 26.0)
		Severe	88	5 (5.7)	(1.9, 12.8)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Headache[d]						
		Any	88	55 (62.5)	(51.5, 72.6)	90	34 (37.8)	(27.8, 48.6)
		Mild	88	25 (28.4)	(19.3, 39.0)	90	15 (16.7)	(9.6, 26.0)
		Moderate	88	26 (29.5)	(20.3, 40.2)	90	17 (18.9)	(11.4, 28.5)
		Severe	88	4 (4.5)	(1.3, 11.2)	90	2 (2.2)	(0.3, 7.8)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Chills[d]						
		Any	88	37 (42.0)	(31.6, 53.0)	90	5 (5.6)	(1.8, 12.5)
		Mild	88	20 (22.7)	(14.5, 32.9)	90	4 (4.4)	(1.2, 11.0)
		Moderate	88	14 (15.9)	(9.0, 25.2)	90	1 (1.1)	(0.0, 6.0)
		Severe	88	3 (3.4)	(0.7, 9.6)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Vomiting[e]						
		Any	88	2 (2.3)	(0.3, 8.0)	90	1 (1.1)	(0.0, 6.0)
		Mild	88	2 (2.3)	(0.3, 8.0)	90	1 (1.1)	(0.0, 6.0)
		Moderate	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Diarrhea[f]						

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	88	26 (29.5)	(20.3, 40.2)	90	17 (18.9)	(11.4, 28.5)
		Mild	88	18 (20.5)	(12.6, 30.4)	90	14 (15.6)	(8.8, 24.7)
		Moderate	88	8 (9.1)	(4.0, 17.1)	90	3 (3.3)	(0.7, 9.4)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		New or worsened muscle pain[d]						
		Any	88	45 (51.1)	(40.2, 61.9)	90	4 (4.4)	(1.2, 11.0)
		Mild	88	18 (20.5)	(12.6, 30.4)	90	2 (2.2)	(0.3, 7.8)
		Moderate	88	25 (28.4)	(19.3, 39.0)	90	2 (2.2)	(0.3, 7.8)
		Severe	88	2 (2.3)	(0.3, 8.0)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		New or worsened joint pain[d]						
		Any	88	18 (20.5)	(12.6, 30.4)	90	4 (4.4)	(1.2, 11.0)
		Mild	88	9 (10.2)	(4.8, 18.5)	90	2 (2.2)	(0.3, 7.8)
		Moderate	88	9 (10.2)	(4.8, 18.5)	90	2 (2.2)	(0.3, 7.8)
		Severe	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Grade 4	88	0	(0.0, 4.1)	90	0	(0.0, 4.0)
		Any systemic event[g]	88	75 (85.2)	(76.1, 91.9)	90	54 (60.0)	(49.1, 70.2)
		Use of antipyretic or pain medication[h]	88	47 (53.4)	(42.5, 64.1)	90	17 (18.9)	(11.4, 28.5)
56-85 Years	1	Fever						
		≥38.0°C	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		≥38.0°C to 38.4°C	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		>38.4°C to 38.9°C	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		>38.9°C to 40.0°C	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		>40.0°C	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Fatigue[d]						
		Any	92	33 (35.9)	(26.1, 46.5)	90	17 (18.9)	(11.4, 28.5)
		Mild	92	16 (17.4)	(10.3, 26.7)	90	11 (12.2)	(6.3, 20.8)
		Moderate	92	17 (18.5)	(11.1, 27.9)	90	6 (6.7)	(2.5, 13.9)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Headache[d]						
		Any	92	25 (27.2)	(18.4, 37.4)	90	16 (17.8)	(10.5, 27.3)
		Mild	92	21 (22.8)	(14.7, 32.8)	90	13 (14.4)	(7.9, 23.4)
		Moderate	92	4 (4.3)	(1.2, 10.8)	90	3 (3.3)	(0.7, 9.4)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Chills[d]						
		Any	92	7 (7.6)	(3.1, 15.1)	90	2 (2.2)	(0.3, 7.8)
		Mild	92	5 (5.4)	(1.8, 12.2)	90	2 (2.2)	(0.3, 7.8)
		Moderate	92	2 (2.2)	(0.3, 7.6)	90	0	(0.0, 4.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Vomiting[e]						

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	92	0	(0.0, 3.9)	90	1 (1.1)	(0.0, 6.0)
		Mild	92	0	(0.0, 3.9)	90	1 (1.1)	(0.0, 6.0)
		Moderate	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Diarrhea[f]						
		Any	92	11 (12.0)	(6.1, 20.4)	90	8 (8.9)	(3.9, 16.8)
		Mild	92	9 (9.8)	(4.6, 17.8)	90	7 (7.8)	(3.2, 15.4)
		Moderate	92	2 (2.2)	(0.3, 7.6)	90	1 (1.1)	(0.0, 6.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		New or worsened muscle pain[d]						
		Any	92	13 (14.1)	(7.7, 23.0)	90	8 (8.9)	(3.9, 16.8)
		Mild	92	8 (8.7)	(3.8, 16.4)	90	6 (6.7)	(2.5, 13.9)
		Moderate	92	5 (5.4)	(1.8, 12.2)	90	2 (2.2)	(0.3, 7.8)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		New or worsened joint pain[d]						
		Any	92	4 (4.3)	(1.2, 10.8)	90	6 (6.7)	(2.5, 13.9)
		Mild	92	3 (3.3)	(0.7, 9.2)	90	3 (3.3)	(0.7, 9.4)
		Moderate	92	1 (1.1)	(0.0, 5.9)	90	3 (3.3)	(0.7, 9.4)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any systemic event[g]	92	47 (51.1)	(40.4, 61.7)	90	33 (36.7)	(26.8, 47.5)
		Use of antipyretic or pain medication[h]	92	18 (19.6)	(12.0, 29.1)	90	9 (10.0)	(4.7, 18.1)
	2	Fever						
		≥38.0°C	91	10 (11.0)	(5.4, 19.3)	88	0	(0.0, 4.1)
		≥38.0°C to 38.4°C	91	7 (7.7)	(3.1, 15.2)	88	0	(0.0, 4.1)
		>38.4°C to 38.9°C	91	3 (3.3)	(0.7, 9.3)	88	0	(0.0, 4.1)
		>38.9°C to 40.0°C	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		>40.0°C	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Fatigue[d]						
		Any	91	48 (52.7)	(42.0, 63.3)	88	15 (17.0)	(9.9, 26.6)
		Mild	91	22 (24.2)	(15.8, 34.3)	88	7 (8.0)	(3.3, 15.7)
		Moderate	91	24 (26.4)	(17.7, 36.7)	88	8 (9.1)	(4.0, 17.1)
		Severe	91	2 (2.2)	(0.3, 7.7)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Headache[d]						
		Any	91	33 (36.3)	(26.4, 47.0)	88	11 (12.5)	(6.4, 21.3)
		Mild	91	18 (19.8)	(12.2, 29.4)	88	8 (9.1)	(4.0, 17.1)
		Moderate	91	14 (15.4)	(8.7, 24.5)	88	3 (3.4)	(0.7, 9.6)
		Severe	91	1 (1.1)	(0.0, 6.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Chills[d]						
		Any	91	19 (20.9)	(13.1, 30.7)	88	2 (2.3)	(0.3, 8.0)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	91	9 (9.9)	(4.6, 17.9)	88	2 (2.3)	(0.3, 8.0)
		Moderate	91	9 (9.9)	(4.6, 17.9)	88	0	(0.0, 4.1)
		Severe	91	1 (1.1)	(0.0, 6.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Vomiting[e]						
		Any	91	0	(0.0, 4.0)	88	1 (1.1)	(0.0, 6.2)
		Mild	91	0	(0.0, 4.0)	88	1 (1.1)	(0.0, 6.2)
		Moderate	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Severe	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Diarrhea[f]						
		Any	91	8 (8.8)	(3.9, 16.6)	88	7 (8.0)	(3.3, 15.7)
		Mild	91	6 (6.6)	(2.5, 13.8)	88	7 (8.0)	(3.3, 15.7)
		Moderate	91	2 (2.2)	(0.3, 7.7)	88	0	(0.0, 4.1)
		Severe	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		New or worsened muscle pain[d]						
		Any	91	26 (28.6)	(19.6, 39.0)	88	4 (4.5)	(1.3, 11.2)
		Mild	91	11 (12.1)	(6.2, 20.6)	88	3 (3.4)	(0.7, 9.6)
		Moderate	91	14 (15.4)	(8.7, 24.5)	88	1 (1.1)	(0.0, 6.2)
		Severe	91	1 (1.1)	(0.0, 6.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		New or worsened joint pain[d]						
		Any	91	15 (16.5)	(9.5, 25.7)	88	5 (5.7)	(1.9, 12.8)
		Mild	91	8 (8.8)	(3.9, 16.6)	88	3 (3.4)	(0.7, 9.6)
		Moderate	91	7 (7.7)	(3.1, 15.2)	88	2 (2.3)	(0.3, 8.0)
		Severe	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Grade 4	91	0	(0.0, 4.0)	88	0	(0.0, 4.1)
		Any systemic event[g]	91	59 (64.8)	(54.1, 74.6)	88	24 (27.3)	(18.3, 37.8)
		Use of antipyretic or pain medication[h]	91	32 (35.2)	(25.4, 45.9)	88	9 (10.2)	(4.8, 18.5)
	Any dose	Fever						
		≥38.0°C	92	10 (10.9)	(5.3, 19.1)	90	0	(0.0, 4.0)
		≥38.0°C to 38.4°C	92	7 (7.6)	(3.1, 15.1)	90	0	(0.0, 4.0)
		>38.4°C to 38.9°C	92	3 (3.3)	(0.7, 9.2)	90	0	(0.0, 4.0)
		>38.9°C to 40.0°C	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		>40.0°C	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Fatigue[d]						
		Any	92	55 (59.8)	(49.0, 69.9)	90	27 (30.0)	(20.8, 40.6)
		Mild	92	21 (22.8)	(14.7, 32.8)	90	14 (15.6)	(8.8, 24.7)
		Moderate	92	32 (34.8)	(25.1, 45.4)	90	13 (14.4)	(7.9, 23.4)
		Severe	92	2 (2.2)	(0.3, 7.6)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Headache[d]						
		Any	92	40 (43.5)	(33.2, 54.2)	90	20 (22.2)	(14.1, 32.2)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	92	23 (25.0)	(16.6, 35.1)	90	14 (15.6)	(8.8, 24.7)
		Moderate	92	16 (17.4)	(10.3, 26.7)	90	6 (6.7)	(2.5, 13.9)
		Severe	92	1 (1.1)	(0.0, 5.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Chills[d]						
		Any	92	24 (26.1)	(17.5, 36.3)	90	4 (4.4)	(1.2, 11.0)
		Mild	92	13 (14.1)	(7.7, 23.0)	90	4 (4.4)	(1.2, 11.0)
		Moderate	92	10 (10.9)	(5.3, 19.1)	90	0	(0.0, 4.0)
		Severe	92	1 (1.1)	(0.0, 5.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Vomiting[e]						
		Any	92	0	(0.0, 3.9)	90	2 (2.2)	(0.3, 7.8)
		Mild	92	0	(0.0, 3.9)	90	2 (2.2)	(0.3, 7.8)
		Moderate	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Diarrhea[f]						
		Any	92	15 (16.3)	(9.4, 25.5)	90	12 (13.3)	(7.1, 22.1)
		Mild	92	11 (12.0)	(6.1, 20.4)	90	11 (12.2)	(6.3, 20.8)
		Moderate	92	4 (4.3)	(1.2, 10.8)	90	1 (1.1)	(0.0, 6.0)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		New or worsened muscle pain[d]						
		Any	92	31 (33.7)	(24.2, 44.3)	90	11 (12.2)	(6.3, 20.8)
		Mild	92	14 (15.2)	(8.6, 24.2)	90	8 (8.9)	(3.9, 16.8)
		Moderate	92	16 (17.4)	(10.3, 26.7)	90	3 (3.3)	(0.7, 9.4)
		Severe	92	1 (1.1)	(0.0, 5.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		New or worsened joint pain[d]						
		Any	92	16 (17.4)	(10.3, 26.7)	90	9 (10.0)	(4.7, 18.1)
		Mild	92	9 (9.8)	(4.6, 17.8)	90	4 (4.4)	(1.2, 11.0)
		Moderate	92	7 (7.6)	(3.1, 15.1)	90	5 (5.6)	(1.8, 12.5)
		Severe	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Grade 4	92	0	(0.0, 3.9)	90	0	(0.0, 4.0)
		Any systemic event[g]	92	65 (70.7)	(60.2, 79.7)	90	41 (45.6)	(35.0, 56.4)
		Use of antipyretic or pain medication[h]	92	38 (41.3)	(31.1, 52.1)	90	14 (15.6)	(8.8, 24.7)

14.220. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:26)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2 unblinded/C4591001 IA P2 2/adce s020 se age p2 saf

14.221. Onset Days for Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years
1	Fever (≥38.0°C)				
	n[a]	3	0	3	0
	Mean (SD)	2.0 (0.00)	NE (NE)	2.0 (0.00)	NE (NE)
	Median	2.0	NE	2.0	NE
	Min, max	(2, 2)	(NE, NE)	(2, 2)	(NE, NE)
	Fatigue				
	n[a]	44	33	77	49
	Mean (SD)	2.0 (1.26)	2.1 (1.08)	2.1 (1.18)	2.3 (1.53)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 6)	(1, 7)	(1, 7)
	Headache				
	n[a]	28	25	53	44
	Mean (SD)	2.5 (1.90)	2.0 (1.27)	2.3 (1.64)	2.9 (1.75)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Chills				
	n[a]	8	7	15	7
	Mean (SD)	1.5 (0.53)	2.0 (0.58)	1.7 (0.59)	2.1 (1.46)
	Median	1.5	2.0	2.0	2.0
	Min, max	(1, 2)	(1, 3)	(1, 3)	(1, 5)
	Vomiting				
	n[a]	0	0	0	2
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	4.5 (0.71)
	Median	NE	NE	NE	4.5
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(4, 5)
	Diarrhea				
	n[a]	15	11	26	22
	Mean (SD)	3.2 (1.90)	3.5 (1.75)	3.3 (1.81)	3.0 (1.40)
	Median	3.0	3.0	3.0	2.0
	Min, max	(1, 7)	(2, 7)	(1, 7)	(1, 6)
	New or worsened muscle pain				
	n[a]	21	13	34	11
	Mean (SD)	3.0 (1.91)	2.2 (0.55)	2.7 (1.59)	3.9 (2.30)
	Median	2.0	2.0	2.0	3.0

14.221. Onset Days for Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years
	Min, max	(1, 7)	(1, 3)	(1, 7)	(1, 7)
	New or worsened joint pain				
	n[a]	8	4	12	7
	Mean (SD)	2.4 (1.06)	2.3 (0.50)	2.3 (0.89)	5.3 (1.80)
	Median	2.5	2.0	2.0	6.0
	Min, max	(1, 4)	(2, 3)	(1, 4)	(2, 7)
	Any systemic event[b]				
	n[a]	57	47	104	78
	Mean (SD)	2.0 (1.38)	2.1 (1.09)	2.0 (1.25)	2.3 (1.36)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 6)	(1, 7)	(1, 6)
	Use of antipyretic or pain medication				
	n[a]	25	18	43	20
	Mean (SD)	2.9 (1.73)	2.0 (0.69)	2.5 (1.45)	3.2 (1.63)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
2	Fever (≥38.0°C)				
	n[a]	15	10	25	0
	Mean (SD)	1.9 (0.46)	2.0 (0.00)	2.0 (0.35)	NE (NE)
	Median	2.0	2.0	2.0	NE
	Min, max	(1, 3)	(2, 2)	(1, 3)	(NE, NE)
	Fatigue				
	n[a]	51	48	99	36
	Mean (SD)	2.0 (0.77)	1.9 (1.03)	2.0 (0.90)	2.3 (1.45)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 6)	(1, 7)	(1, 7)	(1, 7)
	Headache				
	n[a]	44	33	77	29
	Mean (SD)	2.3 (1.12)	1.9 (0.90)	2.2 (1.04)	2.4 (1.09)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 6)	(1, 6)	(1, 6)	(1, 5)
	Chills				
	n[a]	35	19	54	4
	Mean (SD)	2.0 (0.79)	2.3 (0.95)	2.1 (0.85)	2.8 (0.96)
	Median	2.0	2.0	2.0	2.5
	Min, max	(1, 5)	(2, 6)	(1, 6)	(2, 4)

14.221. Onset Days for Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years
	Vomiting				
	n[a]	2	0	2	1
	Mean (SD)	3.0 (2.83)	NE (NE)	3.0 (2.83)	4.0 (NE)
	Median	3.0	NE	3.0	4.0
	Min, max	(1, 5)	(NE, NE)	(1, 5)	(4, 4)
	Diarrhea				
	n[a]	17	8	25	14
	Mean (SD)	3.1 (1.43)	3.4 (2.07)	3.2 (1.62)	2.4 (0.93)
	Median	3.0	2.5	3.0	2.0
	Min, max	(1, 6)	(1, 7)	(1, 7)	(1, 4)
	New or worsened muscle pain				
	n[a]	39	26	65	6
	Mean (SD)	2.0 (0.36)	1.9 (0.48)	2.0 (0.41)	2.7 (1.21)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 3)	(1, 3)	(1, 3)	(2, 5)
	New or worsened joint pain				
	n[a]	15	15	30	8
	Mean (SD)	2.0 (0.38)	1.9 (0.26)	2.0 (0.32)	3.5 (1.77)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 3)	(1, 2)	(1, 3)	(2, 7)
	Any systemic event[b]				
	n[a]	64	59	123	54
	Mean (SD)	1.9 (0.85)	1.8 (0.75)	1.9 (0.81)	2.3 (1.41)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 6)	(1, 6)	(1, 6)	(1, 7)
	Use of antipyretic or pain medication				
	n[a]	42	32	74	15
	Mean (SD)	1.9 (0.57)	2.2 (0.79)	2.0 (0.69)	3.3 (1.83)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 4)	(1, 5)	(1, 5)	(1, 6)

14.221. Onset Days for Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 12SEP2020 (19:59)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_s060_se_onset_p2_saf

14.222. Onset Days for Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
18-55 Years	1	Fever (≥38.0°C)		
		n[a]	3	0
		Mean (SD)	2.0 (0.00)	NE (NE)
		Median	2.0	NE
		Min, max	(2, 2)	(NE, NE)
		Fatigue		
		n[a]	44	32
		Mean (SD)	2.0 (1.26)	1.8 (1.35)
		Median	2.0	1.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	28	28
		Mean (SD)	2.5 (1.90)	3.1 (1.95)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	8	5
		Mean (SD)	1.5 (0.53)	2.4 (1.67)
		Median	1.5	2.0
		Min, max	(1, 2)	(1, 5)
		Vomiting		
		n[a]	0	1
		Mean (SD)	NE (NE)	5.0 (NE)
		Median	NE	5.0
		Min, max	(NE, NE)	(5, 5)
		Diarrhea		
		n[a]	15	14
		Mean (SD)	3.2 (1.90)	3.1 (1.59)
		Median	3.0	2.0
		Min, max	(1, 7)	(1, 6)
		New or worsened muscle pain		
		n[a]	21	3
		Mean (SD)	3.0 (1.91)	3.7 (2.89)
		Median	2.0	2.0
		Min, max	(1, 7)	(2, 7)

14.222. Onset Days for Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		New or worsened joint pain		
		n[a]	8	1
		Mean (SD)	2.4 (1.06)	6.0 (NE)
		Median	2.5	6.0
		Min, max	(1, 4)	(6, 6)
		Any systemic event[b]		
		n[a]	57	45
		Mean (SD)	2.0 (1.38)	2.1 (1.30)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 5)
		Use of antipyretic or pain medication		
		n[a]	25	11
		Mean (SD)	2.9 (1.73)	3.3 (1.42)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 6)
	2	Fever (≥38.0°C)		
		n[a]	15	0
		Mean (SD)	1.9 (0.46)	NE (NE)
		Median	2.0	NE
		Min, max	(1, 3)	(NE, NE)
		Fatigue		
		n[a]	51	21
		Mean (SD)	2.0 (0.77)	2.0 (1.10)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 4)
		Headache		
		n[a]	44	18
		Mean (SD)	2.3 (1.12)	2.3 (1.02)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 4)
		Chills		
		n[a]	35	2
		Mean (SD)	2.0 (0.79)	2.5 (0.71)
		Median	2.0	2.5
		Min, max	(1, 5)	(2, 3)
		Vomiting		
		n[a]	2	0

14.222. Onset Days for Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	3.0 (2.83)	NE (NE)
		Median	3.0	NE
		Min, max	(1, 5)	(NE, NE)
		Diarrhea		
		n[a]	17	7
		Mean (SD)	3.1 (1.43)	2.1 (1.07)
		Median	3.0	2.0
		Min, max	(1, 6)	(1, 4)
		New or worsened muscle pain		
		n[a]	39	2
		Mean (SD)	2.0 (0.36)	2.0 (0.00)
		Median	2.0	2.0
		Min, max	(1, 3)	(2, 2)
		New or worsened joint pain		
		n[a]	15	3
		Mean (SD)	2.0 (0.38)	2.3 (0.58)
		Median	2.0	2.0
		Min, max	(1, 3)	(2, 3)
		Any systemic event[b]		
		n[a]	64	30
		Mean (SD)	1.9 (0.85)	2.0 (1.05)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 4)
		Use of antipyretic or pain medication		
		n[a]	42	6
		Mean (SD)	1.9 (0.57)	3.5 (2.07)
		Median	2.0	3.0
		Min, max	(1, 4)	(1, 6)
56-85 Years	1	Fever (≥38.0°C)		
		n[a]	0	0
		Fatigue		
		n[a]	33	17
		Mean (SD)	2.1 (1.08)	3.2 (1.48)
		Median	2.0	3.0
		Min, max	(1, 6)	(1, 7)
		Headache		
		n[a]	25	16

14.222. Onset Days for Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	2.0 (1.27)	2.5 (1.32)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 5)
		Chills		
		n[a]	7	2
		Mean (SD)	2.0 (0.58)	1.5 (0.71)
		Median	2.0	1.5
		Min, max	(1, 3)	(1, 2)
		Vomiting		
		n[a]	0	1
		Mean (SD)	NE (NE)	4.0 (NE)
		Median	NE	4.0
		Min, max	(NE, NE)	(4, 4)
		Diarrhea		
		n[a]	11	8
		Mean (SD)	3.5 (1.75)	3.0 (1.07)
		Median	3.0	3.0
		Min, max	(2, 7)	(2, 4)
		New or worsened muscle pain		
		n[a]	13	8
		Mean (SD)	2.2 (0.55)	4.0 (2.27)
		Median	2.0	4.0
		Min, max	(1, 3)	(1, 7)
		New or worsened joint pain		
		n[a]	4	6
		Mean (SD)	2.3 (0.50)	5.2 (1.94)
		Median	2.0	5.5
		Min, max	(2, 3)	(2, 7)
		Any systemic event[b]		
		n[a]	47	33
		Mean (SD)	2.1 (1.09)	2.6 (1.39)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 6)
		Use of antipyretic or pain medication		
		n[a]	18	9
		Mean (SD)	2.0 (0.69)	3.0 (1.94)
		Median	2.0	3.0

14.222. Onset Days for Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 4)	(1, 7)
	2	Fever (≥38.0°C)		
		n[a]	10	0
		Mean (SD)	2.0 (0.00)	NE (NE)
		Median	2.0	NE
		Min, max	(2, 2)	(NE, NE)
		Fatigue		
		n[a]	48	15
		Mean (SD)	1.9 (1.03)	2.8 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	33	11
		Mean (SD)	1.9 (0.90)	2.7 (1.19)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 5)
		Chills		
		n[a]	19	2
		Mean (SD)	2.3 (0.95)	3.0 (1.41)
		Median	2.0	3.0
		Min, max	(2, 6)	(2, 4)
		Vomiting		
		n[a]	0	1
		Mean (SD)	NE (NE)	4.0 (NE)
		Median	NE	4.0
		Min, max	(NE, NE)	(4, 4)
		Diarrhea		
		n[a]	8	7
		Mean (SD)	3.4 (2.07)	2.6 (0.79)
		Median	2.5	2.0
		Min, max	(1, 7)	(2, 4)
		New or worsened muscle pain		
		n[a]	26	4
		Mean (SD)	1.9 (0.48)	3.0 (1.41)
		Median	2.0	2.5
		Min, max	(1, 3)	(2, 5)
		New or worsened joint pain		

14.222. Onset Days for Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	15	5
		Mean (SD)	1.9 (0.26)	4.2 (1.92)
		Median	2.0	4.0
		Min, max	(1, 2)	(2, 7)
		Any systemic event[b]		
		n[a]	59	24
		Mean (SD)	1.8 (0.75)	2.8 (1.70)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	32	9
		Mean (SD)	2.2 (0.79)	3.1 (1.76)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 6)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (19:09)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2 2/adce s060 se onset age p2 saf

14.223. Duration (Days) From First to Last Day of Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years
1	Fever (≥38.0°C)				
	n[a]	3	0	3	0
	Mean (SD)	1.0 (0.00)	NE (NE)	1.0 (0.00)	NE (NE)
	Median	1.0	NE	1.0	NE
	Min, max	(1, 1)	(NE, NE)	(1, 1)	(NE, NE)
	Fatigue				
	n[a]	44	33	77	49
	Mean (SD)	2.0 (1.55)	2.4 (1.79)	2.2 (1.66)	2.8 (2.32)
	Median	1.0	2.0	1.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 8)
	Headache				
	n[a]	28	25	53	44
	Mean (SD)	2.3 (2.80)	2.3 (2.23)	2.3 (2.52)	2.5 (3.27)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 14)	(1, 8)	(1, 14)	(1, 20)
	Chills				
	n[a]	8	7	15	7
	Mean (SD)	1.3 (0.46)	1.4 (0.53)	1.3 (0.49)	1.1 (0.38)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 2)	(1, 2)	(1, 2)	(1, 2)
	Vomiting				
	n[a]	0	0	0	2
	Mean (SD)	NE (NE)	NE (NE)	NE (NE)	1.0 (0.00)
	Median	NE	NE	NE	1.0
	Min, max	(NE, NE)	(NE, NE)	(NE, NE)	(1, 1)
	Diarrhea				
	n[a]	15	11	26	22
	Mean (SD)	3.1 (4.67)	1.7 (1.49)	2.5 (3.68)	3.3 (3.46)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 19)	(1, 6)	(1, 19)	(1, 12)
	New or worsened muscle pain				
	n[a]	21	13	34	11
	Mean (SD)	2.2 (2.89)	1.2 (0.55)	1.8 (2.33)	1.3 (0.47)

14.223. Duration (Days) From First to Last Day of Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 14)	(1, 3)	(1, 14)	(1, 2)
	New or worsened joint pain				
	n[a]	8	4	12	7
	Mean (SD)	1.8 (0.89)	1.3 (0.50)	1.6 (0.79)	1.3 (0.49)
	Median	1.5	1.0	1.0	1.0
	Min, max	(1, 3)	(1, 2)	(1, 3)	(1, 2)
	Use of antipyretic or pain medication				
	n[a]	25	18	43	20
	Mean (SD)	2.3 (2.81)	1.9 (1.97)	2.1 (2.47)	2.9 (4.29)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 14)	(1, 8)	(1, 14)	(1, 20)
	Unknown[b]	0	0	0	1
2	Fever (≥38.0°C)				
	n[a]	15	10	25	0
	Mean (SD)	1.1 (0.35)	1.3 (0.67)	1.2 (0.50)	NE (NE)
	Median	1.0	1.0	1.0	NE
	Min, max	(1, 2)	(1, 3)	(1, 3)	(NE, NE)
	Fatigue				
	n[a]	51	48	99	36
	Mean (SD)	1.9 (1.22)	1.8 (1.11)	1.9 (1.16)	2.4 (1.59)
	Median	2.0	1.0	1.0	2.0
	Min, max	(1, 5)	(1, 6)	(1, 6)	(1, 5)
	Unknown[b]	6	4	10	6
	Headache				
	n[a]	44	33	77	29
	Mean (SD)	1.8 (1.37)	1.7 (0.87)	1.7 (1.16)	2.0 (1.61)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 4)	(1, 5)	(1, 6)
	Unknown[b]	6	1	7	3
	Chills				
	n[a]	35	19	54	4
	Mean (SD)	1.2 (0.65)	1.1 (0.32)	1.2 (0.56)	1.3 (0.58)
	Median	1.0	1.0	1.0	1.0

14.223. Duration (Days) From First to Last Day of Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years
	Min, max	(1, 4)	(1, 2)	(1, 4)	(1, 2)
	Unknown[b]	1	0	1	1
	Vomiting				
	n[a]	2	0	2	1
	Mean (SD)	1.0 (0.00)	NE (NE)	1.0 (0.00)	1.0 (NE)
	Median	1.0	NE	1.0	1.0
	Min, max	(1, 1)	(NE, NE)	(1, 1)	(1, 1)
	Diarrhea				
	n[a]	17	8	25	14
	Mean (SD)	1.7 (1.49)	1.2 (0.41)	1.6 (1.31)	2.4 (1.44)
	Median	1.0	1.0	1.0	2.5
	Min, max	(1, 6)	(1, 2)	(1, 6)	(1, 5)
	Unknown[b]	0	2	2	2
	New or worsened muscle pain				
	n[a]	39	26	65	6
	Mean (SD)	1.2 (0.58)	1.2 (0.43)	1.2 (0.52)	1.4 (0.55)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 4)	(1, 2)	(1, 4)	(1, 2)
	Unknown[b]	3	0	3	1
	New or worsened joint pain				
	n[a]	15	15	30	8
	Mean (SD)	1.1 (0.29)	1.4 (0.83)	1.3 (0.66)	1.0 (0.00)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 2)	(1, 4)	(1, 4)	(1, 1)
	Unknown[b]	3	0	3	1
	Use of antipyretic or pain medication				
	n[a]	42	32	74	15
	Mean (SD)	1.5 (1.06)	1.4 (0.91)	1.4 (0.99)	1.5 (1.51)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 5)	(1, 6)
	Unknown[b]	4	1	5	4

14.223. Duration (Days) From First to Last Day of Systemic Events – Phase 2 – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)			Placebo
Dose	Systemic Event	18-55 Years	56-85 Years	18-85 Years	18-85 Years

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive.
Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adcevd Table Generation: 12SEP2020 (20:02)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2/adce s040 se dur p2 saf

14.224. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
18-55 Years	1	Fever (≥38.0°C)		
		n[a]	3	0
		Mean (SD)	1.0 (0.00)	NE (NE)
		Median	1.0	NE
		Min, max	(1, 1)	(NE, NE)
		Fatigue		
		n[a]	44	32
		Mean (SD)	2.0 (1.55)	2.7 (2.39)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 8)
		Headache		
		n[a]	28	28
		Mean (SD)	2.3 (2.80)	2.3 (1.71)
		Median	1.0	1.5
		Min, max	(1, 14)	(1, 6)
		Chills		
		n[a]	8	5
		Mean (SD)	1.3 (0.46)	1.2 (0.45)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 2)
		Vomiting		
		n[a]	0	1
		Mean (SD)	NE (NE)	1.0 (NE)
		Median	NE	1.0
		Min, max	(NE, NE)	(1, 1)
		Diarrhea		
		n[a]	15	14
		Mean (SD)	3.1 (4.67)	2.6 (2.73)
		Median	1.0	1.0
		Min, max	(1, 19)	(1, 8)
		New or worsened muscle pain		
		n[a]	21	3
		Mean (SD)	2.2 (2.89)	1.3 (0.58)
		Median	1.0	1.0
		Min, max	(1, 14)	(1, 2)

14.224. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		New or worsened joint pain		
		n[a]	8	1
		Mean (SD)	1.8 (0.89)	1.0 (NE)
		Median	1.5	1.0
		Min, max	(1, 3)	(1, 1)
		Use of antipyretic or pain medication		
		n[a]	25	11
		Mean (SD)	2.3 (2.81)	1.9 (1.04)
		Median	1.0	1.0
		Min, max	(1, 14)	(1, 3)
	2	Fever (≥38.0°C)		
		n[a]	15	0
		Mean (SD)	1.1 (0.35)	NE (NE)
		Median	1.0	NE
		Min, max	(1, 2)	(NE, NE)
		Fatigue		
		n[a]	51	21
		Mean (SD)	1.9 (1.22)	2.5 (1.72)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 5)
		Unknown[b]	6	3
		Headache		
		n[a]	44	18
		Mean (SD)	1.8 (1.37)	2.3 (1.84)
		Median	1.0	1.0
		Min, max	(1, 5)	(1, 6)
		Unknown[b]	6	2
		Chills		
		n[a]	35	2
		Mean (SD)	1.2 (0.65)	2.0 (NE)
		Median	1.0	2.0
		Min, max	(1, 4)	(2, 2)
		Unknown[b]	1	1
		Vomiting		
		n[a]	2	0
		Mean (SD)	1.0 (0.00)	NE (NE)

14.224. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Median	1.0	NE
		Min, max	(1, 1)	(NE, NE)
		Diarrhea		
		n[a]	17	7
		Mean (SD)	1.7 (1.49)	3.0 (1.22)
		Median	1.0	3.0
		Min, max	(1, 6)	(1, 4)
		Unknown[b]	0	2
		New or worsened muscle pain		
		n[a]	39	2
		Mean (SD)	1.2 (0.58)	1.5 (0.71)
		Median	1.0	1.5
		Min, max	(1, 4)	(1, 2)
		Unknown[b]	3	0
		New or worsened joint pain		
		n[a]	15	3
		Mean (SD)	1.1 (0.29)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 1)
		Unknown[b]	3	0
		Use of antipyretic or pain medication		
		n[a]	42	6
		Mean (SD)	1.5 (1.06)	1.8 (2.04)
		Median	1.0	1.0
		Min, max	(1, 5)	(1, 6)
		Unknown[b]	4	0
56-85 Years	1	Fever (≥38.0°C)		
		n[a]	0	0
		Fatigue		
		n[a]	33	17
		Mean (SD)	2.4 (1.79)	3.0 (2.24)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	25	16
		Mean (SD)	2.3 (2.23)	3.0 (4.99)

14.224. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 20)
		Chills		
		n[a]	7	2
		Mean (SD)	1.4 (0.53)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 1)
		Vomiting		
		n[a]	0	1
		Mean (SD)	NE (NE)	1.0 (NE)
		Median	NE	1.0
		Min, max	(NE, NE)	(1, 1)
		Diarrhea		
		n[a]	11	8
		Mean (SD)	1.7 (1.49)	4.5 (4.41)
		Median	1.0	3.0
		Min, max	(1, 6)	(1, 12)
		New or worsened muscle pain		
		n[a]	13	8
		Mean (SD)	1.2 (0.55)	1.3 (0.46)
		Median	1.0	1.0
		Min, max	(1, 3)	(1, 2)
		New or worsened joint pain		
		n[a]	4	6
		Mean (SD)	1.3 (0.50)	1.3 (0.52)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 2)
		Use of antipyretic or pain medication		
		n[a]	18	9
		Mean (SD)	1.9 (1.97)	4.4 (6.46)
		Median	1.0	2.0
		Min, max	(1, 8)	(1, 20)
		Unknown[b]	0	1
	2	Fever (≥38.0°C)		
		n[a]	10	0
		Mean (SD)	1.3 (0.67)	NE (NE)

14.224. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Median	1.0	NE
		Min, max	(1, 3)	(NE, NE)
		Fatigue		
		n[a]	48	15
		Mean (SD)	1.8 (1.11)	2.2 (1.40)
		Median	1.0	1.5
		Min, max	(1, 6)	(1, 5)
		Unknown[b]	4	3
		Headache		
		n[a]	33	11
		Mean (SD)	1.7 (0.87)	1.5 (1.08)
		Median	1.0	1.0
		Min, max	(1, 4)	(1, 4)
		Unknown[b]	1	1
		Chills		
		n[a]	19	2
		Mean (SD)	1.1 (0.32)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 1)
		Vomiting		
		n[a]	0	1
		Mean (SD)	NE (NE)	1.0 (NE)
		Median	NE	1.0
		Min, max	(NE, NE)	(1, 1)
		Diarrhea		
		n[a]	8	7
		Mean (SD)	1.2 (0.41)	2.0 (1.53)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 5)
		Unknown[b]	2	0
		New or worsened muscle pain		
		n[a]	26	4
		Mean (SD)	1.2 (0.43)	1.3 (0.58)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 2)
		Unknown[b]	0	1

14.224. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Phase 2 – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		New or worsened joint pain		
		n[a]	15	5
		Mean (SD)	1.4 (0.83)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 4)	(1, 1)
		Unknown[b]	0	1
		Use of antipyretic or pain medication		
		n[a]	32	9
		Mean (SD)	1.4 (0.91)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 5)	(1, 1)
		Unknown[b]	1	4

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. For symptoms that are ongoing at the time of next dose, stop date is computed as the next dose date.
Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adcevd Table Generation: 09OCT2020 (19:11)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_s040_se_dur_age_p2_saf

Adverse Events

14.225. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2 – Phase 2 – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			Placebo
Adverse Event	18-55 Years (N[a]=88) n[b] (%)	56-85 Years (N[a]=92) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)	18-85 Years (N[a]=180) n[b] (%)
Any event	8 (9.1)	4 (4.3)	12 (6.7)	18 (10.0)
Related[c]	3 (3.4)	2 (2.2)	5 (2.8)	8 (4.4)
Severe	2 (2.3)	0	2 (1.1)	0
Life-threatening	0	0	0	0
Any serious adverse event	1 (1.1)	0	1 (0.6)	0
Related[c]	0	0	0	0
Severe	1 (1.1)	0	1 (0.6)	0
Life-threatening	0	0	0	0
Any adverse event leading to withdrawal	1 (1.1)	0	1 (0.6)	0
Related[c]	0	0	0	0
Severe	1 (1.1)	0	1 (0.6)	0
Life-threatening	0	0	0	0
Death	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adae Table Generation: 09OCT2020 (19:13)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2 2/adae s091 all pd2 p2 saf

14.226. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020) – Phase 2 – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=180)	Placebo (N[a]=180)
Adverse Event	n[b] (%)	n[b] (%)
Any event	22 (12.2)	29 (16.1)
Related[c]	6 (3.3)	9 (5.0)
Severe	3 (1.7)	1 (0.6)
Life-threatening	2 (1.1)	1 (0.6)
Any serious adverse event	3 (1.7)	1 (0.6)
Related[c]	0	0
Severe	1 (0.6)	1 (0.6)
Life-threatening	2 (1.1)	1 (0.6)
Any adverse event leading to withdrawal	2 (1.1)	0
Related[c]	0	0
Severe	1 (0.6)	0
Life-threatening	1 (0.6)	0
Death	1 (0.6)	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:37)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_p2_saf

14.227. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=88) n[b] (%)	Placebo (N[a]=90) n[b] (%)
Any event	12 (13.6)	16 (17.8)
Related[c]	3 (3.4)	6 (6.7)
Severe	3 (3.4)	0
Life-threatening	0	0
Any serious adverse event	1 (1.1)	0
Related[c]	0	0
Severe	1 (1.1)	0
Life-threatening	0	0
Any adverse event leading to withdrawal	1 (1.1)	0
Related[c]	0	0
Severe	1 (1.1)	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 = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:37)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_age_p2_saf

14.228. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=92)	Placebo (N[a]=90)
Adverse Event	n[b] (%)	n[b] (%)
Any event	10 (10.9)	13 (14.4)
Related[c]	3 (3.3)	3 (3.3)
Severe	0	1 (1.1)
Life-threatening	2 (2.2)	1 (1.1)
Any serious adverse event	2 (2.2)	1 (1.1)
Related[c]	0	0
Severe	0	1 (1.1)
Life-threatening	2 (2.2)	1 (1.1)
Any adverse event leading to withdrawal	1 (1.1)	0
Related[c]	0	0
Severe	0	0
Life-threatening	1 (1.1)	0
Death	1 (1.1)	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:37)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_age_p2_saf

14.229. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	8 (9.1)	(4.0, 17.1)	10 (11.1)	(5.5, 19.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Lymphadenopathy	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
GASTROINTESTINAL DISORDERS	1 (1.1)	(0.0, 6.2)	2 (2.2)	(0.3, 7.8)
Diarrhoea	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 6.0)
Odynophagia	0	(0.0, 4.1)	0	(0.0, 4.0)
Tongue discomfort	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (3.4)	(0.7, 9.6)	3 (3.3)	(0.7, 9.4)
Injection site erythema	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 6.0)
Injection site pain	3 (3.4)	(0.7, 9.6)	0	(0.0, 4.0)
Fatigue	0	(0.0, 4.1)	2 (2.2)	(0.3, 7.8)
Chills	0	(0.0, 4.1)	0	(0.0, 4.0)
Injection site discolouration	0	(0.0, 4.1)	0	(0.0, 4.0)
Injection site swelling	0	(0.0, 4.1)	0	(0.0, 4.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Vulvovaginal mycotic infection	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Contusion	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Fall	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Muscle rupture	0	(0.0, 4.1)	0	(0.0, 4.0)
Tendon rupture	0	(0.0, 4.1)	0	(0.0, 4.0)
INVESTIGATIONS	0	(0.0, 4.1)	0	(0.0, 4.0)
White blood cell count increased	0	(0.0, 4.1)	0	(0.0, 4.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (2.3)	(0.3, 8.0)	1 (1.1)	(0.0, 6.0)
Myalgia	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 6.0)
Arthralgia	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Neck pain	0	(0.0, 4.1)	0	(0.0, 4.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)

14.229. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Headache	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 4.1)	2 (2.2)	(0.3, 7.8)
Oropharyngeal pain	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Productive cough	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Rhinorrhoea	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Dermatitis	0	(0.0, 4.1)	0	(0.0, 4.0)
Hangnail	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Macule	0	(0.0, 4.1)	0	(0.0, 4.0)
Rash macular	0	(0.0, 4.1)	0	(0.0, 4.0)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 09OCT2020 (04:55)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2 2/adae s130 1md2 soc age p2 saf

14.230. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4 (4.3)	(1.2, 10.8)	8 (8.9)	(3.9, 16.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 3.9)	0	(0.0, 4.0)
Lymphadenopathy	0	(0.0, 3.9)	0	(0.0, 4.0)
GASTROINTESTINAL DISORDERS	2 (2.2)	(0.3, 7.6)	0	(0.0, 4.0)
Diarrhoea	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Odynophagia	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Tongue discomfort	0	(0.0, 3.9)	0	(0.0, 4.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 3.9)	4 (4.4)	(1.2, 11.0)
Injection site erythema	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Injection site pain	0	(0.0, 3.9)	0	(0.0, 4.0)
Fatigue	0	(0.0, 3.9)	0	(0.0, 4.0)
Chills	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Injection site discolouration	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Injection site swelling	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 3.9)	0	(0.0, 4.0)
Vulvovaginal mycotic infection	0	(0.0, 3.9)	0	(0.0, 4.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (1.1)	(0.0, 5.9)	2 (2.2)	(0.3, 7.8)
Contusion	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Fall	0	(0.0, 3.9)	0	(0.0, 4.0)
Muscle rupture	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Tendon rupture	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
INVESTIGATIONS	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
White blood cell count increased	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Myalgia	0	(0.0, 3.9)	0	(0.0, 4.0)
Arthralgia	0	(0.0, 3.9)	0	(0.0, 4.0)
Neck pain	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 3.9)	0	(0.0, 4.0)
Adenocarcinoma gastric	0	(0.0, 3.9)	0	(0.0, 4.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 3.9)	0	(0.0, 4.0)

14.230. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Headache	0	(0.0, 3.9)	0	(0.0, 4.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 3.9)	0	(0.0, 4.0)
Oropharyngeal pain	0	(0.0, 3.9)	0	(0.0, 4.0)
Productive cough	0	(0.0, 3.9)	0	(0.0, 4.0)
Rhinorrhoea	0	(0.0, 3.9)	0	(0.0, 4.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (1.1)	(0.0, 5.9)	1 (1.1)	(0.0, 6.0)
Dermatitis	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Hangnail	0	(0.0, 3.9)	0	(0.0, 4.0)
Macule	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Rash macular	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 09OCT2020 (04:55)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2 2/adae s130 1md2 soc age p2 saf

14.231. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2 – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=180)		Placebo (N[a]=180)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	22 (12.2)	(7.8, 17.9)	29 (16.1)	(11.1, 22.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Lymphadenopathy	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
CARDIAC DISORDERS	2 (1.1)	(0.1, 4.0)	0	(0.0, 2.0)
Cardiac arrest	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Coronary artery dissection	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
GASTROINTESTINAL DISORDERS	4 (2.2)	(0.6, 5.6)	2 (1.1)	(0.1, 4.0)
Diarrhoea	2 (1.1)	(0.1, 4.0)	1 (0.6)	(0.0, 3.1)
Abdominal pain	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Odynophagia	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Tongue discomfort	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (2.8)	(0.9, 6.4)	8 (4.4)	(1.9, 8.6)
Injection site pain	4 (2.2)	(0.6, 5.6)	0	(0.0, 2.0)
Fatigue	1 (0.6)	(0.0, 3.1)	2 (1.1)	(0.1, 4.0)
Injection site erythema	1 (0.6)	(0.0, 3.1)	2 (1.1)	(0.1, 4.0)
Chest discomfort	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Chills	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Injection site discolouration	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Injection site swelling	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
IMMUNE SYSTEM DISORDERS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Seasonal allergy	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
INFECTIONS AND INFESTATIONS	3 (1.7)	(0.3, 4.8)	2 (1.1)	(0.1, 4.0)
Cystitis	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Gastroenteritis viral	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Nasopharyngitis	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Tonsillitis	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Vulvovaginal mycotic infection	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.6)	(0.0, 3.1)	4 (2.2)	(0.6, 5.6)
Contusion	1 (0.6)	(0.0, 3.1)	1 (0.6)	(0.0, 3.1)
Fall	0	(0.0, 2.0)	2 (1.1)	(0.1, 4.0)
Fibula fracture	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Muscle rupture	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Tendon rupture	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)

14.231. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=180)		Placebo (N[a]=180)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INVESTIGATIONS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
White blood cell count increased	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Hypercholesterolaemia	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Type 2 diabetes mellitus	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5 (2.8)	(0.9, 6.4)	4 (2.2)	(0.6, 5.6)
Arthralgia	2 (1.1)	(0.1, 4.0)	0	(0.0, 2.0)
Myalgia	1 (0.6)	(0.0, 3.1)	1 (0.6)	(0.0, 3.1)
Arthritis	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Muscle spasms	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Musculoskeletal pain	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Neck pain	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Scleroderma	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Tenosynovitis	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Adenocarcinoma gastric	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Headache	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Menorrhagia	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 2.0)	3 (1.7)	(0.3, 4.8)
Interstitial lung disease	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Oropharyngeal pain	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Productive cough	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Rhinorrhoea	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (1.7)	(0.3, 4.8)	3 (1.7)	(0.3, 4.8)
Dermatitis	1 (0.6)	(0.0, 3.1)	1 (0.6)	(0.0, 3.1)
Dermatitis contact	0	(0.0, 2.0)	2 (1.1)	(0.1, 4.0)
Hangnail	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Hyperhidrosis	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Macule	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
UNCODED TERM	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)

14.231. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=180)		Placebo (N[a]=180)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
VASCULAR DISORDERS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Hypertension	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (08:18)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc p2 saf

14.232. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	12 (13.6)	(7.2, 22.6)	16 (17.8)	(10.5, 27.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Lymphadenopathy	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
GASTROINTESTINAL DISORDERS	2 (2.3)	(0.3, 8.0)	2 (2.2)	(0.3, 7.8)
Diarrhoea	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 6.0)
Abdominal pain	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Tongue discomfort	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (3.4)	(0.7, 9.6)	4 (4.4)	(1.2, 11.0)
Injection site pain	3 (3.4)	(0.7, 9.6)	0	(0.0, 4.0)
Fatigue	0	(0.0, 4.1)	2 (2.2)	(0.3, 7.8)
Injection site erythema	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 6.0)
Chest discomfort	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
INFECTIONS AND INFESTATIONS	2 (2.3)	(0.3, 8.0)	2 (2.2)	(0.3, 7.8)
Gastroenteritis viral	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Nasopharyngitis	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Tonsillitis	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Vulvovaginal mycotic infection	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 4.1)	2 (2.2)	(0.3, 7.8)
Contusion	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Fall	0	(0.0, 4.1)	2 (2.2)	(0.3, 7.8)
Fibula fracture	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (4.5)	(1.3, 11.2)	2 (2.2)	(0.3, 7.8)
Arthralgia	2 (2.3)	(0.3, 8.0)	0	(0.0, 4.0)
Myalgia	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 6.0)
Muscle spasms	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Tenosynovitis	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Headache	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)

14.232. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Menorrhagia	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 4.1)	2 (2.2)	(0.3, 7.8)
Oropharyngeal pain	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Productive cough	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Rhinorrhoea	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (1.1)	(0.0, 6.2)	1 (1.1)	(0.0, 6.0)
Dermatitis contact	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Hangnail	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
VASCULAR DISORDERS	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)
Hypertension	0	(0.0, 4.1)	1 (1.1)	(0.0, 6.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (08:14)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc age p2 saf

14.233. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	10 (10.9)	(5.3, 19.1)	13 (14.4)	(7.9, 23.4)
CARDIAC DISORDERS	2 (2.2)	(0.3, 7.6)	0	(0.0, 4.0)
Cardiac arrest	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Coronary artery dissection	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
GASTROINTESTINAL DISORDERS	2 (2.2)	(0.3, 7.6)	0	(0.0, 4.0)
Diarrhoea	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Odynophagia	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (2.2)	(0.3, 7.6)	4 (4.4)	(1.2, 11.0)
Injection site pain	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Fatigue	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Injection site erythema	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Chills	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Injection site discolouration	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Injection site swelling	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Seasonal allergy	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
INFECTIONS AND INFESTATIONS	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Cystitis	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (1.1)	(0.0, 5.9)	2 (2.2)	(0.3, 7.8)
Contusion	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Muscle rupture	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Tendon rupture	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
INVESTIGATIONS	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
White blood cell count increased	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Hypercholesterolaemia	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Type 2 diabetes mellitus	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (1.1)	(0.0, 5.9)	2 (2.2)	(0.3, 7.8)
Arthritis	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Musculoskeletal pain	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Neck pain	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Scleroderma	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)

14.233. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Interstitial lung disease	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (2.2)	(0.3, 7.6)	2 (2.2)	(0.3, 7.8)
Dermatitis	1 (1.1)	(0.0, 5.9)	1 (1.1)	(0.0, 6.0)
Dermatitis contact	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Hyperhidrosis	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Macule	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
UNCODED TERM	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (08:14)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc age p2 saf

14.234. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)						Placebo	
	18-55 Years (N[a]=88)		56-85 Years (N[a]=92)		18-85 Years (N[a]=180)		18-85 Years (N[a]=180)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (3.4)	(0.7, 9.6)	2 (2.2)	(0.3, 7.6)	5 (2.8)	(0.9, 6.4)	8 (4.4)	(1.9, 8.6)
GASTROINTESTINAL DISORDERS	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	2 (1.1)	(0.1, 4.0)
Diarrhoea	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Tongue discomfort	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (3.4)	(0.7, 9.6)	0	(0.0, 3.9)	3 (1.7)	(0.3, 4.8)	5 (2.8)	(0.9, 6.4)
Injection site pain	3 (3.4)	(0.7, 9.6)	0	(0.0, 3.9)	3 (1.7)	(0.3, 4.8)	0	(0.0, 2.0)
Fatigue	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	2 (1.1)	(0.1, 4.0)
Injection site erythema	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	1 (0.6)	(0.0, 3.1)
Injection site discolouration	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Injection site swelling	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Contusion	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Myalgia	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
NERVOUS SYSTEM DISORDERS	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Headache	0	(0.0, 4.1)	0	(0.0, 3.9)	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Macule	0	(0.0, 4.1)	1 (1.1)	(0.0, 5.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 12SEP2020 (19:59)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adae_s130_1md2_rel_p2_saf

14.235. Number (%) of Subjects Reporting at Least 1 Severe or Life-Threatening Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)						Placebo	
	18-55 Years (N[a]=88)		56-85 Years (N[a]=92)		18-85 Years (N[a]=180)		18-85 Years (N[a]=180)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (2.3)	(0.3, 8.0)	0	(0.0, 3.9)	2 (1.1)	(0.1, 4.0)	0	(0.0, 2.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Myalgia	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 12SEP2020 (19:59)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2/adae s130 1md2 sev p2 saf

14.236. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 10OCT2020 (10:49)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adae_s130_1md2_ser_age_p2_saf

14.237. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 3.9)	0	(0.0, 4.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 3.9)	0	(0.0, 4.0)
Adenocarcinoma gastric	0	(0.0, 3.9)	0	(0.0, 4.0)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 10OCT2020 (10:49)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adae_s130_1md2_ser_age_p2_saf

14.238. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=180)		Placebo (N[a]=180)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (1.7)	(0.3, 4.8)	1 (0.6)	(0.0, 3.1)
CARDIAC DISORDERS	2 (1.1)	(0.1, 4.0)	0	(0.0, 2.0)
Cardiac arrest	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Coronary artery dissection	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Scleroderma	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Adenocarcinoma gastric	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)
Interstitial lung disease	0	(0.0, 2.0)	1 (0.6)	(0.0, 3.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:37)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_ser_vax2_p2_saf

14.239. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 18-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 4.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:37)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 ser vax2 age p2 saf

14.240. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2 – Safety Population Age Group: 56-85 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=90)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (2.2)	(0.3, 7.6)	1 (1.1)	(0.0, 6.0)
CARDIAC DISORDERS	2 (2.2)	(0.3, 7.6)	0	(0.0, 4.0)
Cardiac arrest	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
Coronary artery dissection	1 (1.1)	(0.0, 5.9)	0	(0.0, 4.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Scleroderma	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)
Interstitial lung disease	0	(0.0, 3.9)	1 (1.1)	(0.0, 6.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:37)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 ser vax2 age p2 saf

14.241. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Phase 2 – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)						Placebo	
	18-55 Years (N^a=88)		56-85 Years (N^a=92)		18-85 Years (N^a=180)		18-85 Years (N^a=180)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Any event	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)
Adenocarcinoma gastric	1 (1.1)	(0.0, 6.2)	0	(0.0, 3.9)	1 (0.6)	(0.0, 3.1)	0	(0.0, 2.0)

Note: MedDRA (v23.0) 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: 05SEP2020 (13:08) Source Data: adae Table Generation: 13OCT2020 (00:20)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File:
./nda2 unblinded/C4591001 IA P2 2/adae s130 1md2 wd p2 saf

Phase 2/3

Conduct of Study

14.242. Disposition of All Randomized Subjects, by Age Group – ~38000 Subjects for Phase 2/3 Analysis Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=10915) n[b] (%)	Placebo (N[a]=10925) n[b] (%)	Total (N[a]=21840) n[b] (%)
Randomized	10915 (100.0)	10925 (100.0)	21840 (100.0)
Not vaccinated	25 (0.2)	29 (0.3)	54 (0.2)
Vaccinated			
Dose 1	10890 (99.8)	10896 (99.7)	21786 (99.8)
Dose 2	10665 (97.7)	10666 (97.6)	21331 (97.7)
Completed 1-month post–Dose 2 visit (vaccination period)	9490 (86.9)	9477 (86.7)	18967 (86.8)
Discontinued from vaccination period but continue in the study	96 (0.9)	83 (0.8)	179 (0.8)
Discontinued after Dose 1 and before Dose 2	96 (0.9)	79 (0.7)	175 (0.8)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.0)	4 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	42 (0.4)	62 (0.6)	104 (0.5)
Withdrawal by subject	37 (0.3)	6 (0.1)	43 (0.2)
Adverse event	10 (0.1)	7 (0.1)	17 (0.1)
Pregnancy	4 (0.0)	4 (0.0)	8 (0.0)
Lost to follow-up	0	2 (0.0)	2 (0.0)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)
Medication error without associated adverse event	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	0	2 (0.0)
Withdrawn from the study	135 (1.2)	177 (1.6)	312 (1.4)
Withdrawn after Dose 1 and before Dose 2	97 (0.9)	120 (1.1)	217 (1.0)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	36 (0.3)	52 (0.5)	88 (0.4)
Withdrawn after 1-month post–Dose 2 visit	2 (0.0)	5 (0.0)	7 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	59 (0.5)	96 (0.9)	155 (0.7)
Lost to follow-up	67 (0.6)	71 (0.6)	138 (0.6)
Adverse event	4 (0.0)	1 (0.0)	5 (0.0)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Death	0	2 (0.0)	2 (0.0)
Physician decision	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)

14.242. Disposition of All Randomized Subjects, by Age Group – ~38000 Subjects for Phase 2/3 Analysis Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=10915) n[b] (%)	Placebo (N[a]=10925) n[b] (%)	Total (N[a]=21840) n[b] (%)
Other	3 (0.0)	3 (0.0)	6 (0.0)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 age p3 rand

14.243. Disposition of All Randomized Subjects, by Age Group – ~38000 Subjects for Phase 2/3 Analysis Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=7989) n[b] (%)	Placebo (N[a]=7967) n[b] (%)	Total (N[a]=15956) n[b] (%)
Randomized	7989 (100.0)	7967 (100.0)	15956 (100.0)
Not vaccinated	21 (0.3)	14 (0.2)	35 (0.2)
Vaccinated			
Dose 1	7968 (99.7)	7953 (99.8)	15921 (99.8)
Dose 2	7890 (98.8)	7867 (98.7)	15757 (98.8)
Completed 1-month post–Dose 2 visit (vaccination period)	7412 (92.8)	7327 (92.0)	14739 (92.4)
Discontinued from vaccination period but continue in the study	25 (0.3)	28 (0.4)	53 (0.3)
Discontinued after Dose 1 and before Dose 2	25 (0.3)	28 (0.4)	53 (0.3)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	6 (0.1)	19 (0.2)	25 (0.2)
Adverse event	10 (0.1)	5 (0.1)	15 (0.1)
Withdrawal by subject	8 (0.1)	3 (0.0)	11 (0.1)
Physician decision	1 (0.0)	0	1 (0.0)
Other	0	1 (0.0)	1 (0.0)
Withdrawn from the study	45 (0.6)	82 (1.0)	127 (0.8)
Withdrawn after Dose 1 and before Dose 2	35 (0.4)	44 (0.6)	79 (0.5)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	8 (0.1)	32 (0.4)	40 (0.3)
Withdrawn after 1-month post–Dose 2 visit	2 (0.0)	6 (0.1)	8 (0.1)
Reason for withdrawal from the study			
Withdrawal by subject	25 (0.3)	61 (0.8)	86 (0.5)
Lost to follow-up	13 (0.2)	15 (0.2)	28 (0.2)
Adverse event	4 (0.1)	4 (0.1)	8 (0.1)
Death	2 (0.0)	1 (0.0)	3 (0.0)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)

14.243. Disposition of All Randomized Subjects, by Age Group – ~38000 Subjects for Phase 2/3 Analysis Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=7989) n^b (%)	Placebo (N^a=7967) n^b (%)	Total (N^a=15956) n^b (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_age_p3_rand

14.244. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=558) n^b (%)	Placebo (N^a=590) n^b (%)	Total (N^a=1148) n^b (%)
Randomized	558 (100.0)	590 (100.0)	1148 (100.0)
Not vaccinated	1 (0.2)	2 (0.3)	3 (0.3)
Vaccinated			
Dose 1	557 (99.8)	588 (99.7)	1145 (99.7)
Dose 2	526 (94.3)	562 (95.3)	1088 (94.8)
Completed 1-month post–Dose 2 visit (vaccination period)	403 (72.2)	428 (72.5)	831 (72.4)
Discontinued from vaccination period but continue in the study	14 (2.5)	10 (1.7)	24 (2.1)
Discontinued after Dose 1 and before Dose 2	14 (2.5)	10 (1.7)	24 (2.1)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	13 (2.3)	8 (1.4)	21 (1.8)
Pregnancy	1 (0.2)	1 (0.2)	2 (0.2)
Medication error without associated adverse event	0	1 (0.2)	1 (0.1)
Withdrawn from the study	13 (2.3)	12 (2.0)	25 (2.2)
Withdrawn after Dose 1 and before Dose 2	13 (2.3)	9 (1.5)	22 (1.9)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	3 (0.5)	3 (0.3)
Withdrawn after 1-month post–Dose 2 visit	0	0	0
Reason for withdrawal from the study			
Withdrawal by subject	6 (1.1)	5 (0.8)	11 (1.0)
Lost to follow-up	5 (0.9)	5 (0.8)	10 (0.9)
Death	1 (0.2)	0	1 (0.1)
Physician decision	0	1 (0.2)	1 (0.1)
Refused further study procedures	0	1 (0.2)	1 (0.1)
Other	1 (0.2)	0	1 (0.1)

14.244. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=558) n[b] (%)	Placebo (N[a]=590) n[b] (%)	Total (N[a]=1148) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_bs_p3_rand

14.245. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=17890) n[b] (%)	Placebo (N[a]=17874) n[b] (%)	Total (N[a]=35764) n[b] (%)
Randomized	17890 (100.0)	17874 (100.0)	35764 (100.0)
Not vaccinated	8 (0.0)	13 (0.1)	21 (0.1)
Vaccinated			
Dose 1	17882 (100.0)	17861 (99.9)	35743 (99.9)
Dose 2	17641 (98.6)	17580 (98.4)	35221 (98.5)
Completed 1-month post–Dose 2 visit (vaccination period)	16185 (90.5)	16047 (89.8)	32232 (90.1)
Discontinued from vaccination period but continue in the study	84 (0.5)	98 (0.5)	182 (0.5)
Discontinued after Dose 1 and before Dose 2	84 (0.5)	94 (0.5)	178 (0.5)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.0)	4 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	34 (0.2)	71 (0.4)	105 (0.3)
Withdrawal by subject	24 (0.1)	8 (0.0)	32 (0.1)
Adverse event	19 (0.1)	12 (0.1)	31 (0.1)
Pregnancy	3 (0.0)	3 (0.0)	6 (0.0)
Physician decision	2 (0.0)	1 (0.0)	3 (0.0)
Lost to follow-up	0	2 (0.0)	2 (0.0)
Other	2 (0.0)	1 (0.0)	3 (0.0)
Withdrawn from the study	164 (0.9)	244 (1.4)	408 (1.1)
Withdrawn after Dose 1 and before Dose 2	116 (0.6)	153 (0.9)	269 (0.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	44 (0.2)	80 (0.4)	124 (0.3)
Withdrawn after 1-month post–Dose 2 visit	4 (0.0)	11 (0.1)	15 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	76 (0.4)	150 (0.8)	226 (0.6)
Lost to follow-up	74 (0.4)	81 (0.5)	155 (0.4)
Adverse event	8 (0.0)	5 (0.0)	13 (0.0)
Death	1 (0.0)	3 (0.0)	4 (0.0)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Other	2 (0.0)	2 (0.0)	4 (0.0)

14.245. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=17890) n^b (%)	Placebo (N^a=17874) n^b (%)	Total (N^a=35764) n^b (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_bs_p3_rand

14.246. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=408) n[b] (%)	Placebo (N[a]=437) n[b] (%)	Total (N[a]=845) n[b] (%)
Randomized	408 (100.0)	437 (100.0)	845 (100.0)
Not vaccinated	1 (0.2)	1 (0.2)	2 (0.2)
Vaccinated			
Dose 1	407 (99.8)	436 (99.8)	843 (99.8)
Dose 2	381 (93.4)	418 (95.7)	799 (94.6)
Completed 1-month post–Dose 2 visit (vaccination period)	288 (70.6)	307 (70.3)	595 (70.4)
Discontinued from vaccination period but continue in the study	12 (2.9)	8 (1.8)	20 (2.4)
Discontinued after Dose 1 and before Dose 2	12 (2.9)	8 (1.8)	20 (2.4)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	11 (2.7)	6 (1.4)	17 (2.0)
Pregnancy	1 (0.2)	1 (0.2)	2 (0.2)
Medication error without associated adverse event	0	1 (0.2)	1 (0.1)
Withdrawn from the study	10 (2.5)	8 (1.8)	18 (2.1)
Withdrawn after Dose 1 and before Dose 2	10 (2.5)	5 (1.1)	15 (1.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	3 (0.7)	3 (0.4)
Withdrawn after 1-month post–Dose 2 visit	0	0	0
Reason for withdrawal from the study			
Lost to follow-up	5 (1.2)	4 (0.9)	9 (1.1)
Withdrawal by subject	4 (1.0)	3 (0.7)	7 (0.8)
Refused further study procedures	0	1 (0.2)	1 (0.1)
Other	1 (0.2)	0	1 (0.1)

14.246. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=408) n^b (%)	Placebo (N^a=437) n^b (%)	Total (N^a=845) n^b (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 bsage p3 rand

14.247. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Positive Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=150) n[b] (%)	Placebo (N[a]=153) n[b] (%)	Total (N[a]=303) n[b] (%)
Randomized	150 (100.0)	153 (100.0)	303 (100.0)
Not vaccinated	0	1 (0.7)	1 (0.3)
Vaccinated			
Dose 1	150 (100.0)	152 (99.3)	302 (99.7)
Dose 2	145 (96.7)	144 (94.1)	289 (95.4)
Completed 1-month post–Dose 2 visit (vaccination period)	115 (76.7)	121 (79.1)	236 (77.9)
Discontinued from vaccination period but continue in the study	2 (1.3)	2 (1.3)	4 (1.3)
Discontinued after Dose 1 and before Dose 2	2 (1.3)	2 (1.3)	4 (1.3)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	2 (1.3)	2 (1.3)	4 (1.3)
Withdrawn from the study	3 (2.0)	4 (2.6)	7 (2.3)
Withdrawn after Dose 1 and before Dose 2	3 (2.0)	4 (2.6)	7 (2.3)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Withdrawn after 1-month post–Dose 2 visit	0	0	0
Reason for withdrawal from the study			
Withdrawal by subject	2 (1.3)	2 (1.3)	4 (1.3)
Death	1 (0.7)	0	1 (0.3)
Lost to follow-up	0	1 (0.7)	1 (0.3)
Physician decision	0	1 (0.7)	1 (0.3)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 bsage p3 rand

14.248. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=10226) n[b] (%)	Placebo (N[a]=10233) n[b] (%)	Total (N[a]=20459) n[b] (%)
Randomized	10226 (100.0)	10233 (100.0)	20459 (100.0)
Not vaccinated	5 (0.0)	9 (0.1)	14 (0.1)
Vaccinated			
Dose 1	10221 (100.0)	10224 (99.9)	20445 (99.9)
Dose 2	10048 (98.3)	10019 (97.9)	20067 (98.1)
Completed 1-month post–Dose 2 visit (vaccination period)	9019 (88.2)	8982 (87.8)	18001 (88.0)
Discontinued from vaccination period but continue in the study	65 (0.6)	73 (0.7)	138 (0.7)
Discontinued after Dose 1 and before Dose 2	65 (0.6)	69 (0.7)	134 (0.7)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.0)	4 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	30 (0.3)	55 (0.5)	85 (0.4)
Withdrawal by subject	20 (0.2)	5 (0.0)	25 (0.1)
Adverse event	9 (0.1)	7 (0.1)	16 (0.1)
Pregnancy	3 (0.0)	3 (0.0)	6 (0.0)
Lost to follow-up	0	2 (0.0)	2 (0.0)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)
Other	2 (0.0)	0	2 (0.0)
Withdrawn from the study	122 (1.2)	166 (1.6)	288 (1.4)
Withdrawn after Dose 1 and before Dose 2	84 (0.8)	113 (1.1)	197 (1.0)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	36 (0.4)	48 (0.5)	84 (0.4)
Withdrawn after 1-month post–Dose 2 visit	2 (0.0)	5 (0.0)	7 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	53 (0.5)	91 (0.9)	144 (0.7)
Lost to follow-up	61 (0.6)	67 (0.7)	128 (0.6)
Adverse event	4 (0.0)	1 (0.0)	5 (0.0)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Death	0	2 (0.0)	2 (0.0)
Physician decision	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Other	2 (0.0)	2 (0.0)	4 (0.0)

14.248. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=10226) n^b (%)	Placebo (N^a=10233) n^b (%)	Total (N^a=20459) n^b (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 bsage p3 rand

14.249. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=7664) n[b] (%)	Placebo (N[a]=7641) n[b] (%)	Total (N[a]=15305) n[b] (%)
Randomized	7664 (100.0)	7641 (100.0)	15305 (100.0)
Not vaccinated	3 (0.0)	4 (0.1)	7 (0.0)
Vaccinated			
Dose 1	7661 (100.0)	7637 (99.9)	15298 (100.0)
Dose 2	7593 (99.1)	7561 (99.0)	15154 (99.0)
Completed 1-month post–Dose 2 visit (vaccination period)	7166 (93.5)	7065 (92.5)	14231 (93.0)
Discontinued from vaccination period but continue in the study	19 (0.2)	25 (0.3)	44 (0.3)
Discontinued after Dose 1 and before Dose 2	19 (0.2)	25 (0.3)	44 (0.3)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	4 (0.1)	16 (0.2)	20 (0.1)
Adverse event	10 (0.1)	5 (0.1)	15 (0.1)
Withdrawal by subject	4 (0.1)	3 (0.0)	7 (0.0)
Physician decision	1 (0.0)	0	1 (0.0)
Other	0	1 (0.0)	1 (0.0)
Withdrawn from the study	42 (0.5)	78 (1.0)	120 (0.8)
Withdrawn after Dose 1 and before Dose 2	32 (0.4)	40 (0.5)	72 (0.5)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	8 (0.1)	32 (0.4)	40 (0.3)
Withdrawn after 1-month post–Dose 2 visit	2 (0.0)	6 (0.1)	8 (0.1)
Reason for withdrawal from the study			
Withdrawal by subject	23 (0.3)	59 (0.8)	82 (0.5)
Lost to follow-up	13 (0.2)	14 (0.2)	27 (0.2)
Adverse event	4 (0.1)	4 (0.1)	8 (0.1)
Death	1 (0.0)	1 (0.0)	2 (0.0)
Physician decision	1 (0.0)	0	1 (0.0)

14.249. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=7664) n^b (%)	Placebo (N^a=7641) n^b (%)	Total (N^a=15305) n^b (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 bsage p3 rand

14.250. Disposition of All Randomized Subjects, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis Ethnicity: Hispanic/Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5275) n[b] (%)	Placebo (N[a]=5290) n[b] (%)	Total (N[a]=10565) n[b] (%)
Randomized	5275 (100.0)	5290 (100.0)	10565 (100.0)
Not vaccinated	10 (0.2)	12 (0.2)	22 (0.2)
Vaccinated			
Dose 1	5265 (99.8)	5278 (99.8)	10543 (99.8)
Dose 2	5126 (97.2)	5136 (97.1)	10262 (97.1)
Completed 1-month post–Dose 2 visit (vaccination period)	4656 (88.3)	4655 (88.0)	9311 (88.1)
Discontinued from vaccination period but continue in the study	76 (1.4)	56 (1.1)	132 (1.2)
Discontinued after Dose 1 and before Dose 2	76 (1.4)	56 (1.1)	132 (1.2)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	32 (0.6)	51 (1.0)	83 (0.8)
Withdrawal by subject	36 (0.7)	2 (0.0)	38 (0.4)
Adverse event	6 (0.1)	1 (0.0)	7 (0.1)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)
Lost to follow-up	0	1 (0.0)	1 (0.0)
Pregnancy	1 (0.0)	0	1 (0.0)
Withdrawn from the study	64 (1.2)	106 (2.0)	170 (1.6)
Withdrawn after Dose 1 and before Dose 2	47 (0.9)	69 (1.3)	116 (1.1)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	16 (0.3)	32 (0.6)	48 (0.5)
Withdrawn after 1-month post–Dose 2 visit	1 (0.0)	5 (0.1)	6 (0.1)
Reason for withdrawal from the study			
Withdrawal by subject	37 (0.7)	76 (1.4)	113 (1.1)
Lost to follow-up	26 (0.5)	26 (0.5)	52 (0.5)
No longer meets eligibility criteria	0	2 (0.0)	2 (0.0)
Adverse event	1 (0.0)	0	1 (0.0)
Death	0	1 (0.0)	1 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)

14.250. Disposition of All Randomized Subjects, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis Ethnicity: Hispanic/Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5275) n[b] (%)	Placebo (N[a]=5290) n[b] (%)	Total (N[a]=10565) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_eth_p3_rand

14.251. Disposition of All Randomized Subjects, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=13517) n[b] (%)	Placebo (N[a]=13492) n[b] (%)	Total (N[a]=27009) n[b] (%)
Randomized	13517 (100.0)	13492 (100.0)	27009 (100.0)
Not vaccinated	36 (0.3)	31 (0.2)	67 (0.2)
Vaccinated			
Dose 1	13481 (99.7)	13461 (99.8)	26942 (99.8)
Dose 2	13318 (98.5)	13288 (98.5)	26606 (98.5)
Completed 1-month post–Dose 2 visit (vaccination period)	12142 (89.8)	12048 (89.3)	24190 (89.6)
Discontinued from vaccination period but continue in the study	45 (0.3)	54 (0.4)	99 (0.4)
Discontinued after Dose 1 and before Dose 2	45 (0.3)	50 (0.4)	95 (0.4)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.0)	4 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	16 (0.1)	29 (0.2)	45 (0.2)
Adverse event	14 (0.1)	11 (0.1)	25 (0.1)
Withdrawal by subject	9 (0.1)	7 (0.1)	16 (0.1)
Pregnancy	3 (0.0)	4 (0.0)	7 (0.0)
Lost to follow-up	0	1 (0.0)	1 (0.0)
Physician decision	1 (0.0)	0	1 (0.0)
Medication error without associated adverse event	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	1 (0.0)	3 (0.0)
Withdrawn from the study	115 (0.9)	153 (1.1)	268 (1.0)
Withdrawn after Dose 1 and before Dose 2	84 (0.6)	95 (0.7)	179 (0.7)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	28 (0.2)	52 (0.4)	80 (0.3)
Withdrawn after 1-month post–Dose 2 visit	3 (0.0)	6 (0.0)	9 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	46 (0.3)	81 (0.6)	127 (0.5)
Lost to follow-up	54 (0.4)	60 (0.4)	114 (0.4)
Adverse event	7 (0.1)	5 (0.0)	12 (0.0)
Death	2 (0.0)	2 (0.0)	4 (0.0)
Physician decision	1 (0.0)	2 (0.0)	3 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
No longer meets eligibility criteria	1 (0.0)	0	1 (0.0)
Other	3 (0.0)	3 (0.0)	6 (0.0)

14.251. Disposition of All Randomized Subjects, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=13517) n[b] (%)	Placebo (N[a]=13492) n[b] (%)	Total (N[a]=27009) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_eth_p3_rand

14.252. Disposition of All Randomized Subjects, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis Ethnicity: Not Reported

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=112) n[b] (%)	Placebo (N[a]=110) n[b] (%)	Total (N[a]=222) n[b] (%)
Randomized	112 (100.0)	110 (100.0)	222 (100.0)
Not vaccinated	0	0	0
Vaccinated			
Dose 1	112 (100.0)	110 (100.0)	222 (100.0)
Dose 2	111 (99.1)	109 (99.1)	220 (99.1)
Completed 1-month post–Dose 2 visit (vaccination period)	104 (92.9)	101 (91.8)	205 (92.3)
Discontinued from vaccination period but continue in the study	0	1 (0.9)	1 (0.5)
Discontinued after Dose 1 and before Dose 2	0	1 (0.9)	1 (0.5)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	0	1 (0.9)	1 (0.5)
Withdrawn from the study	1 (0.9)	0	1 (0.5)
Withdrawn after Dose 1 and before Dose 2	1 (0.9)	0	1 (0.5)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Withdrawn after 1-month post–Dose 2 visit	0	0	0
Reason for withdrawal from the study			
Withdrawal by subject	1 (0.9)	0	1 (0.5)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_eth_p3_rand

14.253. Disposition of All Randomized Subjects, by Race – ~38000 Subjects for Phase 2/3 Analysis Race: White

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=15674) n[b] (%)	Placebo (N[a]=15662) n[b] (%)	Total (N[a]=31336) n[b] (%)
Randomized	15674 (100.0)	15662 (100.0)	31336 (100.0)
Not vaccinated	37 (0.2)	32 (0.2)	69 (0.2)
Vaccinated			
Dose 1	15637 (99.8)	15630 (99.8)	31267 (99.8)
Dose 2	15393 (98.2)	15390 (98.3)	30783 (98.2)
Completed 1-month post–Dose 2 visit (vaccination period)	14378 (91.7)	14307 (91.3)	28685 (91.5)
Discontinued from vaccination period but continue in the study	106 (0.7)	91 (0.6)	197 (0.6)
Discontinued after Dose 1 and before Dose 2	106 (0.7)	88 (0.6)	194 (0.6)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	3 (0.0)	3 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	39 (0.2)	73 (0.5)	112 (0.4)
Withdrawal by subject	44 (0.3)	5 (0.0)	49 (0.2)
Adverse event	19 (0.1)	8 (0.1)	27 (0.1)
Pregnancy	2 (0.0)	1 (0.0)	3 (0.0)
Lost to follow-up	0	1 (0.0)	1 (0.0)
Physician decision	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	1 (0.0)	3 (0.0)
Withdrawn from the study	141 (0.9)	209 (1.3)	350 (1.1)
Withdrawn after Dose 1 and before Dose 2	102 (0.7)	122 (0.8)	224 (0.7)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	36 (0.2)	76 (0.5)	112 (0.4)
Withdrawn after 1-month post–Dose 2 visit	3 (0.0)	11 (0.1)	14 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	67 (0.4)	132 (0.8)	199 (0.6)
Lost to follow-up	59 (0.4)	63 (0.4)	122 (0.4)
Adverse event	7 (0.0)	5 (0.0)	12 (0.0)
Death	2 (0.0)	3 (0.0)	5 (0.0)
Physician decision	1 (0.0)	2 (0.0)	3 (0.0)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)
Other	3 (0.0)	1 (0.0)	4 (0.0)

14.253. Disposition of All Randomized Subjects, by Race – ~38000 Subjects for Phase 2/3 Analysis Race: White

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=15674) n[b] (%)	Placebo (N[a]=15662) n[b] (%)	Total (N[a]=31336) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 race p3 rand

14.254. Disposition of All Randomized Subjects, by Race – ~38000 Subjects for Phase 2/3 Analysis Race: Black or African American

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1734) n[b] (%)	Placebo (N[a]=1769) n[b] (%)	Total (N[a]=3503) n[b] (%)
Randomized	1734 (100.0)	1769 (100.0)	3503 (100.0)
Not vaccinated	5 (0.3)	6 (0.3)	11 (0.3)
Vaccinated			
Dose 1	1729 (99.7)	1763 (99.7)	3492 (99.7)
Dose 2	1685 (97.2)	1704 (96.3)	3389 (96.7)
Completed 1-month post–Dose 2 visit (vaccination period)	1274 (73.5)	1269 (71.7)	2543 (72.6)
Discontinued from vaccination period but continue in the study	9 (0.5)	13 (0.7)	22 (0.6)
Discontinued after Dose 1 and before Dose 2	9 (0.5)	13 (0.7)	22 (0.6)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	6 (0.3)	5 (0.3)	11 (0.3)
Pregnancy	2 (0.1)	3 (0.2)	5 (0.1)
Adverse event	0	3 (0.2)	3 (0.1)
Lost to follow-up	0	1 (0.1)	1 (0.0)
Physician decision	1 (0.1)	0	1 (0.0)
Withdrawal by subject	0	1 (0.1)	1 (0.0)
Withdrawn from the study	29 (1.7)	39 (2.2)	68 (1.9)
Withdrawn after Dose 1 and before Dose 2	23 (1.3)	34 (1.9)	57 (1.6)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	5 (0.3)	5 (0.3)	10 (0.3)
Withdrawn after 1-month post–Dose 2 visit	1 (0.1)	0	1 (0.0)
Reason for withdrawal from the study			
Lost to follow-up	15 (0.9)	19 (1.1)	34 (1.0)
Withdrawal by subject	13 (0.7)	18 (1.0)	31 (0.9)
Adverse event	1 (0.1)	0	1 (0.0)
Other	0	2 (0.1)	2 (0.1)

14.254. Disposition of All Randomized Subjects, by Race – ~38000 Subjects for Phase 2/3 Analysis Race: Black or African American

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1734) n[b] (%)	Placebo (N[a]=1769) n[b] (%)	Total (N[a]=3503) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 race p3 rand

14.255. Disposition of All Randomized Subjects, by Race – ~38000 Subjects for Phase 2/3 Analysis Race: All Others

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1496) n[b] (%)	Placebo (N[a]=1461) n[b] (%)	Total (N[a]=2957) n[b] (%)
Randomized	1496 (100.0)	1461 (100.0)	2957 (100.0)
Not vaccinated	4 (0.3)	5 (0.3)	9 (0.3)
Vaccinated			
Dose 1	1492 (99.7)	1456 (99.7)	2948 (99.7)
Dose 2	1477 (98.7)	1439 (98.5)	2916 (98.6)
Completed 1-month post–Dose 2 visit (vaccination period)	1250 (83.6)	1228 (84.1)	2478 (83.8)
Discontinued from vaccination period but continue in the study	6 (0.4)	7 (0.5)	13 (0.4)
Discontinued after Dose 1 and before Dose 2	6 (0.4)	6 (0.4)	12 (0.4)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	1 (0.1)	1 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	3 (0.2)	3 (0.2)	6 (0.2)
Withdrawal by subject	1 (0.1)	3 (0.2)	4 (0.1)
Adverse event	1 (0.1)	1 (0.1)	2 (0.1)
Physician decision	1 (0.1)	0	1 (0.0)
Withdrawn from the study	10 (0.7)	11 (0.8)	21 (0.7)
Withdrawn after Dose 1 and before Dose 2	7 (0.5)	8 (0.5)	15 (0.5)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	3 (0.2)	3 (0.2)	6 (0.2)
Withdrawn after 1-month post–Dose 2 visit	0	0	0
Reason for withdrawal from the study			
Withdrawal by subject	4 (0.3)	7 (0.5)	11 (0.4)
Lost to follow-up	6 (0.4)	4 (0.3)	10 (0.3)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 race p3 rand

14.256. Disposition of All Randomized Subjects, by Sex – ~38000 Subjects for Phase 2/3 Analysis Sex: Male

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=9666) n[b] (%)	Placebo (N[a]=9459) n[b] (%)	Total (N[a]=19125) n[b] (%)
Randomized	9666 (100.0)	9459 (100.0)	19125 (100.0)
Not vaccinated	25 (0.3)	24 (0.3)	49 (0.3)
Vaccinated			
Dose 1	9641 (99.7)	9435 (99.7)	19076 (99.7)
Dose 2	9479 (98.1)	9273 (98.0)	18752 (98.0)
Completed 1-month post–Dose 2 visit (vaccination period)	8629 (89.3)	8386 (88.7)	17015 (89.0)
Discontinued from vaccination period but continue in the study	59 (0.6)	53 (0.6)	112 (0.6)
Discontinued after Dose 1 and before Dose 2	59 (0.6)	50 (0.5)	109 (0.6)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	3 (0.0)	3 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	27 (0.3)	40 (0.4)	67 (0.4)
Withdrawal by subject	25 (0.3)	3 (0.0)	28 (0.1)
Adverse event	4 (0.0)	6 (0.1)	10 (0.1)
Lost to follow-up	0	2 (0.0)	2 (0.0)
Physician decision	1 (0.0)	0	1 (0.0)
Medication error without associated adverse event	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	1 (0.0)	3 (0.0)
Withdrawn from the study	105 (1.1)	141 (1.5)	246 (1.3)
Withdrawn after Dose 1 and before Dose 2	76 (0.8)	85 (0.9)	161 (0.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	26 (0.3)	51 (0.5)	77 (0.4)
Withdrawn after 1-month post–Dose 2 visit	3 (0.0)	5 (0.1)	8 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	48 (0.5)	84 (0.9)	132 (0.7)
Lost to follow-up	49 (0.5)	48 (0.5)	97 (0.5)
Adverse event	2 (0.0)	4 (0.0)	6 (0.0)
Physician decision	1 (0.0)	2 (0.0)	3 (0.0)
No longer meets eligibility criteria	1 (0.0)	1 (0.0)	2 (0.0)
Death	1 (0.0)	0	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	1 (0.0)	3 (0.0)

14.256. Disposition of All Randomized Subjects, by Sex – ~38000 Subjects for Phase 2/3 Analysis Sex: Male

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=9666) n^b (%)	Placebo (N^a=9459) n^b (%)	Total (N^a=19125) n^b (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_sex_p3_rand

14.257. Disposition of All Randomized Subjects, by Sex – ~38000 Subjects for Phase 2/3 Analysis Sex: Female

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=9238) n[b] (%)	Placebo (N[a]=9433) n[b] (%)	Total (N[a]=18671) n[b] (%)
Randomized	9238 (100.0)	9433 (100.0)	18671 (100.0)
Not vaccinated	21 (0.2)	19 (0.2)	40 (0.2)
Vaccinated			
Dose 1	9217 (99.8)	9414 (99.8)	18631 (99.8)
Dose 2	9076 (98.2)	9260 (98.2)	18336 (98.2)
Completed 1-month post–Dose 2 visit (vaccination period)	8273 (89.6)	8418 (89.2)	16691 (89.4)
Discontinued from vaccination period but continue in the study	62 (0.7)	58 (0.6)	120 (0.6)
Discontinued after Dose 1 and before Dose 2	62 (0.7)	57 (0.6)	119 (0.6)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	1 (0.0)	1 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	21 (0.2)	41 (0.4)	62 (0.3)
Withdrawal by subject	20 (0.2)	6 (0.1)	26 (0.1)
Adverse event	16 (0.2)	6 (0.1)	22 (0.1)
Pregnancy	4 (0.0)	4 (0.0)	8 (0.0)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)
Withdrawn from the study	75 (0.8)	118 (1.3)	193 (1.0)
Withdrawn after Dose 1 and before Dose 2	56 (0.6)	79 (0.8)	135 (0.7)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	18 (0.2)	33 (0.3)	51 (0.3)
Withdrawn after 1-month post–Dose 2 visit	1 (0.0)	6 (0.1)	7 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	36 (0.4)	73 (0.8)	109 (0.6)
Lost to follow-up	31 (0.3)	38 (0.4)	69 (0.4)
Adverse event	6 (0.1)	1 (0.0)	7 (0.0)
Death	1 (0.0)	3 (0.0)	4 (0.0)
No longer meets eligibility criteria	0	1 (0.0)	1 (0.0)
Other	1 (0.0)	2 (0.0)	3 (0.0)

14.257. Disposition of All Randomized Subjects, by Sex – ~38000 Subjects for Phase 2/3 Analysis Sex: Female

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=9238) n[b] (%)	Placebo (N[a]=9433) n[b] (%)	Total (N[a]=18671) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_sex_p3_rand

14.258. Disposition of All Randomized Subjects – Phase 2/3 (All Subjects)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21772) n[b] (%)	Placebo (N[a]=21776) n[b] (%)	Total (N[a]=43548) n[b] (%)
Randomized	21772 (100.0)	21776 (100.0)	43548 (100.0)
Not vaccinated	54 (0.2)	45 (0.2)	99 (0.2)
Vaccinated			
Dose 1	21718 (99.8)	21731 (99.8)	43449 (99.8)
Dose 2	20519 (94.2)	20489 (94.1)	41008 (94.2)
Completed 1-month post–Dose 2 visit (vaccination period)	16907 (77.7)	16811 (77.2)	33718 (77.4)
Discontinued from vaccination period but continue in the study	137 (0.6)	129 (0.6)	266 (0.6)
Discontinued after Dose 1 and before Dose 2	137 (0.6)	125 (0.6)	262 (0.6)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.0)	4 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	60 (0.3)	96 (0.4)	156 (0.4)
Withdrawal by subject	47 (0.2)	9 (0.0)	56 (0.1)
Adverse event	21 (0.1)	14 (0.1)	35 (0.1)
Pregnancy	5 (0.0)	4 (0.0)	9 (0.0)
Lost to follow-up	0	3 (0.0)	3 (0.0)
Physician decision	2 (0.0)	1 (0.0)	3 (0.0)
Medication error without associated adverse event	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	1 (0.0)	3 (0.0)
Withdrawn from the study	181 (0.8)	263 (1.2)	444 (1.0)
Withdrawn after Dose 1 and before Dose 2	133 (0.6)	168 (0.8)	301 (0.7)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	44 (0.2)	84 (0.4)	128 (0.3)
Withdrawn after 1-month post–Dose 2 visit	4 (0.0)	11 (0.1)	15 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	85 (0.4)	158 (0.7)	243 (0.6)
Lost to follow-up	80 (0.4)	86 (0.4)	166 (0.4)
Adverse event	8 (0.0)	6 (0.0)	14 (0.0)
Death	2 (0.0)	4 (0.0)	6 (0.0)
No longer meets eligibility criteria	1 (0.0)	3 (0.0)	4 (0.0)
Physician decision	1 (0.0)	2 (0.0)	3 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)
Other	3 (0.0)	3 (0.0)	6 (0.0)

14.258. Disposition of All Randomized Subjects – Phase 2/3 (All Subjects)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21772) n[b] (%)	Placebo (N[a]=21776) n[b] (%)	Total (N[a]=43548) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 17NOV2020 (17:18)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adds_s002_all_p3_rand

14.259. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 (All Subjects) Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=12811) n[b] (%)	Placebo (N[a]=12852) n[b] (%)	Total (N[a]=25663) n[b] (%)
Randomized	12811 (100.0)	12852 (100.0)	25663 (100.0)
Not vaccinated	30 (0.2)	30 (0.2)	60 (0.2)
Vaccinated			
Dose 1	12781 (99.8)	12822 (99.8)	25603 (99.8)
Dose 2	11900 (92.9)	11914 (92.7)	23814 (92.8)
Completed 1-month post–Dose 2 visit (vaccination period)	9494 (74.1)	9481 (73.8)	18975 (73.9)
Discontinued from vaccination period but continue in the study	108 (0.8)	97 (0.8)	205 (0.8)
Discontinued after Dose 1 and before Dose 2	108 (0.8)	93 (0.7)	201 (0.8)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.0)	4 (0.0)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	51 (0.4)	73 (0.6)	124 (0.5)
Withdrawal by subject	39 (0.3)	6 (0.0)	45 (0.2)
Adverse event	10 (0.1)	9 (0.1)	19 (0.1)
Pregnancy	5 (0.0)	4 (0.0)	9 (0.0)
Lost to follow-up	0	3 (0.0)	3 (0.0)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)
Medication error without associated adverse event	0	1 (0.0)	1 (0.0)
Other	2 (0.0)	0	2 (0.0)
Withdrawn from the study	136 (1.1)	179 (1.4)	315 (1.2)
Withdrawn after Dose 1 and before Dose 2	98 (0.8)	122 (0.9)	220 (0.9)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	36 (0.3)	52 (0.4)	88 (0.3)
Withdrawn after 1-month post–Dose 2 visit	2 (0.0)	5 (0.0)	7 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	60 (0.5)	97 (0.8)	157 (0.6)
Lost to follow-up	67 (0.5)	71 (0.6)	138 (0.5)
Adverse event	4 (0.0)	1 (0.0)	5 (0.0)
No longer meets eligibility criteria	1 (0.0)	3 (0.0)	4 (0.0)
Death	0	2 (0.0)	2 (0.0)
Physician decision	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)
Other	3 (0.0)	3 (0.0)	6 (0.0)

14.259. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 (All Subjects) Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=12811) n[b] (%)	Placebo (N[a]=12852) n[b] (%)	Total (N[a]=25663) n[b] (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 all age p3 rand

14.260. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 (All Subjects) Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=8961) n^b (%)	Placebo (N^a=8924) n^b (%)	Total (N^a=17885) n^b (%)
Randomized	8961 (100.0)	8924 (100.0)	17885 (100.0)
Not vaccinated	24 (0.3)	15 (0.2)	39 (0.2)
Vaccinated			
Dose 1	8937 (99.7)	8909 (99.8)	17846 (99.8)
Dose 2	8619 (96.2)	8575 (96.1)	17194 (96.1)
Completed 1-month post–Dose 2 visit (vaccination period)	7413 (82.7)	7330 (82.1)	14743 (82.4)
Discontinued from vaccination period but continue in the study	29 (0.3)	32 (0.4)	61 (0.3)
Discontinued after Dose 1 and before Dose 2	29 (0.3)	32 (0.4)	61 (0.3)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	9 (0.1)	23 (0.3)	32 (0.2)
Adverse event	11 (0.1)	5 (0.1)	16 (0.1)
Withdrawal by subject	8 (0.1)	3 (0.0)	11 (0.1)
Physician decision	1 (0.0)	0	1 (0.0)
Other	0	1 (0.0)	1 (0.0)
Withdrawn from the study	45 (0.5)	84 (0.9)	129 (0.7)
Withdrawn after Dose 1 and before Dose 2	35 (0.4)	46 (0.5)	81 (0.5)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	8 (0.1)	32 (0.4)	40 (0.2)
Withdrawn after 1-month post–Dose 2 visit	2 (0.0)	6 (0.1)	8 (0.0)
Reason for withdrawal from the study			
Withdrawal by subject	25 (0.3)	61 (0.7)	86 (0.5)
Lost to follow-up	13 (0.1)	15 (0.2)	28 (0.2)
Adverse event	4 (0.0)	5 (0.1)	9 (0.1)
Death	2 (0.0)	2 (0.0)	4 (0.0)
Physician decision	1 (0.0)	1 (0.0)	2 (0.0)

14.260. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 (All Subjects) Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=8961) n^b (%)	Placebo (N^a=8924) n^b (%)	Total (N^a=17885) n^b (%)

Note: Subject C4591001 1120 11201299 was randomized but did not sign informed consent and is not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1231 12311057 and C4591001 1177 11771089 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving one dose of BNT162b2 (30 µg) and one dose of placebo.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adds s002 all age p3 rand

14.261. Safety Population, by Age Group – ~38000 Subjects for Phase 2/3 Analysis

Age Group		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
16-55 Years	Randomized[b]			21840
	Vaccinated	10890	10896	21786 (99.8)
	Safety population	10889	10896	21785 (99.7)
	HIV-positive	48	45	93 (0.4)
	Excluded from safety population			55 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			54 (0.2)
	Did not provide informed consent			1 (0.0)
>55 Years	Randomized[b]			15956
	Vaccinated	7971	7950	15921 (99.8)
	Safety population	7971	7950	15921 (99.8)
	HIV-positive	11	16	27 (0.2)
	Excluded from safety population			35 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			35 (0.2)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (07:27)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s003_saf_pop_age_p3

14.262. Safety Population, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis

Baseline SARS-CoV-2 Status		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Positive	Randomized[b]			1148
	Vaccinated	557	588	1145 (99.7)
	Safety population	557	588	1145 (99.7)
	HIV-positive	12	8	20 (1.7)
	Excluded from safety population			3 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			3 (0.3)
Negative	Randomized[b]			35764
	Vaccinated	17885	17858	35743 (99.9)
	Safety population	17884	17858	35742 (99.9)
	HIV-positive	43	50	93 (0.3)
	Excluded from safety population			22 (0.1)
	Reason for exclusion			
	Subject did not receive study vaccine			21 (0.1)
	Did not provide informed consent			1 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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 with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (07:27)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s003_saf_pop_bs_p3

14.263. Safety Population, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis

Baseline SARS-CoV-2 Status	Age Group		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Vaccine Group (as Administered) Placebo n[a]	Total n[a] (%)
Positive	16-55 Years	Randomized[b]			845
		Vaccinated	407	436	843 (99.8)
		Safety population	407	436	843 (99.8)
		HIV-positive	10	7	17 (2.0)
		Excluded from safety population			2 (0.2)
		Reason for exclusion			
		Subject did not receive study vaccine			2 (0.2)
	>55 Years	Randomized[b]			303
		Vaccinated	150	152	302 (99.7)
		Safety population	150	152	302 (99.7)
		HIV-positive	2	1	3 (1.0)
		Excluded from safety population			1 (0.3)
		Reason for exclusion			
		Subject did not receive study vaccine			1 (0.3)
Negative	16-55 Years	Randomized[b]			20459
		Vaccinated	10221	10224	20445 (99.9)
		Safety population	10220	10224	20444 (99.9)
		HIV-positive	34	37	71 (0.3)
		Excluded from safety population			15 (0.1)
		Reason for exclusion			
		Subject did not receive study vaccine			14 (0.1)
		Did not provide informed consent			1 (0.0)
	>55 Years	Randomized[b]			15305
		Vaccinated	7664	7634	15298 (100.0)
		Safety population	7664	7634	15298 (100.0)
		HIV-positive	9	13	22 (0.1)
		Excluded from safety population			7 (0.0)
		Reason for exclusion			
		Subject did not receive study vaccine			7 (0.0)

14.263. Safety Population, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis

Baseline SARS-CoV-2 Status	Age Group	Vaccine Group (as Administered)		
		BNT162b2 (30 µg)	Placebo	Total
		n[a]	n[a]	n[a] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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 with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (09:10)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s003 saf pop bsage p3

14.264. Safety Population, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis

Ethnicity		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Hispanic/Latino	Randomized[b]			10565
	Vaccinated	5266	5277	10543 (99.8)
	Safety population	5266	5277	10543 (99.8)
	HIV-positive	13	8	21 (0.2)
	Excluded from safety population			22 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			22 (0.2)
Non-Hispanic/non-Latino	Randomized[b]			27009
	Vaccinated	13483	13459	26942 (99.8)
	Safety population	13482	13459	26941 (99.7)
	HIV-positive	46	52	98 (0.4)
	Excluded from safety population			68 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			67 (0.2)
	Did not provide informed consent			1 (0.0)
Not reported	Randomized[b]			222
	Vaccinated	112	110	222 (100.0)
	Safety population	112	110	222 (100.0)
	HIV-positive	0	1	1 (0.5)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (07:27)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s003 saf pop eth p3

14.265. Safety Population, by Race – ~38000 Subjects for Phase 2/3 Analysis

Race		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
White	Randomized[b]			31336
	Vaccinated	15637	15630	31267 (99.8)
	Safety population	15636	15630	31266 (99.8)
	HIV-positive	21	15	36 (0.1)
	Excluded from safety population			70 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			69 (0.2)
	Did not provide informed consent			1 (0.0)
Black or African American	Randomized[b]			3503
	Vaccinated	1729	1763	3492 (99.7)
	Safety population	1729	1763	3492 (99.7)
	HIV-positive	35	41	76 (2.2)
	Excluded from safety population			11 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			11 (0.3)
All others	Randomized[b]			2957
	Vaccinated	1495	1453	2948 (99.7)
	Safety population	1495	1453	2948 (99.7)
	HIV-positive	3	5	8 (0.3)
	Excluded from safety population			9 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			9 (0.3)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (07:27)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s003 saf pop race p3

14.266. Safety Population, by Sex – ~38000 Subjects for Phase 2/3 Analysis

Sex		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Male	Randomized[b]			19125
	Vaccinated	9640	9436	19076 (99.7)
	Safety population	9639	9436	19075 (99.7)
	HIV-positive	37	37	74 (0.4)
	Excluded from safety population			50 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			49 (0.3)
	Did not provide informed consent			1 (0.0)
Female	Randomized[b]			18671
	Vaccinated	9221	9410	18631 (99.8)
	Safety population	9221	9410	18631 (99.8)
	HIV-positive	22	24	46 (0.2)
	Excluded from safety population			40 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			40 (0.2)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (07:27)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s003_saf_pop_sex_p3

14.267. Safety Population – Phase 2/3 (All Subjects)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Randomized[b]			43548
Vaccinated	21721	21728	43449 (99.8)
Safety population	21720	21728	43448 (99.8)
HIV-positive	99	97	196 (0.5)
Excluded from safety population			100 (0.2)
Reason for exclusion			
Subject did not receive study vaccine			99 (0.2)
Did not provide informed consent			1 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (16:35)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s003 pop all p3

14.268. Safety Population, by Age Group – Phase 2/3 (All Subjects)

Age Group		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
16-55 Years	Randomized[b]			25663
	Vaccinated	12781	12822	25603 (99.8)
	Safety population	12780	12822	25602 (99.8)
	HIV-positive	74	66	140 (0.5)
	Excluded from safety population			61 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			60 (0.2)
	Did not provide informed consent			1 (0.0)
>55 Years	Randomized[b]			17885
	Vaccinated	8940	8906	17846 (99.8)
	Safety population	8940	8906	17846 (99.8)
	HIV-positive	25	31	56 (0.3)
	Excluded from safety population			39 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			39 (0.2)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (07:27)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s003_pop_all_age_p3

14.269. Follow-Up Time After Dose 2 – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Placebo (N[a]=21728) n[b] (%)	Total (N[a]=43448) n[b] (%)
Subjects (%) with length of follow-up of:			
<2 Months	12189 (56.1)	12192 (56.1)	24381 (56.1)
<2 Weeks	3218 (14.8)	3265 (15.0)	6483 (14.9)
≥2 to <4 Weeks	1228 (5.7)	1205 (5.5)	2433 (5.6)
≥4 to <6 Weeks	3239 (14.9)	3235 (14.9)	6474 (14.9)
≥6 to <8 Weeks	4504 (20.7)	4487 (20.7)	8991 (20.7)
≥2 Months	9531 (43.9)	9536 (43.9)	19067 (43.9)
≥8 to <10 Weeks	6296 (29.0)	6329 (29.1)	12625 (29.1)
≥10 to <12 Weeks	2853 (13.1)	2809 (12.9)	5662 (13.0)
≥12 to <14 Weeks	382 (1.8)	398 (1.8)	780 (1.8)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 18NOV2020 (05:34)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s005_fup_time_d2_all

14.270. Demographic Characteristics, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=10889) n[b] (%)	Placebo (N[a]=10896) n[b] (%)	Total (N[a]=21785) n[b] (%)
Sex			
Male	5490 (50.4)	5283 (48.5)	10773 (49.5)
Female	5399 (49.6)	5613 (51.5)	11012 (50.5)
Race			
White	8606 (79.0)	8615 (79.1)	17221 (79.0)
Black or African American	1166 (10.7)	1184 (10.9)	2350 (10.8)
American Indian or Alaska native	73 (0.7)	68 (0.6)	141 (0.6)
Asian	578 (5.3)	601 (5.5)	1179 (5.4)
Native Hawaiian or other Pacific Islander	37 (0.3)	17 (0.2)	54 (0.2)
Multiracial	357 (3.3)	327 (3.0)	684 (3.1)
Not reported	72 (0.7)	84 (0.8)	156 (0.7)
Ethnicity			
Hispanic/Latino	3709 (34.1)	3696 (33.9)	7405 (34.0)
Non-Hispanic/non-Latino	7124 (65.4)	7143 (65.6)	14267 (65.5)
Not reported	56 (0.5)	57 (0.5)	113 (0.5)
Country			
Argentina	1975 (18.1)	1973 (18.1)	3948 (18.1)
Brazil	949 (8.7)	945 (8.7)	1894 (8.7)
South Africa	303 (2.8)	306 (2.8)	609 (2.8)
USA	7662 (70.4)	7672 (70.4)	15334 (70.4)
Age at vaccination (years)			
Mean (SD)	39.4 (10.28)	39.2 (10.28)	39.3 (10.28)
Median	40.0	40.0	40.0
Min, max	(16, 55)	(16, 55)	(16, 55)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	138 (1.3)	160 (1.5)	298 (1.4)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3446 (31.6)	3476 (31.9)	6922 (31.8)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	3555 (32.6)	3477 (31.9)	7032 (32.3)
Obese (≥30.0 kg/m^2)	3746 (34.4)	3777 (34.7)	7523 (34.5)
Missing	4 (0.0)	6 (0.1)	10 (0.0)

14.270. Demographic Characteristics, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=10889) n^b (%)	Placebo (N^a=10896) n^b (%)	Total (N^a=21785) n^b (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo age p3 saf

14.271. Demographic Characteristics, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=7971) n[b] (%)	Placebo (N[a]=7950) n[b] (%)	Total (N[a]=15921) n[b] (%)
Sex			
Male	4149 (52.1)	4153 (52.2)	8302 (52.1)
Female	3822 (47.9)	3797 (47.8)	7619 (47.9)
Race			
White	7030 (88.2)	7015 (88.2)	14045 (88.2)
Black or African American	563 (7.1)	579 (7.3)	1142 (7.2)
American Indian or Alaska native	29 (0.4)	31 (0.4)	60 (0.4)
Asian	223 (2.8)	206 (2.6)	429 (2.7)
Native Hawaiian or other Pacific Islander	13 (0.2)	9 (0.1)	22 (0.1)
Multiracial	92 (1.2)	79 (1.0)	171 (1.1)
Not reported	21 (0.3)	31 (0.4)	52 (0.3)
Ethnicity			
Hispanic/Latino	1557 (19.5)	1581 (19.9)	3138 (19.7)
Non-Hispanic/non-Latino	6358 (79.8)	6316 (79.4)	12674 (79.6)
Not reported	56 (0.7)	53 (0.7)	109 (0.7)
Country			
Argentina	908 (11.4)	908 (11.4)	1816 (11.4)
Brazil	196 (2.5)	194 (2.4)	390 (2.4)
South Africa	69 (0.9)	66 (0.8)	135 (0.8)
USA	6798 (85.3)	6782 (85.3)	13580 (85.3)
Age at vaccination (years)			
Mean (SD)	65.5 (6.53)	65.5 (6.53)	65.5 (6.53)
Median	65.0	65.0	65.0
Min, max	(56, 89)	(56, 91)	(56, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	63 (0.8)	75 (0.9)	138 (0.9)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	2071 (26.0)	1984 (25.0)	4055 (25.5)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	3023 (37.9)	3004 (37.8)	6027 (37.9)
Obese (≥30.0 kg/m^2)	2810 (35.3)	2885 (36.3)	5695 (35.8)
Missing	4 (0.1)	2 (0.0)	6 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo age p3 saf

14.272. Demographic Characteristics, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=557) n[b] (%)	Placebo (N[a]=588) n[b] (%)	Total (N[a]=1145) n[b] (%)
Sex			
Male	278 (49.9)	268 (45.6)	546 (47.7)
Female	279 (50.1)	320 (54.4)	599 (52.3)
Race			
White	330 (59.2)	325 (55.3)	655 (57.2)
Black or African American	173 (31.1)	198 (33.7)	371 (32.4)
American Indian or Alaska native	4 (0.7)	2 (0.3)	6 (0.5)
Asian	10 (1.8)	15 (2.6)	25 (2.2)
Native Hawaiian or other Pacific Islander	3 (0.5)	0	3 (0.3)
Multiracial	33 (5.9)	43 (7.3)	76 (6.6)
Not reported	4 (0.7)	5 (0.9)	9 (0.8)
Ethnicity			
Hispanic/Latino	182 (32.7)	205 (34.9)	387 (33.8)
Non-Hispanic/non-Latino	374 (67.1)	382 (65.0)	756 (66.0)
Not reported	1 (0.2)	1 (0.2)	2 (0.2)
Country			
Argentina	52 (9.3)	80 (13.6)	132 (11.5)
Brazil	90 (16.2)	89 (15.1)	179 (15.6)
South Africa	69 (12.4)	84 (14.3)	153 (13.4)
USA	346 (62.1)	335 (57.0)	681 (59.5)
Age group			
16-55 Years	407 (73.1)	436 (74.1)	843 (73.6)
>55 Years	150 (26.9)	152 (25.9)	302 (26.4)
Age at vaccination (years)			
Mean (SD)	44.6 (15.65)	44.4 (14.59)	44.4 (15.11)
Median	44.0	43.0	43.0
Min, max	(16, 82)	(16, 82)	(16, 82)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	1 (0.2)	6 (1.0)	7 (0.6)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	123 (22.1)	146 (24.8)	269 (23.5)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	189 (33.9)	196 (33.3)	385 (33.6)
Obese (≥30.0 kg/m^2)	243 (43.6)	240 (40.8)	483 (42.2)
Missing	1 (0.2)	0	1 (0.1)

14.272. Demographic Characteristics, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=557) n[b] (%)	Placebo (N[a]=588) n[b] (%)	Total (N[a]=1145) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 bs p3 saf

14.273. Demographic Characteristics, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=17884) n[b] (%)	Placebo (N[a]=17858) n[b] (%)	Total (N[a]=35742) n[b] (%)
Sex			
Male	9135 (51.1)	8967 (50.2)	18102 (50.6)
Female	8749 (48.9)	8891 (49.8)	17640 (49.4)
Race			
White	14969 (83.7)	14978 (83.9)	29947 (83.8)
Black or African American	1504 (8.4)	1522 (8.5)	3026 (8.5)
American Indian or Alaska native	97 (0.5)	94 (0.5)	191 (0.5)
Asian	778 (4.4)	784 (4.4)	1562 (4.4)
Native Hawaiian or other Pacific Islander	46 (0.3)	26 (0.1)	72 (0.2)
Multiracial	402 (2.2)	347 (1.9)	749 (2.1)
Not reported	88 (0.5)	107 (0.6)	195 (0.5)
Ethnicity			
Hispanic/Latino	4953 (27.7)	4954 (27.7)	9907 (27.7)
Non-Hispanic/non-Latino	12824 (71.7)	12799 (71.7)	25623 (71.7)
Not reported	107 (0.6)	105 (0.6)	212 (0.6)
Country			
Argentina	2736 (15.3)	2719 (15.2)	5455 (15.3)
Brazil	1022 (5.7)	1018 (5.7)	2040 (5.7)
South Africa	280 (1.6)	271 (1.5)	551 (1.5)
USA	13846 (77.4)	13850 (77.6)	27696 (77.5)
Age group			
16-55 Years	10220 (57.1)	10224 (57.3)	20444 (57.2)
>55 Years	7664 (42.9)	7634 (42.7)	15298 (42.8)
Age at vaccination (years)			
Mean (SD)	50.7 (15.62)	50.5 (15.73)	50.6 (15.68)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	197 (1.1)	222 (1.2)	419 (1.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	5279 (29.5)	5205 (29.1)	10484 (29.3)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	6244 (34.9)	6165 (34.5)	12409 (34.7)
Obese (≥30.0 kg/m^2)	6157 (34.4)	6260 (35.1)	12417 (34.7)
Missing	7 (0.0)	6 (0.0)	13 (0.0)

14.273. Demographic Characteristics, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=17884) n[b] (%)	Placebo (N[a]=17858) n[b] (%)	Total (N[a]=35742) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 bs p3 saf

14.274. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=407) n[b] (%)	Placebo (N[a]=436) n[b] (%)	Total (N[a]=843) n[b] (%)
Sex			
Male	192 (47.2)	189 (43.3)	381 (45.2)
Female	215 (52.8)	247 (56.7)	462 (54.8)
Race			
White	224 (55.0)	224 (51.4)	448 (53.1)
Black or African American	135 (33.2)	155 (35.6)	290 (34.4)
American Indian or Alaska native	4 (1.0)	2 (0.5)	6 (0.7)
Asian	7 (1.7)	12 (2.8)	19 (2.3)
Native Hawaiian or other Pacific Islander	3 (0.7)	0	3 (0.4)
Multiracial	30 (7.4)	38 (8.7)	68 (8.1)
Not reported	4 (1.0)	5 (1.1)	9 (1.1)
Ethnicity			
Hispanic/Latino	140 (34.4)	157 (36.0)	297 (35.2)
Non-Hispanic/non-Latino	267 (65.6)	279 (64.0)	546 (64.8)
Not reported	0	0	0
Country			
Argentina	42 (10.3)	58 (13.3)	100 (11.9)
Brazil	82 (20.1)	82 (18.8)	164 (19.5)
South Africa	59 (14.5)	72 (16.5)	131 (15.5)
USA	224 (55.0)	224 (51.4)	448 (53.1)
Age at vaccination (years)			
Mean (SD)	37.0 (10.42)	37.7 (10.27)	37.4 (10.34)
Median	37.0	38.0	38.0
Min, max	(16, 55)	(16, 55)	(16, 55)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	1 (0.2)	4 (0.9)	5 (0.6)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	91 (22.4)	114 (26.1)	205 (24.3)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	138 (33.9)	142 (32.6)	280 (33.2)
Obese (≥30.0 kg/m^2)	177 (43.5)	176 (40.4)	353 (41.9)
Missing	0	0	0

14.274. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=407) n[b] (%)	Placebo (N[a]=436) n[b] (%)	Total (N[a]=843) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 bsage p3 saf

14.275. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=150) n[b] (%)	Placebo (N[a]=152) n[b] (%)	Total (N[a]=302) n[b] (%)
Sex			
Male	86 (57.3)	79 (52.0)	165 (54.6)
Female	64 (42.7)	73 (48.0)	137 (45.4)
Race			
White	106 (70.7)	101 (66.4)	207 (68.5)
Black or African American	38 (25.3)	43 (28.3)	81 (26.8)
American Indian or Alaska native	0	0	0
Asian	3 (2.0)	3 (2.0)	6 (2.0)
Native Hawaiian or other Pacific Islander	0	0	0
Multiracial	3 (2.0)	5 (3.3)	8 (2.6)
Not reported	0	0	0
Ethnicity			
Hispanic/Latino	42 (28.0)	48 (31.6)	90 (29.8)
Non-Hispanic/non-Latino	107 (71.3)	103 (67.8)	210 (69.5)
Not reported	1 (0.7)	1 (0.7)	2 (0.7)
Country			
Argentina	10 (6.7)	22 (14.5)	32 (10.6)
Brazil	8 (5.3)	7 (4.6)	15 (5.0)
South Africa	10 (6.7)	12 (7.9)	22 (7.3)
USA	122 (81.3)	111 (73.0)	233 (77.2)
Age at vaccination (years)			
Mean (SD)	65.0 (6.65)	63.4 (5.58)	64.2 (6.17)
Median	63.0	63.0	63.0
Min, max	(56, 82)	(56, 82)	(56, 82)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	0	2 (1.3)	2 (0.7)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	32 (21.3)	32 (21.1)	64 (21.2)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	51 (34.0)	54 (35.5)	105 (34.8)
Obese (≥30.0 kg/m^2)	66 (44.0)	64 (42.1)	130 (43.0)
Missing	1 (0.7)	0	1 (0.3)

14.275. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=150) n[b] (%)	Placebo (N[a]=152) n[b] (%)	Total (N[a]=302) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 bsage p3 saf

14.276. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=10220) n[b] (%)	Placebo (N[a]=10224) n[b] (%)	Total (N[a]=20444) n[b] (%)
Sex			
Male	5158 (50.5)	4977 (48.7)	10135 (49.6)
Female	5062 (49.5)	5247 (51.3)	10309 (50.4)
Race			
White	8179 (80.0)	8206 (80.3)	16385 (80.1)
Black or African American	991 (9.7)	1004 (9.8)	1995 (9.8)
American Indian or Alaska native	68 (0.7)	63 (0.6)	131 (0.6)
Asian	562 (5.5)	582 (5.7)	1144 (5.6)
Native Hawaiian or other Pacific Islander	34 (0.3)	17 (0.2)	51 (0.2)
Multiracial	318 (3.1)	276 (2.7)	594 (2.9)
Not reported	68 (0.7)	76 (0.7)	144 (0.7)
Ethnicity			
Hispanic/Latino	3478 (34.0)	3455 (33.8)	6933 (33.9)
Non-Hispanic/non-Latino	6687 (65.4)	6714 (65.7)	13401 (65.5)
Not reported	55 (0.5)	55 (0.5)	110 (0.5)
Country			
Argentina	1869 (18.3)	1857 (18.2)	3726 (18.2)
Brazil	841 (8.2)	837 (8.2)	1678 (8.2)
South Africa	224 (2.2)	223 (2.2)	447 (2.2)
USA	7286 (71.3)	7307 (71.5)	14593 (71.4)
Age at vaccination (years)			
Mean (SD)	39.5 (10.25)	39.2 (10.28)	39.4 (10.26)
Median	41.0	40.0	40.0
Min, max	(16, 55)	(16, 55)	(16, 55)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	136 (1.3)	154 (1.5)	290 (1.4)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3283 (32.1)	3296 (32.2)	6579 (32.2)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	3327 (32.6)	3270 (32.0)	6597 (32.3)
Obese (≥30.0 kg/m^2)	3470 (34.0)	3499 (34.2)	6969 (34.1)
Missing	4 (0.0)	5 (0.0)	9 (0.0)

14.276. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=10220) n[b] (%)	Placebo (N[a]=10224) n[b] (%)	Total (N[a]=20444) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 bsage p3 saf

14.277. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=7664) n[b] (%)	Placebo (N[a]=7634) n[b] (%)	Total (N[a]=15298) n[b] (%)
Sex			
Male	3977 (51.9)	3990 (52.3)	7967 (52.1)
Female	3687 (48.1)	3644 (47.7)	7331 (47.9)
Race			
White	6790 (88.6)	6772 (88.7)	13562 (88.7)
Black or African American	513 (6.7)	518 (6.8)	1031 (6.7)
American Indian or Alaska native	29 (0.4)	31 (0.4)	60 (0.4)
Asian	216 (2.8)	202 (2.6)	418 (2.7)
Native Hawaiian or other Pacific Islander	12 (0.2)	9 (0.1)	21 (0.1)
Multiracial	84 (1.1)	71 (0.9)	155 (1.0)
Not reported	20 (0.3)	31 (0.4)	51 (0.3)
Ethnicity			
Hispanic/Latino	1475 (19.2)	1499 (19.6)	2974 (19.4)
Non-Hispanic/non-Latino	6137 (80.1)	6085 (79.7)	12222 (79.9)
Not reported	52 (0.7)	50 (0.7)	102 (0.7)
Country			
Argentina	867 (11.3)	862 (11.3)	1729 (11.3)
Brazil	181 (2.4)	181 (2.4)	362 (2.4)
South Africa	56 (0.7)	48 (0.6)	104 (0.7)
USA	6560 (85.6)	6543 (85.7)	13103 (85.7)
Age at vaccination (years)			
Mean (SD)	65.5 (6.53)	65.5 (6.55)	65.5 (6.54)
Median	65.0	65.0	65.0
Min, max	(56, 89)	(56, 91)	(56, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	61 (0.8)	68 (0.9)	129 (0.8)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	1996 (26.0)	1909 (25.0)	3905 (25.5)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	2917 (38.1)	2895 (37.9)	5812 (38.0)
Obese (≥30.0 kg/m^2)	2687 (35.1)	2761 (36.2)	5448 (35.6)
Missing	3 (0.0)	1 (0.0)	4 (0.0)

14.277. Demographic Characteristics, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=7664) n[b] (%)	Placebo (N[a]=7634) n[b] (%)	Total (N[a]=15298) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
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.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 bsage p3 saf

14.278. Demographic Characteristics, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=5266) n[b] (%)	Placebo (N[a]=5277) n[b] (%)	Total (N[a]=10543) n[b] (%)
Sex			
Male	2891 (54.9)	2790 (52.9)	5681 (53.9)
Female	2375 (45.1)	2487 (47.1)	4862 (46.1)
Race			
White	4972 (94.4)	4972 (94.2)	9944 (94.3)
Black or African American	109 (2.1)	104 (2.0)	213 (2.0)
American Indian or Alaska native	23 (0.4)	29 (0.5)	52 (0.5)
Asian	57 (1.1)	62 (1.2)	119 (1.1)
Native Hawaiian or other Pacific Islander	10 (0.2)	1 (0.0)	11 (0.1)
Multiracial	39 (0.7)	39 (0.7)	78 (0.7)
Not reported	56 (1.1)	70 (1.3)	126 (1.2)
Country			
Argentina	2843 (54.0)	2856 (54.1)	5699 (54.1)
Brazil	556 (10.6)	555 (10.5)	1111 (10.5)
South Africa	2 (0.0)	1 (0.0)	3 (0.0)
USA	1865 (35.4)	1865 (35.3)	3730 (35.4)
Age group			
16-55 Years	3709 (70.4)	3696 (70.0)	7405 (70.2)
>55 Years	1557 (29.6)	1581 (30.0)	3138 (29.8)
Age at vaccination (years)			
Mean (SD)	46.0 (14.91)	46.2 (14.71)	46.1 (14.81)
Median	46.0	46.0	46.0
Min, max	(16, 85)	(16, 84)	(16, 85)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	54 (1.0)	63 (1.2)	117 (1.1)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	1507 (28.6)	1527 (28.9)	3034 (28.8)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	1943 (36.9)	1864 (35.3)	3807 (36.1)
Obese (≥30.0 kg/m^2)	1760 (33.4)	1822 (34.5)	3582 (34.0)
Missing	2 (0.0)	1 (0.0)	3 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo eth p3 saf

14.279. Demographic Characteristics, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=13482) n[b] (%)	Placebo (N[a]=13459) n[b] (%)	Total (N[a]=26941) n[b] (%)
Sex			
Male	6692 (49.6)	6587 (48.9)	13279 (49.3)
Female	6790 (50.4)	6872 (51.1)	13662 (50.7)
Race			
White	10589 (78.5)	10584 (78.6)	21173 (78.6)
Black or African American	1594 (11.8)	1639 (12.2)	3233 (12.0)
American Indian or Alaska native	79 (0.6)	70 (0.5)	149 (0.6)
Asian	738 (5.5)	739 (5.5)	1477 (5.5)
Native Hawaiian or other Pacific Islander	40 (0.3)	25 (0.2)	65 (0.2)
Multiracial	408 (3.0)	364 (2.7)	772 (2.9)
Not reported	34 (0.3)	38 (0.3)	72 (0.3)
Country			
Argentina	37 (0.3)	24 (0.2)	61 (0.2)
Brazil	588 (4.4)	584 (4.3)	1172 (4.4)
South Africa	370 (2.7)	371 (2.8)	741 (2.8)
USA	12487 (92.6)	12480 (92.7)	24967 (92.7)
Age group			
16-55 Years	7124 (52.8)	7143 (53.1)	14267 (53.0)
>55 Years	6358 (47.2)	6316 (46.9)	12674 (47.0)
Age at vaccination (years)			
Mean (SD)	52.2 (15.60)	51.8 (15.81)	52.0 (15.70)
Median	54.0	54.0	54.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	147 (1.1)	171 (1.3)	318 (1.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3983 (29.5)	3903 (29.0)	7886 (29.3)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	4593 (34.1)	4581 (34.0)	9174 (34.1)
Obese (≥30.0 kg/m^2)	4753 (35.3)	4797 (35.6)	9550 (35.4)
Missing	6 (0.0)	7 (0.1)	13 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s005_demo_eth_p3_saf

14.280. Demographic Characteristics, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=112) n[b] (%)	Placebo (N[a]=110) n[b] (%)	Total (N[a]=222) n[b] (%)
Sex			
Male	56 (50.0)	59 (53.6)	115 (51.8)
Female	56 (50.0)	51 (46.4)	107 (48.2)
Race			
White	75 (67.0)	74 (67.3)	149 (67.1)
Black or African American	26 (23.2)	20 (18.2)	46 (20.7)
American Indian or Alaska native	0	0	0
Asian	6 (5.4)	6 (5.5)	12 (5.4)
Native Hawaiian or other Pacific Islander	0	0	0
Multiracial	2 (1.8)	3 (2.7)	5 (2.3)
Not reported	3 (2.7)	7 (6.4)	10 (4.5)
Country			
Argentina	3 (2.7)	1 (0.9)	4 (1.8)
Brazil	1 (0.9)	0	1 (0.5)
South Africa	0	0	0
USA	108 (96.4)	109 (99.1)	217 (97.7)
Age group			
16-55 Years	56 (50.0)	57 (51.8)	113 (50.9)
>55 Years	56 (50.0)	53 (48.2)	109 (49.1)
Age at vaccination (years)			
Mean (SD)	54.0 (13.66)	53.3 (17.12)	53.6 (15.44)
Median	55.5	55.0	55.0
Min, max	(20, 81)	(16, 84)	(16, 84)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	0	1 (0.9)	1 (0.5)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	27 (24.1)	30 (27.3)	57 (25.7)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	42 (37.5)	36 (32.7)	78 (35.1)
Obese (≥30.0 kg/m^2)	43 (38.4)	43 (39.1)	86 (38.7)
Missing	0	0	0

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s005_demo_eth_p3_saf

14.281. Demographic Characteristics, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=15636) n[b] (%)	Placebo (N[a]=15630) n[b] (%)	Total (N[a]=31266) n[b] (%)
Sex			
Male	8000 (51.2)	7828 (50.1)	15828 (50.6)
Female	7636 (48.8)	7802 (49.9)	15438 (49.4)
Ethnicity			
Hispanic/Latino	4972 (31.8)	4972 (31.8)	9944 (31.8)
Non-Hispanic/non-Latino	10589 (67.7)	10584 (67.7)	21173 (67.7)
Not reported	75 (0.5)	74 (0.5)	149 (0.5)
Country			
Argentina	2858 (18.3)	2860 (18.3)	5718 (18.3)
Brazil	639 (4.1)	638 (4.1)	1277 (4.1)
South Africa	101 (0.6)	95 (0.6)	196 (0.6)
USA	12038 (77.0)	12037 (77.0)	24075 (77.0)
Age group			
16-55 Years	8606 (55.0)	8615 (55.1)	17221 (55.1)
>55 Years	7030 (45.0)	7015 (44.9)	14045 (44.9)
Age at vaccination (years)			
Mean (SD)	51.4 (15.68)	51.2 (15.79)	51.3 (15.74)
Median	53.0	53.0	53.0
Min, max	(16, 89)	(16, 88)	(16, 89)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	162 (1.0)	174 (1.1)	336 (1.1)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	4570 (29.2)	4488 (28.7)	9058 (29.0)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	5570 (35.6)	5492 (35.1)	11062 (35.4)
Obese (≥30.0 kg/m^2)	5328 (34.1)	5470 (35.0)	10798 (34.5)
Missing	6 (0.0)	6 (0.0)	12 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo race p3 saf

14.282. Demographic Characteristics, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1729) n[b] (%)	Placebo (N[a]=1763) n[b] (%)	Total (N[a]=3492) n[b] (%)
Sex			
Male	856 (49.5)	852 (48.3)	1708 (48.9)
Female	873 (50.5)	911 (51.7)	1784 (51.1)
Ethnicity			
Hispanic/Latino	109 (6.3)	104 (5.9)	213 (6.1)
Non-Hispanic/non-Latino	1594 (92.2)	1639 (93.0)	3233 (92.6)
Not reported	26 (1.5)	20 (1.1)	46 (1.3)
Country			
Argentina	5 (0.3)	4 (0.2)	9 (0.3)
Brazil	186 (10.8)	197 (11.2)	383 (11.0)
South Africa	196 (11.3)	208 (11.8)	404 (11.6)
USA	1342 (77.6)	1354 (76.8)	2696 (77.2)
Age group			
16-55 Years	1166 (67.4)	1184 (67.2)	2350 (67.3)
>55 Years	563 (32.6)	579 (32.8)	1142 (32.7)
Age at vaccination (years)			
Mean (SD)	46.8 (14.58)	47.0 (14.46)	46.9 (14.52)
Median	48.0	47.0	47.0
Min, max	(16, 83)	(16, 84)	(16, 84)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	17 (1.0)	26 (1.5)	43 (1.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	383 (22.2)	376 (21.3)	759 (21.7)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	487 (28.2)	498 (28.2)	985 (28.2)
Obese (≥30.0 kg/m^2)	840 (48.6)	861 (48.8)	1701 (48.7)
Missing	2 (0.1)	2 (0.1)	4 (0.1)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo race p3 saf

14.283. Demographic Characteristics, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1495) n[b] (%)	Placebo (N[a]=1453) n[b] (%)	Total (N[a]=2948) n[b] (%)
Sex			
Male	783 (52.4)	756 (52.0)	1539 (52.2)
Female	712 (47.6)	697 (48.0)	1409 (47.8)
Ethnicity			
Hispanic/Latino	185 (12.4)	201 (13.8)	386 (13.1)
Non-Hispanic/non-Latino	1299 (86.9)	1236 (85.1)	2535 (86.0)
Not reported	11 (0.7)	16 (1.1)	27 (0.9)
Country			
Argentina	20 (1.3)	17 (1.2)	37 (1.3)
Brazil	320 (21.4)	304 (20.9)	624 (21.2)
South Africa	75 (5.0)	69 (4.7)	144 (4.9)
USA	1080 (72.2)	1063 (73.2)	2143 (72.7)
Age group			
16-55 Years	1117 (74.7)	1097 (75.5)	2214 (75.1)
>55 Years	378 (25.3)	356 (24.5)	734 (24.9)
Age at vaccination (years)			
Mean (SD)	45.1 (14.77)	44.5 (14.62)	44.8 (14.70)
Median	45.0	44.0	44.0
Min, max	(16, 86)	(16, 91)	(16, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	22 (1.5)	35 (2.4)	57 (1.9)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	564 (37.7)	596 (41.0)	1160 (39.3)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	521 (34.8)	491 (33.8)	1012 (34.3)
Obese (≥30.0 kg/m^2)	388 (26.0)	331 (22.8)	719 (24.4)
Missing	0	0	0

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo race p3 saf

14.284. Demographic Characteristics, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=9639) n[b] (%)	Placebo (N[a]=9436) n[b] (%)	Total (N[a]=19075) n[b] (%)
Race			
White	8000 (83.0)	7828 (83.0)	15828 (83.0)
Black or African American	856 (8.9)	852 (9.0)	1708 (9.0)
American Indian or Alaska native	47 (0.5)	47 (0.5)	94 (0.5)
Asian	458 (4.8)	440 (4.7)	898 (4.7)
Native Hawaiian or other Pacific Islander	22 (0.2)	17 (0.2)	39 (0.2)
Multiracial	201 (2.1)	185 (2.0)	386 (2.0)
Not reported	55 (0.6)	67 (0.7)	122 (0.6)
Ethnicity			
Hispanic/Latino	2891 (30.0)	2790 (29.6)	5681 (29.8)
Non-Hispanic/non-Latino	6692 (69.4)	6587 (69.8)	13279 (69.6)
Not reported	56 (0.6)	59 (0.6)	115 (0.6)
Country			
Argentina	1589 (16.5)	1530 (16.2)	3119 (16.4)
Brazil	537 (5.6)	546 (5.8)	1083 (5.7)
South Africa	169 (1.8)	157 (1.7)	326 (1.7)
USA	7344 (76.2)	7203 (76.3)	14547 (76.3)
Age group			
16-55 Years	5490 (57.0)	5283 (56.0)	10773 (56.5)
>55 Years	4149 (43.0)	4153 (44.0)	8302 (43.5)
Age at vaccination (years)			
Mean (SD)	50.7 (15.80)	51.0 (15.86)	50.9 (15.83)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 88)	(16, 89)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	57 (0.6)	68 (0.7)	125 (0.7)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	2352 (24.4)	2244 (23.8)	4596 (24.1)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	3869 (40.1)	3752 (39.8)	7621 (40.0)
Obese (≥30.0 kg/m^2)	3358 (34.8)	3366 (35.7)	6724 (35.3)
Missing	3 (0.0)	6 (0.1)	9 (0.0)

14.284. Demographic Characteristics, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=9639) n^b (%)	Placebo (N^a=9436) n^b (%)	Total (N^a=19075) n^b (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo gen p3 saf

14.285. Demographic Characteristics, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=9221) n[b] (%)	Placebo (N[a]=9410) n[b] (%)	Total (N[a]=18631) n[b] (%)
Race			
White	7636 (82.8)	7802 (82.9)	15438 (82.9)
Black or African American	873 (9.5)	911 (9.7)	1784 (9.6)
American Indian or Alaska native	55 (0.6)	52 (0.6)	107 (0.6)
Asian	343 (3.7)	367 (3.9)	710 (3.8)
Native Hawaiian or other Pacific Islander	28 (0.3)	9 (0.1)	37 (0.2)
Multiracial	248 (2.7)	221 (2.3)	469 (2.5)
Not reported	38 (0.4)	48 (0.5)	86 (0.5)
Ethnicity			
Hispanic/Latino	2375 (25.8)	2487 (26.4)	4862 (26.1)
Non-Hispanic/non-Latino	6790 (73.6)	6872 (73.0)	13662 (73.3)
Not reported	56 (0.6)	51 (0.5)	107 (0.6)
Country			
Argentina	1294 (14.0)	1351 (14.4)	2645 (14.2)
Brazil	608 (6.6)	593 (6.3)	1201 (6.4)
South Africa	203 (2.2)	215 (2.3)	418 (2.2)
USA	7116 (77.2)	7251 (77.1)	14367 (77.1)
Age group			
16-55 Years	5399 (58.6)	5613 (59.6)	11012 (59.1)
>55 Years	3822 (41.4)	3797 (40.4)	7619 (40.9)
Age at vaccination (years)			
Mean (SD)	50.2 (15.47)	49.5 (15.55)	49.9 (15.51)
Median	51.0	51.0	51.0
Min, max	(16, 86)	(16, 91)	(16, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	144 (1.6)	167 (1.8)	311 (1.7)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3165 (34.3)	3216 (34.2)	6381 (34.2)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	2709 (29.4)	2729 (29.0)	5438 (29.2)
Obese (≥30.0 kg/m^2)	3198 (34.7)	3296 (35.0)	6494 (34.9)
Missing	5 (0.1)	2 (0.0)	7 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo gen p3 saf

14.286. Demographic Characteristics – 16-17 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=138) n[b] (%)	Placebo (N[a]=145) n[b] (%)	Total (N[a]=283) n[b] (%)
Sex			
Male	75 (54.3)	73 (50.3)	148 (52.3)
Female	63 (45.7)	72 (49.7)	135 (47.7)
Race			
White	102 (73.9)	118 (81.4)	220 (77.7)
Black or African American	21 (15.2)	11 (7.6)	32 (11.3)
American Indian or Alaska native	0	4 (2.8)	4 (1.4)
Asian	7 (5.1)	2 (1.4)	9 (3.2)
Native Hawaiian or other Pacific Islander	2 (1.4)	0	2 (0.7)
Multiracial	6 (4.3)	7 (4.8)	13 (4.6)
Not reported	0	3 (2.1)	3 (1.1)
Ethnicity			
Hispanic/Latino	17 (12.3)	19 (13.1)	36 (12.7)
Non-Hispanic/non-Latino	121 (87.7)	125 (86.2)	246 (86.9)
Not reported	0	1 (0.7)	1 (0.4)
Country			
Brazil	2 (1.4)	4 (2.8)	6 (2.1)
South Africa	4 (2.9)	4 (2.8)	8 (2.8)
USA	132 (95.7)	137 (94.5)	269 (95.1)
Age group			
16-55 Years	138 (100.0)	145 (100.0)	283 (100.0)
Age at vaccination (years)			
Mean (SD)	16.4 (0.50)	16.5 (0.50)	16.5 (0.50)
Median	16.0	16.0	16.0
Min, max	(16, 17)	(16, 17)	(16, 17)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	17 (12.3)	12 (8.3)	29 (10.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	81 (58.7)	78 (53.8)	159 (56.2)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	29 (21.0)	25 (17.2)	54 (19.1)
Obese (≥30.0 kg/m^2)	11 (8.0)	30 (20.7)	41 (14.5)

14.286. Demographic Characteristics – 16-17 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=138) n^b (%)	Placebo (N^a=145) n^b (%)	Total (N^a=283) n^b (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (22:50)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adsl s005 demo all lowage p3 saf

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Any medical history	15324 (81.3)	15411 (81.8)
**Uncoded Body System or Organ Class	9 (0.0)	4 (0.0)
ALLERGY, AZITHROMYCIN	0	1 (0.0)
ALLERGY, ENVIRONMENTAL	0	1 (0.0)
Allergic Rhinitis	1 (0.0)	0
BENIGN PROSTATE HYPERPLASIA	0	1 (0.0)
Benign prostatic hyperplasia	1 (0.0)	0
Childhood seizure	1 (0.0)	0
EPICONDYLOTOMY, ELBOW, RIGHT	0	1 (0.0)
Elevated Prostate-Specific Antigen	1 (0.0)	0
Erectile Dysfunction	1 (0.0)	0
GLAUCOMA, BILATERAL	0	1 (0.0)
HYPERLIPIDEMIA	0	1 (0.0)
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	0	1 (0.0)
IRRATATABLE BOWEL SYNDROME, CONSTIPATION TYPE	0	1 (0.0)
Implantable Cardioverter Defibrillator	1 (0.0)	0
MACULAR DEGENERATION, AGE RELATED, BILATERAL	0	1 (0.0)
Nodular Prostate	1 (0.0)	0
OSTEOARTHRITIS	0	1 (0.0)
OSTEOPOROSIS, HIP, RIGHT	1 (0.0)	0
PLANTAR NERVE NEUROMA, LEFT	0	1 (0.0)
POSTIONAL VERTIGO, BENIGN	0	1 (0.0)
Seasonal allergies	1 (0.0)	0
Testicular Hypofunction	1 (0.0)	0
Testicular Hypogonadism	1 (0.0)	0
VESTIBULOPATHY, RIGHT EAR	0	1 (0.0)
intermittent headaches	1 (0.0)	0
migraines	1 (0.0)	0
tramadol allergy	1 (0.0)	0
trazadone allergy	1 (0.0)	0
Blood and lymphatic system disorders	289 (1.5)	281 (1.5)
Activated protein C resistance	1 (0.0)	0
Anaemia	167 (0.9)	174 (0.9)
Anaemia macrocytic	2 (0.0)	0
Anaemia vitamin B12 deficiency	2 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Antiphospholipid syndrome	3 (0.0)	4 (0.0)
Blood loss anaemia	1 (0.0)	1 (0.0)
Coagulopathy	2 (0.0)	3 (0.0)
Eosinophilia	1 (0.0)	0
Haemolytic anaemia	0	3 (0.0)
Haemolytic uraemic syndrome	1 (0.0)	0
Hypercoagulation	4 (0.0)	2 (0.0)
Hypochromic anaemia	1 (0.0)	0
Immune thrombocytopenia	6 (0.0)	4 (0.0)
Increased tendency to bruise	2 (0.0)	1 (0.0)
Iron deficiency anaemia	48 (0.3)	50 (0.3)
Leukocytosis	3 (0.0)	0
Leukopenia	5 (0.0)	5 (0.0)
Lymphadenitis	0	1 (0.0)
Lymphadenopathy	8 (0.0)	6 (0.0)
Lymphatic disorder	1 (0.0)	0
Lymphocytosis	0	1 (0.0)
Lymphoid tissue hyperplasia	1 (0.0)	0
Macrocytosis	0	2 (0.0)
Mast cell activation syndrome	1 (0.0)	0
Mastocytosis	1 (0.0)	0
Microcytic anaemia	1 (0.0)	1 (0.0)
Microcytosis	0	1 (0.0)
Monoclonal B-cell lymphocytosis	0	1 (0.0)
Neutropenia	1 (0.0)	2 (0.0)
Normocytic anaemia	0	1 (0.0)
Pancytopenia	0	2 (0.0)
Pernicious anaemia	7 (0.0)	2 (0.0)
Polycythaemia	5 (0.0)	3 (0.0)
Pseudolymphoma	0	1 (0.0)
Splenic lesion	1 (0.0)	0
Splenomegaly	1 (0.0)	2 (0.0)
Thrombocytopenia	14 (0.1)	14 (0.1)
Thrombocytosis	3 (0.0)	2 (0.0)
Thrombotic thrombocytopenic purpura	0	1 (0.0)
Thymic cyst	1 (0.0)	0
Cardiac disorders	1114 (5.9)	1069 (5.7)
Acute coronary syndrome	0	2 (0.0)
Acute myocardial infarction	39 (0.2)	22 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Adams-Stokes syndrome	1 (0.0)	0
Angina pectoris	44 (0.2)	39 (0.2)
Angina unstable	2 (0.0)	3 (0.0)
Aortic valve disease	2 (0.0)	2 (0.0)
Aortic valve incompetence	10 (0.1)	10 (0.1)
Aortic valve prolapse	1 (0.0)	0
Aortic valve sclerosis	1 (0.0)	0
Aortic valve stenosis	8 (0.0)	6 (0.0)
Arrhythmia	73 (0.4)	74 (0.4)
Arrhythmia supraventricular	1 (0.0)	2 (0.0)
Arteriosclerosis coronary artery	20 (0.1)	21 (0.1)
Arteriospasm coronary	2 (0.0)	4 (0.0)
Atrial fibrillation	220 (1.2)	217 (1.2)
Atrial flutter	15 (0.1)	15 (0.1)
Atrial tachycardia	8 (0.0)	3 (0.0)
Atrioventricular block	3 (0.0)	5 (0.0)
Atrioventricular block complete	3 (0.0)	4 (0.0)
Atrioventricular block first degree	5 (0.0)	5 (0.0)
Atrioventricular block second degree	1 (0.0)	0
Bifascicular block	0	1 (0.0)
Bradyarrhythmia	0	1 (0.0)
Bradycardia	23 (0.1)	21 (0.1)
Bundle branch block	0	1 (0.0)
Bundle branch block left	11 (0.1)	5 (0.0)
Bundle branch block right	9 (0.0)	14 (0.1)
Cardiac amyloidosis	1 (0.0)	0
Cardiac aneurysm	0	2 (0.0)
Cardiac arrest	2 (0.0)	2 (0.0)
Cardiac disorder	6 (0.0)	6 (0.0)
Cardiac failure	11 (0.1)	8 (0.0)
Cardiac failure acute	1 (0.0)	1 (0.0)
Cardiac failure chronic	4 (0.0)	2 (0.0)
Cardiac failure congestive	51 (0.3)	43 (0.2)
Cardiac flutter	0	2 (0.0)
Cardiac septal hypertrophy	1 (0.0)	0
Cardiac valve disease	2 (0.0)	1 (0.0)
Cardiac ventricular thrombosis	1 (0.0)	0
Cardio-respiratory arrest	0	1 (0.0)
Cardiomegaly	2 (0.0)	3 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Cardiomyopathy	13 (0.1)	10 (0.1)
Cardiomyopathy alcoholic	0	1 (0.0)
Cardiovascular disorder	4 (0.0)	8 (0.0)
Chronic left ventricular failure	1 (0.0)	2 (0.0)
Congestive cardiomyopathy	3 (0.0)	2 (0.0)
Coronary artery disease	251 (1.3)	259 (1.4)
Coronary artery dissection	2 (0.0)	0
Coronary artery insufficiency	2 (0.0)	5 (0.0)
Coronary artery occlusion	20 (0.1)	12 (0.1)
Coronary artery stenosis	2 (0.0)	2 (0.0)
Diastolic dysfunction	0	3 (0.0)
Extrasystoles	4 (0.0)	1 (0.0)
Heart valve incompetence	2 (0.0)	0
Hypertensive heart disease	0	3 (0.0)
Ischaemic cardiomyopathy	2 (0.0)	1 (0.0)
Left ventricular failure	1 (0.0)	7 (0.0)
Left ventricular hypertrophy	7 (0.0)	7 (0.0)
Microvascular coronary artery disease	1 (0.0)	0
Mitral valve disease	5 (0.0)	2 (0.0)
Mitral valve incompetence	17 (0.1)	11 (0.1)
Mitral valve prolapse	70 (0.4)	44 (0.2)
Mitral valve stenosis	3 (0.0)	0
Myocardial infarction	134 (0.7)	154 (0.8)
Myocardial ischaemia	6 (0.0)	4 (0.0)
Myocarditis	1 (0.0)	0
Palpitations	47 (0.2)	43 (0.2)
Pericardial effusion	1 (0.0)	1 (0.0)
Pericarditis	3 (0.0)	4 (0.0)
Postural orthostatic tachycardia syndrome	5 (0.0)	1 (0.0)
Prinzmetal angina	1 (0.0)	2 (0.0)
Pulmonary valve incompetence	1 (0.0)	0
Pulmonary valve stenosis	1 (0.0)	2 (0.0)
Right atrial enlargement	0	1 (0.0)
Right ventricular failure	1 (0.0)	0
Silent myocardial infarction	1 (0.0)	0
Sinus arrhythmia	6 (0.0)	1 (0.0)
Sinus bradycardia	3 (0.0)	7 (0.0)
Sinus node dysfunction	9 (0.0)	2 (0.0)
Sinus tachycardia	7 (0.0)	12 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Stress cardiomyopathy	3 (0.0)	2 (0.0)
Supraventricular extrasystoles	7 (0.0)	8 (0.0)
Supraventricular tachycardia	52 (0.3)	42 (0.2)
Tachyarrhythmia	3 (0.0)	1 (0.0)
Tachycardia	27 (0.1)	31 (0.2)
Tachycardia paroxysmal	3 (0.0)	1 (0.0)
Tricuspid valve disease	1 (0.0)	1 (0.0)
Tricuspid valve incompetence	1 (0.0)	2 (0.0)
Ventricular arrhythmia	1 (0.0)	1 (0.0)
Ventricular extrasystoles	45 (0.2)	48 (0.3)
Ventricular fibrillation	1 (0.0)	1 (0.0)
Ventricular tachycardia	9 (0.0)	7 (0.0)
Wolff-Parkinson-White syndrome	9 (0.0)	11 (0.1)
Congenital, familial and genetic disorders	352 (1.9)	356 (1.9)
Acrocephalosyndactyly	1 (0.0)	0
Adrenogenital syndrome	1 (0.0)	0
Alpha-1 antitrypsin deficiency	3 (0.0)	0
Amniotic band syndrome	1 (0.0)	0
Ankyloglossia congenital	0	1 (0.0)
Anomalous pulmonary venous connection	0	1 (0.0)
Anomaly of external ear congenital	0	1 (0.0)
Antithrombin III deficiency	0	2 (0.0)
Arnold-Chiari malformation	7 (0.0)	4 (0.0)
Arterial tortuosity syndrome	1 (0.0)	0
Arteriovenous malformation	5 (0.0)	1 (0.0)
Asplenia	1 (0.0)	0
Asymptomatic gene carrier	1 (0.0)	0
Ataxia telangiectasia	0	1 (0.0)
Atrial septal defect	7 (0.0)	16 (0.1)
BRCA2 gene mutation	0	2 (0.0)
Benign familial pemphigus	1 (0.0)	0
Bicuspid aortic valve	8 (0.0)	4 (0.0)
Bicuspid pulmonary valve	0	1 (0.0)
Blindness congenital	2 (0.0)	0
Branchial cyst	1 (0.0)	0
Breast malformation	1 (0.0)	0
Cancer gene carrier	1 (0.0)	3 (0.0)
Carpus curvus	0	1 (0.0)
Cataract congenital	2 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Cerebral palsy	2 (0.0)	10 (0.1)
Cerebrovascular arteriovenous malformation	0	3 (0.0)
Cleft lip	0	1 (0.0)
Cleft palate	2 (0.0)	2 (0.0)
Coarctation of the aorta	1 (0.0)	1 (0.0)
Colour blindness	1 (0.0)	1 (0.0)
Congenital absence of vertebra	1 (0.0)	0
Congenital anomaly	1 (0.0)	1 (0.0)
Congenital aortic anomaly	0	1 (0.0)
Congenital aortic stenosis	2 (0.0)	1 (0.0)
Congenital benign neoplasm	0	1 (0.0)
Congenital cerebrovascular anomaly	1 (0.0)	1 (0.0)
Congenital coronary artery malformation	0	1 (0.0)
Congenital cystic kidney disease	10 (0.1)	4 (0.0)
Congenital cystic lung	2 (0.0)	0
Congenital ectodermal dysplasia	0	1 (0.0)
Congenital eye disorder	1 (0.0)	1 (0.0)
Congenital flat feet	1 (0.0)	0
Congenital foot malformation	0	2 (0.0)
Congenital hand malformation	0	1 (0.0)
Congenital hearing disorder	1 (0.0)	0
Congenital heart valve disorder	0	2 (0.0)
Congenital hydronephrosis	0	1 (0.0)
Congenital hypothyroidism	1 (0.0)	1 (0.0)
Congenital intestinal malformation	0	2 (0.0)
Congenital jaw malformation	4 (0.0)	1 (0.0)
Congenital joint malformation	2 (0.0)	1 (0.0)
Congenital lymphoedema	0	2 (0.0)
Congenital multiplex arthrogryposis	1 (0.0)	0
Congenital musculoskeletal anomaly	1 (0.0)	1 (0.0)
Congenital myopathy	0	1 (0.0)
Congenital myopia	1 (0.0)	0
Congenital neoplasm	0	1 (0.0)
Congenital osteodystrophy	1 (0.0)	0
Congenital pulmonary valve disorder	1 (0.0)	0
Congenital renal disorder	1 (0.0)	1 (0.0)
Congenital scoliosis	1 (0.0)	0
Congenital skin disorder	0	1 (0.0)
Congenital small intestinal atresia	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Congenital spinal cord anomaly	1 (0.0)	0
Congenital spinal stenosis	1 (0.0)	0
Congenital spondylolisthesis	1 (0.0)	0
Congenital toxoplasmosis	1 (0.0)	0
Congenital ureteric anomaly	0	1 (0.0)
Congenital urethral anomaly	0	1 (0.0)
Congenital uterine anomaly	1 (0.0)	1 (0.0)
Congenital vas deferens absence	1 (0.0)	0
Corneal dystrophy	12 (0.1)	8 (0.0)
Cornelia de Lange syndrome	0	1 (0.0)
Craniosynostosis	0	1 (0.0)
Cryptorchism	2 (0.0)	3 (0.0)
Deafness congenital	2 (0.0)	2 (0.0)
Dermoid cyst	0	1 (0.0)
Developmental hip dysplasia	3 (0.0)	7 (0.0)
Diverticulitis Meckel's	1 (0.0)	0
Dolichocolon	2 (0.0)	1 (0.0)
Dopa-responsive dystonia	1 (0.0)	0
Duodenal atresia	1 (0.0)	0
Dysmorphism	2 (0.0)	0
Dysplastic naevus syndrome	1 (0.0)	0
Eagle Barrett syndrome	1 (0.0)	0
Ear malformation	2 (0.0)	0
Ectopic kidney	1 (0.0)	0
Ectrodactyly	1 (0.0)	0
Ehlers-Danlos syndrome	12 (0.1)	6 (0.0)
Factor II mutation	2 (0.0)	1 (0.0)
Factor V Leiden carrier	3 (0.0)	3 (0.0)
Factor V Leiden mutation	15 (0.1)	19 (0.1)
Factor V deficiency	3 (0.0)	1 (0.0)
Factor VIII deficiency	1 (0.0)	1 (0.0)
Factor XI deficiency	1 (0.0)	1 (0.0)
Factor XII deficiency	1 (0.0)	2 (0.0)
Factor XIII deficiency	1 (0.0)	0
Fallot's tetralogy	1 (0.0)	2 (0.0)
Familial hypertriglyceridaemia	1 (0.0)	0
Familial mediterranean fever	1 (0.0)	0
Familial polycythaemia	1 (0.0)	0
Familial tremor	4 (0.0)	3 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Gastrointestinal arteriovenous malformation	0	1 (0.0)
Gaucher's disease	0	1 (0.0)
Gene mutation	1 (0.0)	1 (0.0)
Gilbert's syndrome	11 (0.1)	8 (0.0)
Glucose-6-phosphate dehydrogenase deficiency	2 (0.0)	6 (0.0)
Haemangioma congenital	1 (0.0)	0
Haemoglobin C trait	0	1 (0.0)
Haemoglobinopathy	3 (0.0)	3 (0.0)
Haemophilia	0	1 (0.0)
Hamartoma	0	1 (0.0)
Heart disease congenital	3 (0.0)	3 (0.0)
Hepato-lenticular degeneration	0	1 (0.0)
Hereditary haemochromatosis	2 (0.0)	2 (0.0)
Hereditary motor and sensory neuropathy	2 (0.0)	1 (0.0)
Hereditary non-polyposis colorectal cancer syndrome	0	2 (0.0)
Hereditary pancreatitis	0	1 (0.0)
Hereditary spherocytosis	2 (0.0)	1 (0.0)
Heterotaxia	1 (0.0)	0
Hydrocele	8 (0.0)	2 (0.0)
Hypertrophic cardiomyopathy	1 (0.0)	5 (0.0)
Hypochondroplasia	0	1 (0.0)
Hypophosphatasia	1 (0.0)	0
Ichthyosis	2 (0.0)	1 (0.0)
Intestinal malrotation	0	1 (0.0)
Intracranial lipoma	0	1 (0.0)
Keratosis follicular	1 (0.0)	0
Klinefelter's syndrome	1 (0.0)	0
Klippel-Feil syndrome	2 (0.0)	1 (0.0)
Kyphosis congenital	1 (0.0)	0
Leptin receptor deficiency	0	1 (0.0)
Limb malformation	0	2 (0.0)
Limb reduction defect	1 (0.0)	1 (0.0)
Malformation venous	0	1 (0.0)
Marfan's syndrome	2 (0.0)	1 (0.0)
Methylenetetrahydrofolate reductase gene mutation	0	5 (0.0)
Micrognathia	0	2 (0.0)
Microphthalmos	1 (0.0)	0
Morton's syndrome	0	1 (0.0)
Myoclonic dystonia	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Myotonia congenita	0	1 (0.0)
Myotonic dystrophy	0	1 (0.0)
Naevus flammeus	1 (0.0)	0
Neurofibromatosis	6 (0.0)	5 (0.0)
Oesophageal cyst	0	1 (0.0)
Olfacto genital dysplasia	0	1 (0.0)
Otospondylomegaepiphyseal dysplasia	1 (0.0)	0
PTEN gene mutation	0	1 (0.0)
Pancreas divisum	1 (0.0)	0
Patent ductus arteriosus	0	2 (0.0)
Pectus carinatum	0	1 (0.0)
Pectus excavatum	4 (0.0)	3 (0.0)
Pelvic kidney	0	1 (0.0)
Phimosis	1 (0.0)	3 (0.0)
Poland's syndrome	2 (0.0)	0
Polycystic liver disease	2 (0.0)	1 (0.0)
Polydactyly	0	1 (0.0)
Porokeratosis	1 (0.0)	1 (0.0)
Porphyria	1 (0.0)	0
Primary familial brain calcification	0	1 (0.0)
Protein C deficiency	0	1 (0.0)
Protein S deficiency	4 (0.0)	2 (0.0)
Pseudoxanthoma elasticum	1 (0.0)	0
Pulmonary hypoplasia	1 (0.0)	0
Pulmonary malformation	1 (0.0)	0
Pyloric stenosis	3 (0.0)	10 (0.1)
Renal aplasia	3 (0.0)	3 (0.0)
Renal dysplasia	1 (0.0)	0
Renal fusion anomaly	2 (0.0)	0
Renal hypoplasia	0	1 (0.0)
Retinal anomaly congenital	1 (0.0)	0
Retinitis pigmentosa	1 (0.0)	1 (0.0)
Schizencephaly	0	1 (0.0)
Schmid Fraccaro syndrome	1 (0.0)	0
Sebaceous naevus	0	1 (0.0)
Sickle cell anaemia	1 (0.0)	1 (0.0)
Sickle cell trait	4 (0.0)	8 (0.0)
Spina bifida	2 (0.0)	4 (0.0)
Spina bifida occulta	0	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Spine malformation	0	2 (0.0)
Stargardt's disease	1 (0.0)	4 (0.0)
Supernumerary nipple	1 (0.0)	0
Syndactyly	1 (0.0)	1 (0.0)
Syringomyelia	1 (0.0)	0
Talipes	4 (0.0)	4 (0.0)
Thalassaemia	11 (0.1)	6 (0.0)
Thalassaemia alpha	0	3 (0.0)
Thalassaemia beta	3 (0.0)	8 (0.0)
Thalassaemia minor	8 (0.0)	10 (0.1)
Thyroglossal cyst	0	2 (0.0)
Tourette's disorder	1 (0.0)	2 (0.0)
Tracheo-oesophageal fistula	1 (0.0)	0
Transitional vertebrae	1 (0.0)	0
Tuberous sclerosis complex	1 (0.0)	2 (0.0)
Type II hyperlipidaemia	0	1 (0.0)
Type IIa hyperlipidaemia	16 (0.1)	14 (0.1)
Type V hyperlipidaemia	41 (0.2)	26 (0.1)
Umbilical malformation	0	1 (0.0)
Urethral valves	1 (0.0)	0
Venous angioma of brain	1 (0.0)	0
Ventricular septal defect	2 (0.0)	8 (0.0)
Vitello-intestinal duct remnant	2 (0.0)	0
Von Willebrand's disease	3 (0.0)	3 (0.0)
Wolff-Parkinson-White syndrome congenital	1 (0.0)	0
Ear and labyrinth disorders	555 (2.9)	569 (3.0)
Auditory disorder	5 (0.0)	6 (0.0)
Aural polyp	0	1 (0.0)
Cerumen impaction	6 (0.0)	4 (0.0)
Conductive deafness	0	1 (0.0)
Deafness	97 (0.5)	93 (0.5)
Deafness bilateral	93 (0.5)	117 (0.6)
Deafness neurosensory	14 (0.1)	14 (0.1)
Deafness transitory	1 (0.0)	0
Deafness unilateral	42 (0.2)	54 (0.3)
Ear congestion	1 (0.0)	0
Ear disorder	2 (0.0)	3 (0.0)
Ear pain	1 (0.0)	7 (0.0)
Ear pruritus	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Endolymphatic hydrops	0	2 (0.0)
Eustachian tube dysfunction	4 (0.0)	4 (0.0)
Eustachian tube patulous	1 (0.0)	0
Eustachian tube stenosis	0	1 (0.0)
Excessive cerumen production	1 (0.0)	1 (0.0)
Exostosis of external ear canal	1 (0.0)	1 (0.0)
Hyperacusis	1 (0.0)	0
Hypoacusis	44 (0.2)	50 (0.3)
Inner ear disorder	2 (0.0)	0
Meniere's disease	40 (0.2)	27 (0.1)
Mixed deafness	1 (0.0)	1 (0.0)
Motion sickness	3 (0.0)	3 (0.0)
Otosclerosis	7 (0.0)	6 (0.0)
Presbyacusis	6 (0.0)	1 (0.0)
Sudden hearing loss	2 (0.0)	0
Superior semicircular canal dehiscence	1 (0.0)	0
Tinnitus	130 (0.7)	130 (0.7)
Tympanic membrane perforation	10 (0.1)	9 (0.0)
Tympanic membrane scarring	1 (0.0)	0
Vertigo	82 (0.4)	92 (0.5)
Vertigo positional	13 (0.1)	10 (0.1)
Vestibular disorder	1 (0.0)	1 (0.0)
Endocrine disorders	1830 (9.7)	1902 (10.1)
Acromegaly	0	1 (0.0)
Addison's disease	1 (0.0)	0
Adrenal cyst	2 (0.0)	0
Adrenal disorder	0	1 (0.0)
Adrenal insufficiency	2 (0.0)	0
Adrenal mass	1 (0.0)	1 (0.0)
Androgen deficiency	3 (0.0)	6 (0.0)
Anovulatory cycle	1 (0.0)	1 (0.0)
Autoimmune hypothyroidism	2 (0.0)	2 (0.0)
Autoimmune thyroiditis	60 (0.3)	40 (0.2)
Basedow's disease	23 (0.1)	22 (0.1)
Diabetes insipidus	0	3 (0.0)
Empty sella syndrome	1 (0.0)	0
Endocrine disorder	1 (0.0)	1 (0.0)
Goitre	35 (0.2)	53 (0.3)
Gonadotrophin deficiency	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Growth hormone deficiency	2 (0.0)	0
Hyperaldosteronism	0	5 (0.0)
Hypergonadism	2 (0.0)	1 (0.0)
Hyperparathyroidism	19 (0.1)	9 (0.0)
Hyperparathyroidism primary	1 (0.0)	2 (0.0)
Hyperplasia adrenal	1 (0.0)	0
Hyperprolactinaemia	3 (0.0)	2 (0.0)
Hyperthyroidism	85 (0.5)	77 (0.4)
Hypogonadism	73 (0.4)	66 (0.4)
Hypogonadism male	11 (0.1)	5 (0.0)
Hypoparathyroidism	2 (0.0)	3 (0.0)
Hypoprogesteronism	1 (0.0)	0
Hypothyroidism	1523 (8.1)	1602 (8.5)
Immune-mediated thyroiditis	0	1 (0.0)
Oestrogen deficiency	6 (0.0)	6 (0.0)
Parathyroid disorder	1 (0.0)	0
Pituitary enlargement	1 (0.0)	0
Pituitary-dependent Cushing's syndrome	1 (0.0)	0
Primary hypogonadism	1 (0.0)	1 (0.0)
Secondary hypogonadism	0	1 (0.0)
Secondary hypothyroidism	0	1 (0.0)
Testicular failure	4 (0.0)	4 (0.0)
Thyroid atrophy	0	1 (0.0)
Thyroid calcification	1 (0.0)	0
Thyroid cyst	8 (0.0)	6 (0.0)
Thyroid disorder	10 (0.1)	4 (0.0)
Thyroid mass	41 (0.2)	55 (0.3)
Thyroid stimulating hormone deficiency	0	1 (0.0)
Thyroiditis	3 (0.0)	2 (0.0)
Thyroiditis subacute	0	2 (0.0)
Toxic nodular goitre	0	2 (0.0)
Eye disorders	1997 (10.6)	1959 (10.4)
Age-related macular degeneration	3 (0.0)	2 (0.0)
Amaurosis	1 (0.0)	1 (0.0)
Amaurosis fugax	1 (0.0)	0
Amblyopia	13 (0.1)	15 (0.1)
Amblyopia strabismic	0	1 (0.0)
Angle closure glaucoma	5 (0.0)	2 (0.0)
Anisometropia	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Asthenopia	0	1 (0.0)
Astigmatism	66 (0.3)	69 (0.4)
Binocular eye movement disorder	1 (0.0)	0
Blepharitis	5 (0.0)	3 (0.0)
Blepharospasm	2 (0.0)	2 (0.0)
Blindness	4 (0.0)	1 (0.0)
Blindness unilateral	21 (0.1)	12 (0.1)
Borderline glaucoma	5 (0.0)	2 (0.0)
Cataract	455 (2.4)	445 (2.4)
Cataract cortical	0	1 (0.0)
Cataract diabetic	1 (0.0)	0
Cataract nuclear	7 (0.0)	6 (0.0)
Central vision loss	0	1 (0.0)
Chalazion	1 (0.0)	2 (0.0)
Chorioretinopathy	9 (0.0)	2 (0.0)
Cogan's syndrome	0	1 (0.0)
Conjunctival haemorrhage	1 (0.0)	1 (0.0)
Conjunctivitis allergic	12 (0.1)	5 (0.0)
Conjunctivochalasis	0	1 (0.0)
Corneal degeneration	1 (0.0)	1 (0.0)
Corneal disorder	1 (0.0)	1 (0.0)
Corneal epithelium defect	0	1 (0.0)
Corneal opacity	2 (0.0)	0
Corneal scar	2 (0.0)	1 (0.0)
Dacryostenosis acquired	3 (0.0)	3 (0.0)
Dermatochalasis	5 (0.0)	0
Diabetic eye disease	1 (0.0)	0
Diabetic retinopathy	12 (0.1)	11 (0.1)
Diplopia	1 (0.0)	2 (0.0)
Dry age-related macular degeneration	7 (0.0)	1 (0.0)
Dry eye	103 (0.5)	98 (0.5)
Endocrine ophthalmopathy	0	2 (0.0)
Entropion	1 (0.0)	1 (0.0)
Exfoliation glaucoma	0	1 (0.0)
Exfoliation syndrome	0	1 (0.0)
Exophthalmos	0	1 (0.0)
Extraocular muscle disorder	0	1 (0.0)
Extraocular muscle paresis	0	1 (0.0)
Eye allergy	1 (0.0)	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Eye disorder	2 (0.0)	5 (0.0)
Eye haemorrhage	1 (0.0)	1 (0.0)
Eye inflammation	2 (0.0)	0
Eye irritation	1 (0.0)	2 (0.0)
Eye movement disorder	1 (0.0)	1 (0.0)
Eye pruritus	1 (0.0)	1 (0.0)
Eye swelling	1 (0.0)	1 (0.0)
Eyelid cyst	1 (0.0)	2 (0.0)
Eyelid ptosis	20 (0.1)	7 (0.0)
Fuchs' syndrome	0	1 (0.0)
Giant papillary conjunctivitis	0	1 (0.0)
Glaucoma	204 (1.1)	206 (1.1)
Holmes-Adie pupil	1 (0.0)	0
Hyalosis asteroid	0	1 (0.0)
Hypermetropia	230 (1.2)	223 (1.2)
Idiopathic orbital inflammation	1 (0.0)	0
Iridocorneal endothelial syndrome	1 (0.0)	0
Iridocyclitis	0	1 (0.0)
Iris disorder	1 (0.0)	1 (0.0)
Iritis	3 (0.0)	5 (0.0)
Keratitis	3 (0.0)	1 (0.0)
Keratoconus	8 (0.0)	9 (0.0)
Keratomalacia	1 (0.0)	0
Lacrimal disorder	0	1 (0.0)
Lenticular opacities	1 (0.0)	0
Macular degeneration	49 (0.3)	47 (0.2)
Macular fibrosis	5 (0.0)	7 (0.0)
Macular hole	1 (0.0)	4 (0.0)
Macular oedema	2 (0.0)	2 (0.0)
Macular scar	0	1 (0.0)
Macular telangiectasia	1 (0.0)	0
Maculopathy	5 (0.0)	4 (0.0)
Meibomian gland dysfunction	3 (0.0)	0
Mydriasis	0	1 (0.0)
Myopia	699 (3.7)	691 (3.7)
Myopic chorioretinal degeneration	2 (0.0)	2 (0.0)
Narrow anterior chamber angle	0	1 (0.0)
Necrotising retinitis	1 (0.0)	0
Neovascular age-related macular degeneration	3 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Non-proliferative retinopathy	0	1 (0.0)
Normal tension glaucoma	1 (0.0)	3 (0.0)
Ocular discomfort	1 (0.0)	1 (0.0)
Ocular fistula	0	1 (0.0)
Ocular hypertension	4 (0.0)	7 (0.0)
Ocular ischaemic syndrome	0	1 (0.0)
Ocular pemphigoid	1 (0.0)	0
Ocular rosacea	2 (0.0)	1 (0.0)
Ocular vascular disorder	2 (0.0)	2 (0.0)
Open angle glaucoma	6 (0.0)	8 (0.0)
Optic atrophy	1 (0.0)	1 (0.0)
Optic disc drusen	1 (0.0)	0
Optic ischaemic neuropathy	0	3 (0.0)
Optic nerve cupping	0	1 (0.0)
Optic neuropathy	0	1 (0.0)
Oscillopsia	0	2 (0.0)
Photophobia	1 (0.0)	1 (0.0)
Pigment dispersion syndrome	1 (0.0)	0
Pigmentary glaucoma	1 (0.0)	0
Pinguecula	1 (0.0)	0
Posterior capsule opacification	1 (0.0)	0
Presbyopia	255 (1.4)	248 (1.3)
Pterygium	8 (0.0)	4 (0.0)
Punctate keratitis	2 (0.0)	0
Pupils unequal	0	2 (0.0)
Refraction disorder	3 (0.0)	4 (0.0)
Refractive amblyopia	0	1 (0.0)
Retinal artery occlusion	1 (0.0)	1 (0.0)
Retinal artery thrombosis	1 (0.0)	0
Retinal degeneration	4 (0.0)	2 (0.0)
Retinal detachment	39 (0.2)	32 (0.2)
Retinal disorder	4 (0.0)	3 (0.0)
Retinal drusen	1 (0.0)	0
Retinal dystrophy	0	1 (0.0)
Retinal haemorrhage	1 (0.0)	0
Retinal oedema	0	1 (0.0)
Retinal scar	2 (0.0)	1 (0.0)
Retinal tear	10 (0.1)	11 (0.1)
Retinal vascular disorder	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Retinal vein occlusion	3 (0.0)	3 (0.0)
Retinal vein thrombosis	0	1 (0.0)
Retinopathy	2 (0.0)	1 (0.0)
Retinopathy proliferative	2 (0.0)	1 (0.0)
Scintillating scotoma	0	1 (0.0)
Strabismus	23 (0.1)	29 (0.2)
Subretinal fluid	1 (0.0)	0
Ulcerative keratitis	0	1 (0.0)
Uveitis	4 (0.0)	4 (0.0)
Vision blurred	5 (0.0)	3 (0.0)
Visual acuity reduced	108 (0.6)	118 (0.6)
Visual impairment	26 (0.1)	36 (0.2)
Vitreous degeneration	2 (0.0)	2 (0.0)
Vitreous detachment	9 (0.0)	7 (0.0)
Vitreous disorder	0	1 (0.0)
Vitreous floaters	4 (0.0)	2 (0.0)
Vitreous haemorrhage	1 (0.0)	2 (0.0)
Gastrointestinal disorders	3356 (17.8)	3321 (17.6)
Abdominal adhesions	2 (0.0)	2 (0.0)
Abdominal discomfort	0	3 (0.0)
Abdominal distension	4 (0.0)	7 (0.0)
Abdominal hernia	52 (0.3)	48 (0.3)
Abdominal mass	1 (0.0)	1 (0.0)
Abdominal migraine	1 (0.0)	0
Abdominal pain	20 (0.1)	15 (0.1)
Abdominal pain lower	2 (0.0)	2 (0.0)
Abdominal pain upper	8 (0.0)	6 (0.0)
Abdominal wall mass	1 (0.0)	0
Acquired oesophageal web	4 (0.0)	2 (0.0)
Anal fissure	4 (0.0)	12 (0.1)
Anal fistula	4 (0.0)	7 (0.0)
Anal haemorrhage	0	1 (0.0)
Anal incontinence	1 (0.0)	3 (0.0)
Anal prolapse	0	1 (0.0)
Anal skin tags	1 (0.0)	0
Angular cheilitis	1 (0.0)	0
Anogenital dysplasia	1 (0.0)	1 (0.0)
Aphthous ulcer	5 (0.0)	4 (0.0)
Appendiceal mucocoele	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Appendicitis noninfective	0	1 (0.0)
Appendix disorder	1 (0.0)	1 (0.0)
Barrett's oesophagus	35 (0.2)	38 (0.2)
Bile acid malabsorption	1 (0.0)	2 (0.0)
Cannabinoid hyperemesis syndrome	0	1 (0.0)
Chronic gastritis	9 (0.0)	11 (0.1)
Coeliac artery stenosis	0	1 (0.0)
Coeliac disease	40 (0.2)	40 (0.2)
Colitis	8 (0.0)	9 (0.0)
Colitis ischaemic	1 (0.0)	4 (0.0)
Colitis microscopic	6 (0.0)	7 (0.0)
Colitis ulcerative	22 (0.1)	27 (0.1)
Constipation	187 (1.0)	187 (1.0)
Crohn's disease	11 (0.1)	14 (0.1)
Cyclic vomiting syndrome	1 (0.0)	0
Defaecation disorder	1 (0.0)	0
Dental caries	10 (0.1)	9 (0.0)
Dental plaque	1 (0.0)	0
Diaphragmatic hernia	1 (0.0)	1 (0.0)
Diarrhoea	53 (0.3)	55 (0.3)
Diverticulum	96 (0.5)	86 (0.5)
Diverticulum intestinal	23 (0.1)	28 (0.1)
Diverticulum oesophageal	0	2 (0.0)
Dry mouth	7 (0.0)	7 (0.0)
Dumping syndrome	0	1 (0.0)
Duodenal stenosis	0	1 (0.0)
Duodenal ulcer	7 (0.0)	9 (0.0)
Duodenogastric reflux	3 (0.0)	9 (0.0)
Dyspepsia	301 (1.6)	273 (1.4)
Dysphagia	12 (0.1)	11 (0.1)
Encapsulating peritoneal sclerosis	0	1 (0.0)
Enlarged uvula	0	1 (0.0)
Enteritis	1 (0.0)	0
Enterovesical fistula	2 (0.0)	2 (0.0)
Eosinophilic oesophagitis	10 (0.1)	7 (0.0)
Epigastric discomfort	1 (0.0)	0
Epiploic appendagitis	0	1 (0.0)
Erosive oesophagitis	1 (0.0)	0
Eructation	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Faeces hard	0	1 (0.0)
Faeces soft	2 (0.0)	1 (0.0)
Femoral hernia	1 (0.0)	3 (0.0)
Flatulence	3 (0.0)	3 (0.0)
Food poisoning	1 (0.0)	5 (0.0)
Functional gastrointestinal disorder	1 (0.0)	0
Gastric disorder	3 (0.0)	2 (0.0)
Gastric haemorrhage	1 (0.0)	1 (0.0)
Gastric ileus	1 (0.0)	0
Gastric mucosal lesion	1 (0.0)	0
Gastric ulcer	33 (0.2)	43 (0.2)
Gastric ulcer haemorrhage	1 (0.0)	0
Gastric ulcer perforation	1 (0.0)	1 (0.0)
Gastritis	63 (0.3)	58 (0.3)
Gastritis erosive	3 (0.0)	1 (0.0)
Gastrointestinal disorder	5 (0.0)	4 (0.0)
Gastrointestinal fistula	0	1 (0.0)
Gastrointestinal haemorrhage	10 (0.1)	10 (0.1)
Gastrointestinal hypomotility	1 (0.0)	2 (0.0)
Gastrointestinal inflammation	0	1 (0.0)
Gastrointestinal necrosis	1 (0.0)	0
Gastrointestinal pain	4 (0.0)	0
Gastrointestinal perforation	2 (0.0)	1 (0.0)
Gastrointestinal polyp	1 (0.0)	2 (0.0)
Gastrointestinal scarring	0	1 (0.0)
Gastrointestinal ulcer	2 (0.0)	1 (0.0)
Gastrointestinal ulcer haemorrhage	2 (0.0)	0
Gastrooesophageal reflux disease	1843 (9.8)	1833 (9.7)
Gingival blister	0	1 (0.0)
Gingival discomfort	0	1 (0.0)
Gingival disorder	0	1 (0.0)
Gingival recession	1 (0.0)	4 (0.0)
Haematochezia	2 (0.0)	4 (0.0)
Haemorrhoids	153 (0.8)	152 (0.8)
Hiatus hernia	88 (0.5)	117 (0.6)
Hyperaesthesia teeth	1 (0.0)	0
Hyperchlorhydria	1 (0.0)	0
Impaired gastric emptying	15 (0.1)	12 (0.1)
Inflammatory bowel disease	2 (0.0)	5 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Inguinal hernia	237 (1.3)	251 (1.3)
Internal hernia	1 (0.0)	0
Intestinal cyst	2 (0.0)	1 (0.0)
Intestinal obstruction	15 (0.1)	9 (0.0)
Intestinal perforation	3 (0.0)	2 (0.0)
Intestinal polyp	6 (0.0)	2 (0.0)
Intestinal prolapse	0	1 (0.0)
Intestinal pseudo-obstruction	1 (0.0)	0
Intestinal strangulation	1 (0.0)	0
Intussusception	1 (0.0)	1 (0.0)
Irritable bowel syndrome	268 (1.4)	251 (1.3)
Large intestinal obstruction	3 (0.0)	1 (0.0)
Large intestinal stenosis	0	1 (0.0)
Large intestinal ulcer	1 (0.0)	0
Large intestine perforation	5 (0.0)	2 (0.0)
Large intestine polyp	101 (0.5)	96 (0.5)
Leukoplakia oral	0	1 (0.0)
Lower gastrointestinal haemorrhage	1 (0.0)	1 (0.0)
Lumbar hernia	8 (0.0)	2 (0.0)
Lymphangiectasia intestinal	0	1 (0.0)
Malabsorption	2 (0.0)	2 (0.0)
Malocclusion	3 (0.0)	4 (0.0)
Mouth cyst	1 (0.0)	0
Mouth ulceration	4 (0.0)	4 (0.0)
Nausea	23 (0.1)	31 (0.2)
Necrotising colitis	1 (0.0)	0
Noninfective gingivitis	0	1 (0.0)
Noninfective sialoadenitis	1 (0.0)	0
Obstruction gastric	0	2 (0.0)
Obstructive pancreatitis	0	1 (0.0)
Odynophagia	1 (0.0)	0
Oesophageal achalasia	3 (0.0)	5 (0.0)
Oesophageal dilatation	1 (0.0)	0
Oesophageal disorder	1 (0.0)	1 (0.0)
Oesophageal fistula	1 (0.0)	0
Oesophageal haemorrhage	1 (0.0)	0
Oesophageal motility disorder	0	1 (0.0)
Oesophageal perforation	1 (0.0)	2 (0.0)
Oesophageal spasm	6 (0.0)	4 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Oesophageal stenosis	8 (0.0)	4 (0.0)
Oesophageal ulcer	5 (0.0)	1 (0.0)
Oesophagitis	12 (0.1)	10 (0.1)
Oral disorder	0	1 (0.0)
Oral lichen planus	1 (0.0)	1 (0.0)
Oral mucosal blistering	1 (0.0)	1 (0.0)
Pancreatic cyst	8 (0.0)	3 (0.0)
Pancreatic failure	1 (0.0)	4 (0.0)
Pancreatic mass	0	1 (0.0)
Pancreatitis	22 (0.1)	17 (0.1)
Pancreatitis acute	3 (0.0)	2 (0.0)
Pancreatitis chronic	4 (0.0)	5 (0.0)
Pancreatitis necrotising	0	1 (0.0)
Pelvic floor dysfunction	2 (0.0)	1 (0.0)
Peptic ulcer	10 (0.1)	19 (0.1)
Peptic ulcer haemorrhage	0	1 (0.0)
Periodontal disease	2 (0.0)	2 (0.0)
Peritoneal cyst	0	1 (0.0)
Pharyngo-oesophageal diverticulum	2 (0.0)	0
Precancerous lesion of digestive tract	1 (0.0)	0
Proctalgia	0	2 (0.0)
Proctitis	0	1 (0.0)
Proctitis ulcerative	1 (0.0)	3 (0.0)
Rectal fissure	4 (0.0)	3 (0.0)
Rectal haemorrhage	6 (0.0)	6 (0.0)
Rectal polyp	0	1 (0.0)
Rectal prolapse	3 (0.0)	4 (0.0)
Rectal spasm	1 (0.0)	0
Reflux gastritis	1 (0.0)	0
Salivary gland calculus	1 (0.0)	1 (0.0)
Salivary gland cyst	3 (0.0)	0
Short-bowel syndrome	2 (0.0)	1 (0.0)
Small intestinal obstruction	13 (0.1)	3 (0.0)
Small intestinal perforation	1 (0.0)	1 (0.0)
Small intestinal stenosis	1 (0.0)	1 (0.0)
Small intestine ulcer	1 (0.0)	0
Spigelian hernia	1 (0.0)	0
Splenic artery aneurysm	0	2 (0.0)
Steatorrhoea	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Stomatitis	1 (0.0)	4 (0.0)
Superior mesenteric artery syndrome	0	1 (0.0)
Swollen tongue	1 (0.0)	1 (0.0)
Tongue coated	0	1 (0.0)
Tongue discomfort	0	1 (0.0)
Tongue geographic	0	1 (0.0)
Tooth disorder	2 (0.0)	0
Tooth impacted	21 (0.1)	22 (0.1)
Tooth loss	3 (0.0)	3 (0.0)
Toothache	5 (0.0)	11 (0.1)
Umbilical hernia	131 (0.7)	116 (0.6)
Upper gastrointestinal haemorrhage	1 (0.0)	0
Uvulitis	1 (0.0)	0
Varices oesophageal	1 (0.0)	2 (0.0)
Volvulus	1 (0.0)	5 (0.0)
Vomiting	6 (0.0)	6 (0.0)
General disorders and administration site conditions	419 (2.2)	409 (2.2)
Adverse drug reaction	14 (0.1)	13 (0.1)
Adverse food reaction	1 (0.0)	0
Application site vesicles	0	1 (0.0)
Asthenia	1 (0.0)	2 (0.0)
Atrophy	1 (0.0)	3 (0.0)
Axillary pain	0	1 (0.0)
Calcinosis	2 (0.0)	1 (0.0)
Chest discomfort	1 (0.0)	2 (0.0)
Chest pain	20 (0.1)	10 (0.1)
Chronic fatigue syndrome	5 (0.0)	3 (0.0)
Complication associated with device	0	1 (0.0)
Cyst	14 (0.1)	21 (0.1)
Cyst rupture	1 (0.0)	1 (0.0)
Device intolerance	0	1 (0.0)
Discomfort	0	2 (0.0)
Drug intolerance	49 (0.3)	51 (0.3)
Dysplasia	2 (0.0)	0
Face oedema	1 (0.0)	0
Facial pain	0	1 (0.0)
Fat tissue increased	1 (0.0)	1 (0.0)
Fatigue	25 (0.1)	30 (0.2)
Fibrosis	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Gait disturbance	6 (0.0)	1 (0.0)
Generalised oedema	1 (0.0)	0
Granuloma	0	1 (0.0)
Gravitational oedema	1 (0.0)	1 (0.0)
Hernia	40 (0.2)	35 (0.2)
Hyperplasia	3 (0.0)	0
Hyperthermia malignant	1 (0.0)	0
Inflammation	1 (0.0)	3 (0.0)
Inflammatory pain	1 (0.0)	0
Injection site erythema	0	1 (0.0)
Injection site swelling	0	1 (0.0)
Lithiasis	0	1 (0.0)
Localised oedema	1 (0.0)	1 (0.0)
Malaise	0	2 (0.0)
Medical device site scar	0	1 (0.0)
Necrosis	1 (0.0)	0
Nodule	0	1 (0.0)
Non-cardiac chest pain	1 (0.0)	2 (0.0)
Oedema	23 (0.1)	12 (0.1)
Oedema peripheral	119 (0.6)	113 (0.6)
Pain	66 (0.3)	76 (0.4)
Pelvic mass	1 (0.0)	1 (0.0)
Perforated ulcer	2 (0.0)	0
Peripheral swelling	11 (0.1)	12 (0.1)
Polyp	2 (0.0)	1 (0.0)
Pre-existing condition improved	1 (0.0)	0
Precancerous condition	4 (0.0)	2 (0.0)
Procedural failure	0	1 (0.0)
Pyrexia	1 (0.0)	1 (0.0)
Stenosis	2 (0.0)	1 (0.0)
Surgical failure	0	2 (0.0)
Swelling face	1 (0.0)	0
Therapeutic response unexpected	0	1 (0.0)
Therapy responder	0	1 (0.0)
Treatment noncompliance	1 (0.0)	2 (0.0)
Ulcer	3 (0.0)	1 (0.0)
Ulcer haemorrhage	0	1 (0.0)
Vaccination site reaction	0	1 (0.0)
Vaccination site swelling	2 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Vascular stent occlusion	0	2 (0.0)
Xerosis	3 (0.0)	0
Hepatobiliary disorders	697 (3.7)	681 (3.6)
Bile duct stone	4 (0.0)	4 (0.0)
Biliary colic	7 (0.0)	1 (0.0)
Biliary cyst	0	1 (0.0)
Biliary dyskinesia	3 (0.0)	1 (0.0)
Biliary obstruction	0	1 (0.0)
Biliary polyp	0	1 (0.0)
Biliary tract disorder	4 (0.0)	1 (0.0)
Cholangitis sclerosing	2 (0.0)	0
Cholecystitis	130 (0.7)	158 (0.8)
Cholecystitis acute	1 (0.0)	6 (0.0)
Cholecystitis chronic	1 (0.0)	0
Cholelithiasis	391 (2.1)	375 (2.0)
Cholelithiasis obstructive	1 (0.0)	1 (0.0)
Cholestasis	2 (0.0)	2 (0.0)
Cirrhosis alcoholic	3 (0.0)	0
Drug-induced liver injury	1 (0.0)	1 (0.0)
Fatty liver alcoholic	1 (0.0)	0
Gallbladder cholesterolosis	1 (0.0)	0
Gallbladder disorder	46 (0.2)	36 (0.2)
Gallbladder enlargement	0	1 (0.0)
Gallbladder hypofunction	4 (0.0)	5 (0.0)
Gallbladder obstruction	1 (0.0)	1 (0.0)
Gallbladder oedema	1 (0.0)	0
Gallbladder polyp	2 (0.0)	5 (0.0)
Gallbladder rupture	1 (0.0)	1 (0.0)
Hepatic artery stenosis	0	1 (0.0)
Hepatic atrophy	0	1 (0.0)
Hepatic cirrhosis	7 (0.0)	2 (0.0)
Hepatic cyst	2 (0.0)	7 (0.0)
Hepatic fibrosis	0	1 (0.0)
Hepatic function abnormal	0	1 (0.0)
Hepatic lesion	2 (0.0)	0
Hepatic mass	0	4 (0.0)
Hepatic steatosis	75 (0.4)	52 (0.3)
Hepatitis	0	4 (0.0)
Hepatobiliary disease	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Hepatomegaly	5 (0.0)	0
Hyperbilirubinaemia	1 (0.0)	0
Jaundice	1 (0.0)	1 (0.0)
Liver disorder	1 (0.0)	4 (0.0)
Non-alcoholic steatohepatitis	14 (0.1)	8 (0.0)
Nonalcoholic fatty liver disease	9 (0.0)	13 (0.1)
Portal vein thrombosis	0	1 (0.0)
Primary biliary cholangitis	1 (0.0)	0
Immune system disorders	5097 (27.0)	5062 (26.9)
Allergic oedema	6 (0.0)	5 (0.0)
Allergic reaction to excipient	0	1 (0.0)
Allergy to animal	108 (0.6)	103 (0.5)
Allergy to arthropod bite	3 (0.0)	5 (0.0)
Allergy to arthropod sting	61 (0.3)	61 (0.3)
Allergy to chemicals	17 (0.1)	14 (0.1)
Allergy to metals	22 (0.1)	18 (0.1)
Allergy to plants	20 (0.1)	26 (0.1)
Allergy to silk	0	1 (0.0)
Allergy to surgical sutures	0	4 (0.0)
Allergy to synthetic fabric	1 (0.0)	0
Allergy to vaccine	9 (0.0)	11 (0.1)
Allergy to venom	0	2 (0.0)
Amyloidosis	1 (0.0)	1 (0.0)
Anaphylactic reaction	13 (0.1)	21 (0.1)
Anaphylactic shock	1 (0.0)	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	1 (0.0)	0
Atopy	2 (0.0)	2 (0.0)
Cockroach allergy	0	1 (0.0)
Contrast media allergy	32 (0.2)	34 (0.2)
Contrast media reaction	1 (0.0)	1 (0.0)
Device allergy	1 (0.0)	0
Drug hypersensitivity	2440 (12.9)	2330 (12.4)
Dust allergy	24 (0.1)	39 (0.2)
Food allergy	322 (1.7)	309 (1.6)
Hypersensitivity	166 (0.9)	156 (0.8)
Iodine allergy	38 (0.2)	50 (0.3)
Milk allergy	17 (0.1)	16 (0.1)
Mite allergy	16 (0.1)	18 (0.1)
Multiple allergies	18 (0.1)	23 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Mycotic allergy	27 (0.1)	23 (0.1)
Oral allergy syndrome	1 (0.0)	0
Perennial allergy	26 (0.1)	35 (0.2)
Perfume sensitivity	2 (0.0)	5 (0.0)
Reaction to colouring	5 (0.0)	7 (0.0)
Reaction to food additive	8 (0.0)	9 (0.0)
Reaction to preservatives	2 (0.0)	2 (0.0)
Rubber sensitivity	105 (0.6)	111 (0.6)
Sarcoidosis	10 (0.1)	13 (0.1)
Seasonal allergy	2804 (14.9)	2839 (15.1)
Serum sickness	0	2 (0.0)
Smoke sensitivity	3 (0.0)	2 (0.0)
Sunscreen sensitivity	0	2 (0.0)
Infections and infestations	2077 (11.0)	1992 (10.6)
Abdominal infection	0	1 (0.0)
Abscess limb	1 (0.0)	1 (0.0)
Abscess neck	2 (0.0)	0
Abscess soft tissue	0	1 (0.0)
Acarodermatitis	0	1 (0.0)
Acquired immunodeficiency syndrome	0	1 (0.0)
Actinomycosis	0	1 (0.0)
Acute hepatitis B	0	1 (0.0)
Acute sinusitis	1 (0.0)	6 (0.0)
Adenoiditis	14 (0.1)	11 (0.1)
American trypanosomiasis	2 (0.0)	1 (0.0)
Anal abscess	0	1 (0.0)
Appendiceal abscess	1 (0.0)	0
Appendicitis	429 (2.3)	415 (2.2)
Appendicitis perforated	15 (0.1)	9 (0.0)
Arthritis bacterial	3 (0.0)	3 (0.0)
Arthritis infective	0	3 (0.0)
Asymptomatic HIV infection	1 (0.0)	1 (0.0)
Atypical pneumonia	2 (0.0)	0
Babesiosis	0	1 (0.0)
Bacterial infection	2 (0.0)	0
Bacterial toxaemia	1 (0.0)	0
Bacterial tracheitis	1 (0.0)	0
Bacterial vaginosis	3 (0.0)	4 (0.0)
Bacterial vulvovaginitis	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Bartonellosis	0	1 (0.0)
Beta haemolytic streptococcal infection	0	1 (0.0)
Body tinea	1 (0.0)	1 (0.0)
Bone abscess	1 (0.0)	0
Brain abscess	0	2 (0.0)
Breast abscess	2 (0.0)	0
Bronchitis	34 (0.2)	33 (0.2)
Bronchitis bacterial	1 (0.0)	0
Candida infection	2 (0.0)	3 (0.0)
Carbuncle	1 (0.0)	0
Cat scratch disease	3 (0.0)	3 (0.0)
Cellulitis	14 (0.1)	11 (0.1)
Cellulitis orbital	0	1 (0.0)
Central nervous system viral infection	0	1 (0.0)
Cervicitis human papilloma virus	2 (0.0)	2 (0.0)
Chikungunya virus infection	5 (0.0)	3 (0.0)
Chlamydial cervicitis	0	1 (0.0)
Chlamydial infection	9 (0.0)	6 (0.0)
Cholecystitis infective	2 (0.0)	1 (0.0)
Chronic hepatitis C	1 (0.0)	1 (0.0)
Chronic pulmonary histoplasmosis	0	1 (0.0)
Chronic sinusitis	55 (0.3)	66 (0.4)
Chronic tonsillitis	11 (0.1)	7 (0.0)
Clostridial infection	1 (0.0)	0
Clostridium difficile colitis	2 (0.0)	1 (0.0)
Clostridium difficile infection	8 (0.0)	4 (0.0)
Coccidioidomycosis	2 (0.0)	0
Conjunctivitis	3 (0.0)	4 (0.0)
Conjunctivitis viral	1 (0.0)	1 (0.0)
Croup infectious	0	1 (0.0)
Cyclosporidium infection	0	1 (0.0)
Cystitis	7 (0.0)	5 (0.0)
Cytomegalovirus hepatitis	0	1 (0.0)
Cytomegalovirus infection	1 (0.0)	2 (0.0)
Dengue fever	4 (0.0)	7 (0.0)
Dermatophytosis	0	1 (0.0)
Device related infection	2 (0.0)	0
Diverticulitis	90 (0.5)	80 (0.4)
Ear infection	24 (0.1)	27 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Ear infection viral	1 (0.0)	0
Eczema infected	1 (0.0)	0
Eczema vaccinatum	0	1 (0.0)
Empyema	1 (0.0)	1 (0.0)
Encephalitis	3 (0.0)	2 (0.0)
Encephalitis eastern equine	0	1 (0.0)
Encephalomyelitis	1 (0.0)	0
Endocarditis	1 (0.0)	2 (0.0)
Endometritis	0	1 (0.0)
Epididymitis	2 (0.0)	1 (0.0)
Epiglottitis	0	1 (0.0)
Epstein-Barr virus infection	0	1 (0.0)
Erysipelas	0	2 (0.0)
Escherichia bacteraemia	0	1 (0.0)
Escherichia infection	1 (0.0)	1 (0.0)
Escherichia sepsis	0	1 (0.0)
Extradural abscess	0	1 (0.0)
Eye infection toxoplasmal	0	2 (0.0)
Eyelid infection	1 (0.0)	1 (0.0)
Folliculitis	4 (0.0)	6 (0.0)
Fracture infection	1 (0.0)	0
Fungal infection	10 (0.1)	2 (0.0)
Fungal skin infection	8 (0.0)	14 (0.1)
Furuncle	1 (0.0)	2 (0.0)
Gangrene	1 (0.0)	0
Gastroenteritis	4 (0.0)	6 (0.0)
Gastroenteritis norovirus	1 (0.0)	0
Gastroenteritis viral	0	1 (0.0)
Gastrointestinal bacterial overgrowth	1 (0.0)	1 (0.0)
Gastrointestinal infection	0	1 (0.0)
Genital herpes	45 (0.2)	43 (0.2)
Genital herpes simplex	16 (0.1)	11 (0.1)
Giardiasis	1 (0.0)	0
Gingivitis	0	2 (0.0)
Gonorrhoea	3 (0.0)	1 (0.0)
Groin abscess	1 (0.0)	0
Groin infection	1 (0.0)	0
HIV infection	11 (0.1)	13 (0.1)
Hand-foot-and-mouth disease	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Helicobacter gastritis	3 (0.0)	1 (0.0)
Helicobacter infection	7 (0.0)	9 (0.0)
Hepatitis A	36 (0.2)	27 (0.1)
Hepatitis B	11 (0.1)	7 (0.0)
Hepatitis C	26 (0.1)	32 (0.2)
Herpes dermatitis	0	2 (0.0)
Herpes ophthalmic	1 (0.0)	3 (0.0)
Herpes simplex	158 (0.8)	133 (0.7)
Herpes simplex meningitis	1 (0.0)	0
Herpes virus infection	18 (0.1)	18 (0.1)
Herpes zoster	95 (0.5)	93 (0.5)
Herpes zoster oticus	1 (0.0)	0
Histoplasmosis	5 (0.0)	0
Hordeolum	2 (0.0)	3 (0.0)
Human ehrlichiosis	0	1 (0.0)
Impetigo	1 (0.0)	2 (0.0)
Infected bite	1 (0.0)	0
Infected cyst	0	1 (0.0)
Infected dermal cyst	1 (0.0)	0
Infection	2 (0.0)	1 (0.0)
Infectious mononucleosis	9 (0.0)	6 (0.0)
Infective tenosynovitis	1 (0.0)	0
Influenza	4 (0.0)	5 (0.0)
Joint abscess	0	2 (0.0)
Kidney infection	3 (0.0)	9 (0.0)
Labyrinthitis	9 (0.0)	7 (0.0)
Large intestine infection	0	2 (0.0)
Laryngitis	3 (0.0)	0
Latent tuberculosis	7 (0.0)	5 (0.0)
Liver abscess	0	1 (0.0)
Localised infection	5 (0.0)	3 (0.0)
Ludwig angina	1 (0.0)	0
Lung abscess	1 (0.0)	0
Lyme disease	8 (0.0)	19 (0.1)
Lymph gland infection	0	1 (0.0)
Lymph node abscess	1 (0.0)	0
Malaria	2 (0.0)	2 (0.0)
Mastitis	0	4 (0.0)
Mastoiditis	0	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Measles	0	1 (0.0)
Mediastinitis	1 (0.0)	0
Meningitis	7 (0.0)	4 (0.0)
Meningitis viral	4 (0.0)	3 (0.0)
Mycobacterium avium complex infection	1 (0.0)	1 (0.0)
Myiasis	0	1 (0.0)
Myocarditis infectious	0	1 (0.0)
Myringitis	1 (0.0)	0
Nasopharyngitis	2 (0.0)	2 (0.0)
Nocardiosis	1 (0.0)	0
Oesophageal candidiasis	1 (0.0)	0
Oesophagitis bacterial	1 (0.0)	0
Onychomycosis	53 (0.3)	61 (0.3)
Ophthalmic herpes simplex	0	2 (0.0)
Ophthalmic herpes zoster	1 (0.0)	3 (0.0)
Oral candidiasis	1 (0.0)	1 (0.0)
Oral herpes	81 (0.4)	103 (0.5)
Oral infection	1 (0.0)	0
Orchitis	0	1 (0.0)
Osteomyelitis	10 (0.1)	10 (0.1)
Otitis externa	1 (0.0)	3 (0.0)
Otitis media	7 (0.0)	11 (0.1)
Otitis media acute	1 (0.0)	1 (0.0)
Otitis media chronic	5 (0.0)	3 (0.0)
Otosalpingitis	1 (0.0)	0
Overgrowth bacterial	0	1 (0.0)
Papilloma viral infection	10 (0.1)	6 (0.0)
Parasite allergy	1 (0.0)	0
Paronychia	0	3 (0.0)
Parotitis	0	1 (0.0)
Pelvic infection	0	1 (0.0)
Pelvic inflammatory disease	3 (0.0)	2 (0.0)
Periodontal destruction	1 (0.0)	0
Periodontitis	2 (0.0)	1 (0.0)
Perirectal abscess	0	2 (0.0)
Peritonitis	6 (0.0)	5 (0.0)
Peritonsillar abscess	2 (0.0)	1 (0.0)
Pertussis	1 (0.0)	3 (0.0)
Pharyngitis	4 (0.0)	3 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Pharyngitis streptococcal	19 (0.1)	15 (0.1)
Pharyngotonsillitis	0	2 (0.0)
Pilonidal cyst	13 (0.1)	15 (0.1)
Plasmodium falciparum infection	1 (0.0)	0
Pleurisy viral	0	1 (0.0)
Pneumocystis jirovecii pneumonia	0	1 (0.0)
Pneumonia	83 (0.4)	72 (0.4)
Pneumonia adenoviral	0	1 (0.0)
Pneumonia bacterial	2 (0.0)	1 (0.0)
Pneumonia legionella	0	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0
Pneumonia viral	0	1 (0.0)
Poliomyelitis	7 (0.0)	10 (0.1)
Post procedural infection	0	1 (0.0)
Post procedural sepsis	0	1 (0.0)
Post treatment Lyme disease syndrome	0	1 (0.0)
Postoperative wound infection	0	1 (0.0)
Presumed ocular histoplasmosis syndrome	0	1 (0.0)
Prostate infection	1 (0.0)	0
Pulmonary mycosis	0	1 (0.0)
Pulmonary sepsis	0	1 (0.0)
Pulmonary tuberculosis	5 (0.0)	3 (0.0)
Pyelonephritis	0	3 (0.0)
Rectal abscess	1 (0.0)	1 (0.0)
Renal abscess	1 (0.0)	0
Renal tuberculosis	0	1 (0.0)
Respiratory syncytial virus infection	0	1 (0.0)
Respiratory tract infection	1 (0.0)	0
Rhinitis	34 (0.2)	33 (0.2)
Rocky mountain spotted fever	2 (0.0)	1 (0.0)
Root canal infection	0	1 (0.0)
Rubella	0	1 (0.0)
Salpingitis	2 (0.0)	1 (0.0)
Scarlet fever	3 (0.0)	3 (0.0)
Scrotal infection	1 (0.0)	0
Sepsis	5 (0.0)	9 (0.0)
Sepsis syndrome	1 (0.0)	0
Septic arthritis staphylococcal	3 (0.0)	0
Septic shock	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Sinusitis	96 (0.5)	83 (0.4)
Sinusitis bacterial	1 (0.0)	0
Sinusitis fungal	2 (0.0)	1 (0.0)
Skin bacterial infection	2 (0.0)	0
Skin candida	0	1 (0.0)
Skin infection	0	3 (0.0)
Soft tissue infection	1 (0.0)	0
Staphylococcal bacteraemia	0	1 (0.0)
Staphylococcal infection	20 (0.1)	14 (0.1)
Staphylococcal skin infection	2 (0.0)	2 (0.0)
Streptococcal infection	7 (0.0)	0
Subacute endocarditis	1 (0.0)	0
Subcutaneous abscess	2 (0.0)	1 (0.0)
Syphilis	8 (0.0)	2 (0.0)
Tinea capitis	1 (0.0)	0
Tinea cruris	2 (0.0)	1 (0.0)
Tinea infection	1 (0.0)	1 (0.0)
Tinea pedis	11 (0.1)	3 (0.0)
Tinea versicolour	14 (0.1)	12 (0.1)
Tonsillitis	440 (2.3)	390 (2.1)
Tonsillitis streptococcal	1 (0.0)	1 (0.0)
Tooth abscess	2 (0.0)	4 (0.0)
Tooth infection	0	4 (0.0)
Toxic shock syndrome	2 (0.0)	2 (0.0)
Trichomoniasis	1 (0.0)	0
Tropical ulcer	0	1 (0.0)
Tuberculosis	13 (0.1)	8 (0.0)
Tuberculous pleurisy	1 (0.0)	2 (0.0)
Tubo-ovarian abscess	0	1 (0.0)
Typhoid fever	0	1 (0.0)
Typhus	1 (0.0)	1 (0.0)
Upper respiratory tract infection	7 (0.0)	9 (0.0)
Urethritis	0	2 (0.0)
Urinary tract infection	108 (0.6)	98 (0.5)
Urinary tract infection bacterial	1 (0.0)	1 (0.0)
Urosepsis	1 (0.0)	1 (0.0)
Uterine infection	2 (0.0)	0
Vaginal infection	4 (0.0)	4 (0.0)
Vaginitis chlamydial	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Vaginitis gardnerella	1 (0.0)	0
Varicella	11 (0.1)	7 (0.0)
Varicella zoster virus infection	1 (0.0)	0
Vestibular neuronitis	0	2 (0.0)
Viral cardiomyopathy	0	1 (0.0)
Viral infection	1 (0.0)	0
Viral myocarditis	0	1 (0.0)
Vulval abscess	1 (0.0)	0
Vulvovaginal candidiasis	1 (0.0)	4 (0.0)
Vulvovaginal mycotic infection	3 (0.0)	4 (0.0)
West Nile viral infection	0	1 (0.0)
Injury, poisoning and procedural complications	1381 (7.3)	1375 (7.3)
Abdominal injury	2 (0.0)	1 (0.0)
Accident	4 (0.0)	2 (0.0)
Accident at work	0	1 (0.0)
Acetabulum fracture	1 (0.0)	1 (0.0)
Alcohol poisoning	0	1 (0.0)
Anaemia postoperative	0	1 (0.0)
Animal bite	3 (0.0)	1 (0.0)
Ankle fracture	108 (0.6)	90 (0.5)
Arterial injury	1 (0.0)	2 (0.0)
Arthropod bite	8 (0.0)	4 (0.0)
Arthropod sting	2 (0.0)	1 (0.0)
Avulsion fracture	0	1 (0.0)
Back injury	21 (0.1)	13 (0.1)
Bite	1 (0.0)	0
Bladder injury	1 (0.0)	1 (0.0)
Blindness traumatic	1 (0.0)	1 (0.0)
Brachial plexus injury	1 (0.0)	0
Burns second degree	2 (0.0)	0
Burns third degree	1 (0.0)	3 (0.0)
Bursa injury	0	1 (0.0)
Cardiac valve rupture	1 (0.0)	0
Cartilage injury	42 (0.2)	35 (0.2)
Cataract traumatic	0	1 (0.0)
Cervical vertebral fracture	16 (0.1)	9 (0.0)
Chemical poisoning	0	1 (0.0)
Chest injury	1 (0.0)	1 (0.0)
Clavicle fracture	22 (0.1)	38 (0.2)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Colon injury	0	1 (0.0)
Compression fracture	1 (0.0)	1 (0.0)
Concussion	19 (0.1)	11 (0.1)
Contusion	4 (0.0)	3 (0.0)
Corneal abrasion	0	1 (0.0)
Craniocerebral injury	10 (0.1)	6 (0.0)
Craniofacial fracture	0	1 (0.0)
Deafness traumatic	0	2 (0.0)
Decompression sickness	1 (0.0)	0
Dislocation of vertebra	2 (0.0)	0
Donor site complication	0	1 (0.0)
Epicondylitis	16 (0.1)	11 (0.1)
Exposure to communicable disease	1 (0.0)	2 (0.0)
Exposure to radiation	1 (0.0)	0
Eye injury	1 (0.0)	7 (0.0)
Eyelid contusion	1 (0.0)	0
Face injury	2 (0.0)	2 (0.0)
Facial bones fracture	36 (0.2)	43 (0.2)
Fall	14 (0.1)	10 (0.1)
Fascial rupture	2 (0.0)	0
Femoral neck fracture	0	2 (0.0)
Femur fracture	34 (0.2)	23 (0.1)
Fibula fracture	16 (0.1)	15 (0.1)
Flail chest	0	1 (0.0)
Foot fracture	64 (0.3)	57 (0.3)
Forearm fracture	11 (0.1)	8 (0.0)
Foreign body	3 (0.0)	1 (0.0)
Foreign body in ear	0	1 (0.0)
Foreign body in eye	0	2 (0.0)
Foreign body in gastrointestinal tract	1 (0.0)	0
Fracture	4 (0.0)	3 (0.0)
Fractured coccyx	1 (0.0)	3 (0.0)
Gastrointestinal injury	0	1 (0.0)
Gastrointestinal procedural complication	0	1 (0.0)
Glaucoma traumatic	1 (0.0)	0
Gun shot wound	9 (0.0)	13 (0.1)
Hand fracture	65 (0.3)	61 (0.3)
Head injury	11 (0.1)	23 (0.1)
Hepatic rupture	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Hip fracture	18 (0.1)	19 (0.1)
Humerus fracture	16 (0.1)	15 (0.1)
Iatrogenic injury	1 (0.0)	0
Iliotibial band syndrome	0	8 (0.0)
Ilium fracture	0	1 (0.0)
Incisional hernia	7 (0.0)	9 (0.0)
Injury	1 (0.0)	3 (0.0)
Injury corneal	0	2 (0.0)
Intentional overdose	0	1 (0.0)
Intentional product misuse	0	1 (0.0)
Intervertebral disc injury	4 (0.0)	0
Iris injury	0	1 (0.0)
Jaw fracture	12 (0.1)	9 (0.0)
Joint dislocation	43 (0.2)	41 (0.2)
Joint injury	48 (0.3)	57 (0.3)
Kidney rupture	0	1 (0.0)
Lacrimal structure injury	1 (0.0)	0
Laryngeal injury	0	1 (0.0)
Ligament injury	13 (0.1)	11 (0.1)
Ligament rupture	135 (0.7)	111 (0.6)
Ligament sprain	13 (0.1)	16 (0.1)
Limb crushing injury	2 (0.0)	2 (0.0)
Limb fracture	2 (0.0)	1 (0.0)
Limb injury	52 (0.3)	53 (0.3)
Limb traumatic amputation	3 (0.0)	3 (0.0)
Lisfranc fracture	1 (0.0)	0
Lower limb fracture	49 (0.3)	47 (0.2)
Lumbar vertebral fracture	11 (0.1)	7 (0.0)
Mallet finger	1 (0.0)	1 (0.0)
Maternal drugs affecting foetus	1 (0.0)	0
Meniscus injury	189 (1.0)	193 (1.0)
Multiple fractures	0	3 (0.0)
Muscle injury	4 (0.0)	7 (0.0)
Muscle rupture	24 (0.1)	15 (0.1)
Muscle strain	16 (0.1)	13 (0.1)
Nail injury	0	1 (0.0)
Nasal injury	2 (0.0)	5 (0.0)
Neck injury	8 (0.0)	8 (0.0)
Nerve injury	10 (0.1)	13 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Nerve root injury lumbar	0	1 (0.0)
Neurological procedural complication	0	1 (0.0)
Oesophageal injury	1 (0.0)	0
Optic nerve injury	1 (0.0)	0
Overdose	2 (0.0)	0
Pancreatic injury	1 (0.0)	0
Paranasal sinus injury	0	1 (0.0)
Patella fracture	12 (0.1)	5 (0.0)
Pelvic fracture	8 (0.0)	7 (0.0)
Penetrating abdominal trauma	1 (0.0)	0
Penis injury	0	1 (0.0)
Periorbital haematoma	1 (0.0)	0
Periorbital haemorrhage	1 (0.0)	0
Peripheral nerve injury	2 (0.0)	7 (0.0)
Persistent corneal epithelial defect	0	1 (0.0)
Pneumothorax traumatic	1 (0.0)	0
Post concussion syndrome	1 (0.0)	3 (0.0)
Post procedural complication	1 (0.0)	2 (0.0)
Post procedural diarrhoea	1 (0.0)	2 (0.0)
Post procedural haemorrhage	1 (0.0)	0
Post procedural hypothyroidism	9 (0.0)	9 (0.0)
Post procedural pulmonary embolism	0	1 (0.0)
Post-traumatic neck syndrome	2 (0.0)	1 (0.0)
Post-traumatic pain	1 (0.0)	0
Postoperative adhesion	1 (0.0)	0
Postoperative thrombosis	2 (0.0)	0
Procedural intestinal perforation	1 (0.0)	0
Procedural pain	4 (0.0)	3 (0.0)
Procedural pneumothorax	1 (0.0)	0
Radiation proctitis	0	1 (0.0)
Radius fracture	10 (0.1)	14 (0.1)
Repetitive strain injury	3 (0.0)	0
Respiratory fume inhalation disorder	0	2 (0.0)
Retinal injury	0	1 (0.0)
Rib fracture	17 (0.1)	23 (0.1)
Road traffic accident	27 (0.1)	37 (0.2)
Scapula fracture	0	4 (0.0)
Scar	46 (0.2)	47 (0.2)
Sciatic nerve injury	2 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Scrotal injury	1 (0.0)	0
Seroma	0	1 (0.0)
Silicosis	1 (0.0)	1 (0.0)
Sinus barotrauma	0	1 (0.0)
Skeletal injury	8 (0.0)	9 (0.0)
Skin abrasion	3 (0.0)	1 (0.0)
Skin injury	0	2 (0.0)
Skin laceration	11 (0.1)	15 (0.1)
Skull fracture	3 (0.0)	5 (0.0)
Skull fractured base	2 (0.0)	1 (0.0)
Snake bite	3 (0.0)	1 (0.0)
Soft tissue injury	1 (0.0)	0
Spinal column injury	8 (0.0)	3 (0.0)
Spinal compression fracture	8 (0.0)	12 (0.1)
Spinal cord injury	3 (0.0)	2 (0.0)
Spinal cord injury cervical	2 (0.0)	0
Spinal fracture	9 (0.0)	12 (0.1)
Splenic injury	1 (0.0)	2 (0.0)
Splenic rupture	4 (0.0)	5 (0.0)
Sports injury	4 (0.0)	2 (0.0)
Stab wound	4 (0.0)	1 (0.0)
Sternal fracture	2 (0.0)	1 (0.0)
Stress fracture	5 (0.0)	5 (0.0)
Subarachnoid haematoma	1 (0.0)	0
Subdural haematoma	4 (0.0)	5 (0.0)
Subdural haemorrhage	0	1 (0.0)
Superficial injury of eye	0	1 (0.0)
Suture related complication	1 (0.0)	0
Suture rupture	1 (0.0)	0
Tendon dislocation	1 (0.0)	0
Tendon injury	13 (0.1)	9 (0.0)
Tendon rupture	61 (0.3)	67 (0.4)
Testicular injury	0	1 (0.0)
Thermal burn	3 (0.0)	2 (0.0)
Thermal burns of eye	1 (0.0)	1 (0.0)
Thoracic vertebral fracture	1 (0.0)	4 (0.0)
Tibia fracture	33 (0.2)	24 (0.1)
Tooth fracture	2 (0.0)	0
Tooth injury	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Traumatic arthritis	2 (0.0)	1 (0.0)
Traumatic ear amputation	1 (0.0)	0
Traumatic haematoma	1 (0.0)	1 (0.0)
Traumatic liver injury	0	1 (0.0)
Traumatic lung injury	0	6 (0.0)
Traumatic renal injury	2 (0.0)	1 (0.0)
Ulna fracture	4 (0.0)	10 (0.1)
Ulnar nerve injury	0	3 (0.0)
Upper limb fracture	74 (0.4)	77 (0.4)
Ureteric injury	1 (0.0)	0
Urethral stricture traumatic	0	1 (0.0)
Uterine perforation	1 (0.0)	0
Uterine rupture	1 (0.0)	0
Vascular pseudoaneurysm	2 (0.0)	2 (0.0)
Venomous sting	0	1 (0.0)
Vth nerve injury	1 (0.0)	1 (0.0)
Wound	1 (0.0)	1 (0.0)
Wrist fracture	68 (0.4)	78 (0.4)
Investigations	1460 (7.7)	1459 (7.7)
Alanine aminotransferase increased	2 (0.0)	1 (0.0)
Androgens abnormal	0	1 (0.0)
Angiocardiogram	3 (0.0)	7 (0.0)
Angiogram	1 (0.0)	2 (0.0)
Angiogram peripheral	0	1 (0.0)
Anti-platelet antibody positive	1 (0.0)	0
Anti-thyroid antibody positive	1 (0.0)	0
Anticoagulation drug level	1 (0.0)	0
Antinuclear antibody positive	0	1 (0.0)
Aortic bruit	0	1 (0.0)
Apnoea test	0	1 (0.0)
Apolipoprotein E	1 (0.0)	0
Arteriogram	1 (0.0)	0
Arthroscopy	117 (0.6)	123 (0.7)
Aspartate aminotransferase increased	1 (0.0)	0
Aspiration bone marrow	1 (0.0)	0
Aspiration breast	1 (0.0)	0
Aspiration bursa	0	1 (0.0)
Aspiration joint	0	1 (0.0)
Aspiration pleural cavity	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Bacterial test positive	0	1 (0.0)
Biopsy	5 (0.0)	6 (0.0)
Biopsy bone	1 (0.0)	0
Biopsy bone marrow	0	1 (0.0)
Biopsy breast	30 (0.2)	24 (0.1)
Biopsy breast normal	14 (0.1)	10 (0.1)
Biopsy cervix	3 (0.0)	6 (0.0)
Biopsy cervix abnormal	1 (0.0)	0
Biopsy cervix normal	2 (0.0)	0
Biopsy colon	4 (0.0)	5 (0.0)
Biopsy colon normal	1 (0.0)	0
Biopsy endometrium normal	1 (0.0)	1 (0.0)
Biopsy larynx normal	1 (0.0)	0
Biopsy liver	2 (0.0)	2 (0.0)
Biopsy liver normal	1 (0.0)	1 (0.0)
Biopsy lung	1 (0.0)	4 (0.0)
Biopsy lymph gland	2 (0.0)	3 (0.0)
Biopsy lymph gland normal	1 (0.0)	0
Biopsy pharynx normal	1 (0.0)	0
Biopsy prostate	8 (0.0)	8 (0.0)
Biopsy prostate normal	1 (0.0)	3 (0.0)
Biopsy salivary gland	0	1 (0.0)
Biopsy site unspecified normal	1 (0.0)	0
Biopsy skin	3 (0.0)	8 (0.0)
Biopsy skin normal	0	1 (0.0)
Biopsy small intestine normal	0	1 (0.0)
Biopsy soft tissue	0	1 (0.0)
Biopsy testes	0	1 (0.0)
Biopsy thyroid gland	2 (0.0)	2 (0.0)
Biopsy uterus	1 (0.0)	0
Biopsy vulva	0	1 (0.0)
Blood bilirubin increased	1 (0.0)	2 (0.0)
Blood calcium abnormal	0	1 (0.0)
Blood calcium decreased	2 (0.0)	0
Blood calcium increased	1 (0.0)	2 (0.0)
Blood cholesterol	4 (0.0)	4 (0.0)
Blood cholesterol increased	611 (3.2)	608 (3.2)
Blood cholinesterase decreased	0	1 (0.0)
Blood chromium increased	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Blood cobalt increased	1 (0.0)	0
Blood creatinine abnormal	1 (0.0)	0
Blood glucose	1 (0.0)	0
Blood glucose abnormal	3 (0.0)	0
Blood glucose increased	8 (0.0)	8 (0.0)
Blood iron decreased	1 (0.0)	2 (0.0)
Blood magnesium decreased	0	1 (0.0)
Blood oestrogen	0	1 (0.0)
Blood oestrogen decreased	2 (0.0)	2 (0.0)
Blood oestrogen increased	2 (0.0)	0
Blood parathyroid hormone abnormal	0	1 (0.0)
Blood potassium decreased	6 (0.0)	7 (0.0)
Blood pressure diastolic increased	0	1 (0.0)
Blood pressure increased	14 (0.1)	15 (0.1)
Blood pressure measurement	1 (0.0)	1 (0.0)
Blood prolactin increased	1 (0.0)	1 (0.0)
Blood testosterone	0	1 (0.0)
Blood testosterone decreased	111 (0.6)	122 (0.6)
Blood testosterone increased	1 (0.0)	0
Blood thyroid stimulating hormone abnormal	1 (0.0)	0
Blood thyroid stimulating hormone decreased	1 (0.0)	1 (0.0)
Blood triglycerides	1 (0.0)	0
Blood triglycerides increased	43 (0.2)	38 (0.2)
Blood uric acid increased	2 (0.0)	5 (0.0)
Blood urine present	1 (0.0)	0
Body mass index decreased	0	1 (0.0)
Bone density abnormal	1 (0.0)	0
Bone density decreased	1 (0.0)	0
Bronchoscopy	2 (0.0)	1 (0.0)
Bronchoscopy abnormal	1 (0.0)	0
C-reactive protein increased	1 (0.0)	2 (0.0)
Carbon dioxide increased	0	1 (0.0)
Cardiac murmur	96 (0.5)	110 (0.6)
Cardiac murmur functional	2 (0.0)	1 (0.0)
Cardiac stress test	0	2 (0.0)
Cardiac stress test abnormal	0	1 (0.0)
Carotid bruit	0	3 (0.0)
Catheterisation cardiac	25 (0.1)	25 (0.1)
Chlamydia test positive	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Coagulation factor V level	1 (0.0)	2 (0.0)
Colonoscopy	120 (0.6)	103 (0.5)
Colonoscopy abnormal	0	1 (0.0)
Colonoscopy normal	3 (0.0)	1 (0.0)
Colposcopy	4 (0.0)	2 (0.0)
Colposcopy normal	0	1 (0.0)
Computerised tomogram coronary artery	1 (0.0)	0
Continuous glucose monitoring	0	2 (0.0)
Cortisol increased	0	1 (0.0)
Cystoscopy	6 (0.0)	4 (0.0)
Cytology abnormal	1 (0.0)	0
Dehydroepiandrosterone increased	1 (0.0)	0
Diagnostic procedure	3 (0.0)	0
Discogram	1 (0.0)	0
Echocardiogram	2 (0.0)	1 (0.0)
Ejection fraction decreased	1 (0.0)	1 (0.0)
Electrocardiogram PR shortened	1 (0.0)	0
Electrocardiogram QT prolonged	2 (0.0)	1 (0.0)
Electrocardiogram ST segment abnormal	0	1 (0.0)
Electrocardiogram ST segment depression	1 (0.0)	0
Electrocardiogram T wave inversion	2 (0.0)	0
Electrocardiogram abnormal	2 (0.0)	4 (0.0)
Endoscopic retrograde cholangiopancreatography	1 (0.0)	1 (0.0)
Endoscopy	13 (0.1)	9 (0.0)
Endoscopy gastrointestinal	0	1 (0.0)
Endoscopy upper gastrointestinal tract	8 (0.0)	7 (0.0)
Eosinophil count increased	1 (0.0)	0
Epinephrine	0	1 (0.0)
Epstein-Barr virus test positive	0	1 (0.0)
False positive investigation result	1 (0.0)	1 (0.0)
Full blood count	0	1 (0.0)
Gastrointestinal tract biopsy	0	1 (0.0)
Gene mutation identification test positive	1 (0.0)	1 (0.0)
Glomerular filtration rate	1 (0.0)	0
Glomerular filtration rate decreased	2 (0.0)	0
Glycosylated haemoglobin	0	1 (0.0)
Glycosylated haemoglobin increased	3 (0.0)	1 (0.0)
HIV test positive	47 (0.2)	47 (0.2)
HLA marker study	0	3 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Haemoglobin decreased	0	1 (0.0)
Haemoglobin increased	1 (0.0)	0
Heart rate decreased	3 (0.0)	1 (0.0)
Heart rate increased	1 (0.0)	4 (0.0)
Heart rate irregular	25 (0.1)	39 (0.2)
Helicobacter test positive	2 (0.0)	0
Hepatic enzyme abnormal	1 (0.0)	0
Hepatic enzyme increased	12 (0.1)	4 (0.0)
Hepatitis A antibody positive	1 (0.0)	0
Hepatitis B antibody positive	1 (0.0)	0
Hepatitis B surface antibody positive	1 (0.0)	1 (0.0)
Hepatitis B test negative	0	1 (0.0)
Hepatitis C antibody positive	2 (0.0)	0
Hepatitis C core antibody negative	0	1 (0.0)
Hepatitis C test negative	0	1 (0.0)
High density lipoprotein decreased	6 (0.0)	4 (0.0)
Hormone level abnormal	6 (0.0)	4 (0.0)
Human papilloma virus test	0	1 (0.0)
Human papilloma virus test positive	27 (0.1)	23 (0.1)
Hysteroscopy	7 (0.0)	5 (0.0)
Intraocular pressure decreased	0	1 (0.0)
Intraocular pressure increased	4 (0.0)	8 (0.0)
Intraocular pressure test	1 (0.0)	0
Investigation	1 (0.0)	0
Laparoscopy	23 (0.1)	17 (0.1)
Lipids	0	1 (0.0)
Lipids increased	8 (0.0)	5 (0.0)
Lipoprotein (a) abnormal	1 (0.0)	0
Lipoprotein (a) increased	0	2 (0.0)
Liver function test abnormal	1 (0.0)	1 (0.0)
Liver function test increased	8 (0.0)	5 (0.0)
Low density lipoprotein increased	2 (0.0)	7 (0.0)
Lumbar puncture	0	1 (0.0)
Lumbar puncture normal	1 (0.0)	0
Magnetic resonance imaging joint	0	1 (0.0)
Mammogram	1 (0.0)	2 (0.0)
Mammogram abnormal	5 (0.0)	1 (0.0)
Mean cell volume increased	0	1 (0.0)
Medical observation	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Metabolic function test	0	1 (0.0)
Mumps antibody test positive	1 (0.0)	0
Mycobacterium tuberculosis complex test negative	1 (0.0)	0
Mycobacterium tuberculosis complex test positive	3 (0.0)	1 (0.0)
Nasoendoscopy	2 (0.0)	0
Occult blood positive	0	1 (0.0)
Oesophageal manometry	0	1 (0.0)
Oesophageal pH	0	1 (0.0)
Oesophagogastroduodenoscopy	6 (0.0)	4 (0.0)
Oesophagoscopy	1 (0.0)	0
Oestradiol decreased	1 (0.0)	0
Oestrogen receptor assay negative	0	1 (0.0)
Pelvic laparoscopy	4 (0.0)	1 (0.0)
Plasminogen activator inhibitor increased	0	1 (0.0)
Platelet count decreased	0	2 (0.0)
Precancerous cells present	8 (0.0)	12 (0.1)
Proctoscopy	0	1 (0.0)
Progesterone decreased	1 (0.0)	5 (0.0)
Prostatic specific antigen increased	16 (0.1)	20 (0.1)
Pulmonary function test decreased	0	2 (0.0)
Red blood cell count increased	0	1 (0.0)
Rheumatoid factor	1 (0.0)	0
Scan myocardial perfusion	0	1 (0.0)
Seroconversion test positive	0	1 (0.0)
Serum ferritin decreased	0	1 (0.0)
Serum ferritin increased	0	1 (0.0)
Sigmoidoscopy	1 (0.0)	0
Sleep study	1 (0.0)	0
Smear cervix abnormal	19 (0.1)	13 (0.1)
Smooth muscle antibody	1 (0.0)	0
Staphylococcus test positive	0	1 (0.0)
Stool analysis abnormal	1 (0.0)	0
Thyroid function test normal	0	1 (0.0)
Total bile acids increased	0	1 (0.0)
Transaminases increased	3 (0.0)	1 (0.0)
Tuberculin test	0	1 (0.0)
Tuberculin test positive	7 (0.0)	8 (0.0)
Ureteroscopy	2 (0.0)	1 (0.0)
Urogram	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Vitamin B12 decreased	3 (0.0)	0
Vitamin D abnormal	0	1 (0.0)
Vitamin D decreased	8 (0.0)	10 (0.1)
Weight decreased	4 (0.0)	2 (0.0)
Weight increased	4 (0.0)	3 (0.0)
White blood cell count decreased	2 (0.0)	0
White blood cell count increased	2 (0.0)	0
X-ray	1 (0.0)	0
Metabolism and nutrition disorders	5663 (30.0)	5526 (29.3)
Abnormal loss of weight	0	1 (0.0)
Abnormal weight gain	0	1 (0.0)
Acidosis	1 (0.0)	0
Calcium deficiency	1 (0.0)	2 (0.0)
Central obesity	2 (0.0)	0
Cholesterosis	2 (0.0)	0
Dairy intolerance	3 (0.0)	1 (0.0)
Decreased appetite	1 (0.0)	4 (0.0)
Dehydration	3 (0.0)	3 (0.0)
Diabetes mellitus	16 (0.1)	14 (0.1)
Diabetes mellitus inadequate control	1 (0.0)	0
Diabetic complication	1 (0.0)	0
Diabetic dyslipidaemia	1 (0.0)	0
Diabetic ketoacidosis	1 (0.0)	3 (0.0)
Dyslipidaemia	474 (2.5)	441 (2.3)
Electrolyte imbalance	1 (0.0)	0
Fluid retention	20 (0.1)	12 (0.1)
Folate deficiency	0	2 (0.0)
Food intolerance	2 (0.0)	2 (0.0)
Fructose intolerance	1 (0.0)	0
Glucose tolerance impaired	205 (1.1)	204 (1.1)
Gluten sensitivity	21 (0.1)	23 (0.1)
Gout	242 (1.3)	252 (1.3)
Haemochromatosis	11 (0.1)	5 (0.0)
Histamine intolerance	0	1 (0.0)
Hyperamylasaemia	1 (0.0)	0
Hypercalcaemia	10 (0.1)	1 (0.0)
Hypercholesterolaemia	1418 (7.5)	1434 (7.6)
Hyperglycaemia	19 (0.1)	20 (0.1)
Hyperhomocysteinaemia	3 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Hyperinsulinaemia	0	1 (0.0)
Hyperinsulinism	1 (0.0)	0
Hyperkalaemia	3 (0.0)	1 (0.0)
Hyperlactacidaemia	0	1 (0.0)
Hyperlipidaemia	1344 (7.1)	1301 (6.9)
Hypernatraemia	1 (0.0)	0
Hyperphagia	1 (0.0)	0
Hypertriglyceridaemia	78 (0.4)	74 (0.4)
Hyperuricaemia	15 (0.1)	23 (0.1)
Hypocalcaemia	1 (0.0)	1 (0.0)
Hypocholesterolaemia	7 (0.0)	5 (0.0)
Hypoglycaemia	9 (0.0)	7 (0.0)
Hypokalaemia	30 (0.2)	25 (0.1)
Hypolipidaemia	1 (0.0)	4 (0.0)
Hypomagnesaemia	0	4 (0.0)
Hypometabolism	0	1 (0.0)
Hyponatraemia	5 (0.0)	2 (0.0)
Hypophosphataemia	2 (0.0)	0
Hypovitaminosis	1 (0.0)	3 (0.0)
Impaired fasting glucose	29 (0.2)	17 (0.1)
Insulin resistance	11 (0.1)	15 (0.1)
Insulin-requiring type 2 diabetes mellitus	0	2 (0.0)
Iron deficiency	20 (0.1)	33 (0.2)
Iron metabolism disorder	1 (0.0)	0
Ketoacidosis	1 (0.0)	1 (0.0)
Lactose intolerance	58 (0.3)	63 (0.3)
Latent autoimmune diabetes in adults	1 (0.0)	0
Lipoedema	1 (0.0)	1 (0.0)
Lipomatosis	0	1 (0.0)
Lipoprotein deficiency	0	1 (0.0)
Magnesium deficiency	2 (0.0)	1 (0.0)
Malnutrition	2 (0.0)	0
Metabolic acidosis	1 (0.0)	0
Metabolic disorder	1 (0.0)	0
Metabolic syndrome	19 (0.1)	6 (0.0)
Monogenic diabetes	0	1 (0.0)
Obesity	1333 (7.1)	1354 (7.2)
Overweight	291 (1.5)	276 (1.5)
Polydipsia	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Postprandial hypoglycaemia	0	1 (0.0)
Protein intolerance	0	1 (0.0)
Refeeding syndrome	0	1 (0.0)
Type 1 diabetes mellitus	82 (0.4)	78 (0.4)
Type 2 diabetes mellitus	1374 (7.3)	1384 (7.3)
Underweight	2 (0.0)	4 (0.0)
Vitamin A deficiency	1 (0.0)	1 (0.0)
Vitamin B complex deficiency	9 (0.0)	10 (0.1)
Vitamin B12 deficiency	64 (0.3)	65 (0.3)
Vitamin B6 deficiency	0	1 (0.0)
Vitamin D deficiency	366 (1.9)	339 (1.8)
Vitamin K deficiency	0	1 (0.0)
Musculoskeletal and connective tissue disorders	3822 (20.3)	3716 (19.7)
Ankle impingement	0	1 (0.0)
Ankylosing spondylitis	5 (0.0)	7 (0.0)
Arthralgia	374 (2.0)	388 (2.1)
Arthritis	207 (1.1)	202 (1.1)
Arthritis reactive	1 (0.0)	0
Arthropathy	13 (0.1)	8 (0.0)
Articular calcification	2 (0.0)	3 (0.0)
Back disorder	3 (0.0)	2 (0.0)
Back pain	736 (3.9)	732 (3.9)
Blount's disease	0	1 (0.0)
Bone cyst	5 (0.0)	5 (0.0)
Bone deformity	0	2 (0.0)
Bone disorder	0	1 (0.0)
Bone erosion	0	1 (0.0)
Bone hypertrophy	1 (0.0)	1 (0.0)
Bone lesion	1 (0.0)	1 (0.0)
Bone loss	0	1 (0.0)
Bone pain	1 (0.0)	1 (0.0)
Bursa disorder	1 (0.0)	0
Bursitis	27 (0.1)	45 (0.2)
CREST syndrome	1 (0.0)	1 (0.0)
Cervical spinal stenosis	9 (0.0)	7 (0.0)
Chondromalacia	4 (0.0)	1 (0.0)
Chondropathy	4 (0.0)	7 (0.0)
Coccydynia	2 (0.0)	0
Compartment syndrome	5 (0.0)	5 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Connective tissue disorder	0	1 (0.0)
Costochondritis	3 (0.0)	4 (0.0)
Degenerative bone disease	0	1 (0.0)
Diastasis recti abdominis	4 (0.0)	1 (0.0)
Diffuse idiopathic skeletal hyperostosis	1 (0.0)	0
Dupuytren's contracture	13 (0.1)	20 (0.1)
Dwarfism	1 (0.0)	0
Eagle's syndrome	1 (0.0)	0
Enthesopathy	2 (0.0)	1 (0.0)
Epiphysiolysis	1 (0.0)	0
Exostosis	44 (0.2)	48 (0.3)
Exostosis of jaw	0	1 (0.0)
Extremity contracture	1 (0.0)	0
Facet joint syndrome	4 (0.0)	2 (0.0)
Femoroacetabular impingement	2 (0.0)	2 (0.0)
Fibromyalgia	147 (0.8)	103 (0.5)
Finger deformity	1 (0.0)	1 (0.0)
Fistula	2 (0.0)	1 (0.0)
Floating patella	1 (0.0)	2 (0.0)
Foot deformity	95 (0.5)	93 (0.5)
Fracture nonunion	0	1 (0.0)
Gouty arthritis	1 (0.0)	3 (0.0)
Growth retardation	0	1 (0.0)
Hypermobility syndrome	3 (0.0)	3 (0.0)
Inclusion body myositis	1 (0.0)	1 (0.0)
Intervertebral disc compression	7 (0.0)	10 (0.1)
Intervertebral disc degeneration	151 (0.8)	115 (0.6)
Intervertebral disc disorder	5 (0.0)	12 (0.1)
Intervertebral disc displacement	2 (0.0)	2 (0.0)
Intervertebral disc protrusion	249 (1.3)	225 (1.2)
Jaw cyst	1 (0.0)	1 (0.0)
Jaw disorder	2 (0.0)	4 (0.0)
Joint contracture	1 (0.0)	0
Joint effusion	1 (0.0)	1 (0.0)
Joint instability	3 (0.0)	2 (0.0)
Joint range of motion decreased	2 (0.0)	5 (0.0)
Joint stiffness	2 (0.0)	1 (0.0)
Joint swelling	7 (0.0)	5 (0.0)
Juvenile idiopathic arthritis	2 (0.0)	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Knee deformity	0	1 (0.0)
Kyphosis	9 (0.0)	4 (0.0)
Ligament calcification	1 (0.0)	0
Ligament disorder	1 (0.0)	1 (0.0)
Ligament laxity	1 (0.0)	1 (0.0)
Limb asymmetry	2 (0.0)	1 (0.0)
Limb deformity	1 (0.0)	1 (0.0)
Limb mass	2 (0.0)	1 (0.0)
Loose body in joint	0	2 (0.0)
Lordosis	0	1 (0.0)
Lumbar spinal stenosis	18 (0.1)	21 (0.1)
Metatarsalgia	2 (0.0)	1 (0.0)
Mixed connective tissue disease	2 (0.0)	0
Mobility decreased	0	1 (0.0)
Morphoea	0	1 (0.0)
Muscle atrophy	1 (0.0)	1 (0.0)
Muscle contracture	0	1 (0.0)
Muscle disorder	0	1 (0.0)
Muscle fatigue	0	1 (0.0)
Muscle spasms	115 (0.6)	128 (0.7)
Muscle tightness	2 (0.0)	1 (0.0)
Muscle twitching	2 (0.0)	2 (0.0)
Muscular weakness	6 (0.0)	5 (0.0)
Musculoskeletal chest pain	3 (0.0)	3 (0.0)
Musculoskeletal disorder	1 (0.0)	0
Musculoskeletal pain	3 (0.0)	2 (0.0)
Musculoskeletal stiffness	4 (0.0)	2 (0.0)
Myalgia	90 (0.5)	103 (0.5)
Myalgia intercostal	0	1 (0.0)
Myofascial pain syndrome	2 (0.0)	4 (0.0)
Myopathy	1 (0.0)	1 (0.0)
Myositis	1 (0.0)	0
Neck mass	1 (0.0)	2 (0.0)
Neck pain	90 (0.5)	88 (0.5)
Neuropathic arthropathy	1 (0.0)	0
Osteitis	2 (0.0)	0
Osteitis deformans	0	2 (0.0)
Osteoarthritis	1365 (7.2)	1372 (7.3)
Osteochondritis	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Osteochondrosis	6 (0.0)	4 (0.0)
Osteolysis	0	1 (0.0)
Osteomalacia	1 (0.0)	0
Osteonecrosis	8 (0.0)	9 (0.0)
Osteonecrosis of jaw	0	1 (0.0)
Osteopenia	261 (1.4)	247 (1.3)
Osteoporosis	305 (1.6)	262 (1.4)
Osteoporosis postmenopausal	1 (0.0)	0
Osteosclerosis	0	1 (0.0)
Pain in extremity	58 (0.3)	64 (0.3)
Pain in jaw	2 (0.0)	4 (0.0)
Patellofemoral pain syndrome	5 (0.0)	5 (0.0)
Periarthritis	14 (0.1)	12 (0.1)
Perthes disease	2 (0.0)	0
Plantar fascial fibromatosis	1 (0.0)	4 (0.0)
Plantar fasciitis	43 (0.2)	56 (0.3)
Plica syndrome	0	1 (0.0)
Polyarthritis	12 (0.1)	6 (0.0)
Polymyalgia rheumatica	6 (0.0)	3 (0.0)
Posterior tibial tendon dysfunction	1 (0.0)	1 (0.0)
Prognathism	0	1 (0.0)
Psoriatic arthropathy	4 (0.0)	4 (0.0)
Retrognathia	1 (0.0)	1 (0.0)
Rhabdomyolysis	1 (0.0)	3 (0.0)
Rheumatic disorder	1 (0.0)	0
Rheumatic fever	4 (0.0)	5 (0.0)
Rheumatoid arthritis	33 (0.2)	31 (0.2)
Rickets	1 (0.0)	0
Rotator cuff syndrome	220 (1.2)	153 (0.8)
Sacroiliac joint dysfunction	0	1 (0.0)
Sacroiliitis	3 (0.0)	2 (0.0)
Scapholunate dissociation	0	1 (0.0)
Scleroderma	2 (0.0)	1 (0.0)
Scoliosis	70 (0.4)	66 (0.4)
Senile osteoporosis	0	2 (0.0)
Seronegative arthritis	1 (0.0)	1 (0.0)
Sinus tarsi syndrome	1 (0.0)	0
Sjogren's syndrome	5 (0.0)	4 (0.0)
Soft tissue disorder	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Somatic dysfunction	0	1 (0.0)
Spinal deformity	0	2 (0.0)
Spinal disorder	2 (0.0)	0
Spinal osteoarthritis	165 (0.9)	185 (1.0)
Spinal pain	13 (0.1)	16 (0.1)
Spinal stenosis	54 (0.3)	51 (0.3)
Spinal synovial cyst	0	2 (0.0)
Spondylitis	20 (0.1)	28 (0.1)
Spondyloarthropathy	4 (0.0)	1 (0.0)
Spondylolisthesis	16 (0.1)	12 (0.1)
Spondylolysis	4 (0.0)	0
Symphysiolysis	0	1 (0.0)
Synovial cyst	29 (0.2)	28 (0.1)
Synovitis	1 (0.0)	1 (0.0)
Systemic lupus erythematosus	5 (0.0)	1 (0.0)
Temporomandibular joint syndrome	32 (0.2)	25 (0.1)
Tendon disorder	4 (0.0)	3 (0.0)
Tendon laxity	0	2 (0.0)
Tendon pain	0	1 (0.0)
Tendonitis	49 (0.3)	55 (0.3)
Tenosynovitis	2 (0.0)	4 (0.0)
Tenosynovitis stenosans	9 (0.0)	8 (0.0)
Torticollis	2 (0.0)	3 (0.0)
Trigger finger	46 (0.2)	38 (0.2)
Ulnocarpal abutment syndrome	1 (0.0)	0
Undifferentiated connective tissue disease	0	1 (0.0)
Vertebral foraminal stenosis	1 (0.0)	3 (0.0)
Vertebral osteophyte	3 (0.0)	7 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1636 (8.7)	1635 (8.7)
Abdominal neoplasm	1 (0.0)	0
Acanthoma	0	1 (0.0)
Acinic cell carcinoma of salivary gland	1 (0.0)	0
Acoustic neuroma	9 (0.0)	9 (0.0)
Acrochordon	0	3 (0.0)
Acute lymphocytic leukaemia	1 (0.0)	1 (0.0)
Acute myeloid leukaemia	2 (0.0)	1 (0.0)
Adenocarcinoma	0	1 (0.0)
Adenocarcinoma of appendix	1 (0.0)	0
Adenocarcinoma of colon	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Adenocarcinoma of the cervix	0	1 (0.0)
Adenoid cystic carcinoma	1 (0.0)	1 (0.0)
Adenoma benign	4 (0.0)	5 (0.0)
Adrenal adenoma	2 (0.0)	2 (0.0)
Adrenal neoplasm	0	1 (0.0)
Anal cancer	2 (0.0)	0
Angiofibroma	1 (0.0)	0
Angiomyolipoma	0	1 (0.0)
Anogenital warts	1 (0.0)	2 (0.0)
Appendix cancer	2 (0.0)	3 (0.0)
Astrocytoma	1 (0.0)	0
B-cell lymphoma	1 (0.0)	0
Basal cell carcinoma	256 (1.4)	267 (1.4)
Basosquamous carcinoma	3 (0.0)	2 (0.0)
Basosquamous carcinoma of skin	0	2 (0.0)
Benign bone neoplasm	4 (0.0)	6 (0.0)
Benign breast neoplasm	34 (0.2)	26 (0.1)
Benign cardiac neoplasm	0	1 (0.0)
Benign gastric neoplasm	1 (0.0)	0
Benign gastrointestinal neoplasm	1 (0.0)	2 (0.0)
Benign hydatidiform mole	1 (0.0)	0
Benign joint neoplasm	1 (0.0)	0
Benign lung neoplasm	4 (0.0)	11 (0.1)
Benign mediastinal neoplasm	0	1 (0.0)
Benign muscle neoplasm	2 (0.0)	0
Benign neoplasm	7 (0.0)	8 (0.0)
Benign neoplasm of adrenal gland	0	1 (0.0)
Benign neoplasm of bladder	2 (0.0)	0
Benign neoplasm of cornea	1 (0.0)	0
Benign neoplasm of eye	0	1 (0.0)
Benign neoplasm of eyelid	0	1 (0.0)
Benign neoplasm of prostate	0	1 (0.0)
Benign neoplasm of skin	2 (0.0)	2 (0.0)
Benign neoplasm of spinal cord	0	1 (0.0)
Benign neoplasm of testis	2 (0.0)	2 (0.0)
Benign neoplasm of thymus	1 (0.0)	0
Benign neoplasm of thyroid gland	23 (0.1)	32 (0.2)
Benign ovarian tumour	4 (0.0)	7 (0.0)
Benign pancreatic neoplasm	1 (0.0)	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Benign renal neoplasm	0	1 (0.0)
Benign salivary gland neoplasm	3 (0.0)	0
Benign uterine neoplasm	5 (0.0)	2 (0.0)
Benign vascular neoplasm	0	2 (0.0)
Bladder cancer	19 (0.1)	12 (0.1)
Bladder cancer stage 0, with cancer in situ	1 (0.0)	0
Bladder neoplasm	1 (0.0)	1 (0.0)
Bladder transitional cell carcinoma	0	1 (0.0)
Bone cancer	1 (0.0)	0
Bone neoplasm	2 (0.0)	2 (0.0)
Bowen's disease	0	1 (0.0)
Brain neoplasm	4 (0.0)	1 (0.0)
Brain neoplasm benign	2 (0.0)	8 (0.0)
Brain neoplasm malignant	1 (0.0)	1 (0.0)
Breast cancer	176 (0.9)	173 (0.9)
Breast cancer female	1 (0.0)	0
Breast cancer in situ	3 (0.0)	1 (0.0)
Breast cancer metastatic	1 (0.0)	0
Breast cancer recurrent	1 (0.0)	0
Breast cancer stage I	6 (0.0)	4 (0.0)
Breast cancer stage II	5 (0.0)	0
Breast cancer stage III	1 (0.0)	1 (0.0)
Breast fibroma	4 (0.0)	2 (0.0)
Breast neoplasm	2 (0.0)	3 (0.0)
Bronchial neoplasm	1 (0.0)	0
Cancer in remission	1 (0.0)	0
Carcinoid tumour	1 (0.0)	0
Cervix carcinoma	30 (0.2)	25 (0.1)
Cervix carcinoma stage 0	1 (0.0)	1 (0.0)
Cervix carcinoma stage I	0	1 (0.0)
Cholesteatoma	3 (0.0)	2 (0.0)
Choroid melanoma	1 (0.0)	2 (0.0)
Chromophobe renal cell carcinoma	1 (0.0)	0
Chronic lymphocytic leukaemia	4 (0.0)	4 (0.0)
Chronic myeloid leukaemia	0	1 (0.0)
Clear cell renal cell carcinoma	3 (0.0)	0
Colon adenoma	21 (0.1)	13 (0.1)
Colon cancer	29 (0.2)	23 (0.1)
Colon cancer stage I	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Colon cancer stage II	0	1 (0.0)
Colon cancer stage III	1 (0.0)	0
Colon cancer stage IV	1 (0.0)	0
Colorectal cancer	0	3 (0.0)
Colorectal cancer metastatic	1 (0.0)	0
Cutaneous T-cell lymphoma	1 (0.0)	1 (0.0)
Cutaneous lymphoma	0	1 (0.0)
Dermatofibrosarcoma protuberans	1 (0.0)	0
Desmoid tumour	2 (0.0)	1 (0.0)
Desmoplastic melanoma	0	1 (0.0)
Diffuse large B-cell lymphoma	1 (0.0)	0
Dysplastic naevus	2 (0.0)	2 (0.0)
Ear neoplasm	0	1 (0.0)
Ear neoplasm malignant	0	1 (0.0)
Elastofibroma	1 (0.0)	0
Enchondromatosis	1 (0.0)	2 (0.0)
Endocrine neoplasm malignant	1 (0.0)	0
Endometrial cancer	13 (0.1)	13 (0.1)
Endometrial cancer stage III	1 (0.0)	0
Essential thrombocythaemia	1 (0.0)	1 (0.0)
Ewing's sarcoma	0	1 (0.0)
Extragonadal primary seminoma (pure)	0	2 (0.0)
Eye naevus	1 (0.0)	2 (0.0)
Eyelid haemangioma	1 (0.0)	0
Fallopian tube cancer	1 (0.0)	0
Fibroadenoma of breast	7 (0.0)	8 (0.0)
Fibroma	16 (0.1)	16 (0.1)
Fibrosarcoma	1 (0.0)	0
Fibrous histiocytoma	1 (0.0)	1 (0.0)
Follicle centre lymphoma, follicular grade I, II, III	0	1 (0.0)
Follicular thyroid cancer	0	1 (0.0)
Ganglioneuroblastoma	0	1 (0.0)
Gastric cancer	1 (0.0)	1 (0.0)
Gastric neoplasm	1 (0.0)	0
Gastrinoma	0	1 (0.0)
Gastrointestinal melanoma	1 (0.0)	0
Gastrointestinal stromal tumour	0	1 (0.0)
Gastrointestinal tract adenoma	2 (0.0)	1 (0.0)
Gestational trophoblastic tumour	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Giant cell tumour of tendon sheath	0	1 (0.0)
Glomus tumour	0	1 (0.0)
Haemangioma	1 (0.0)	5 (0.0)
Haemangioma of liver	2 (0.0)	1 (0.0)
Haemangioma of skin	2 (0.0)	0
Haemangioma of spleen	1 (0.0)	0
Hair follicle tumour benign	1 (0.0)	0
Hairy cell leukaemia	0	1 (0.0)
Hepatic adenoma	0	1 (0.0)
Hepatic cancer	1 (0.0)	0
Hodgkin's disease	7 (0.0)	7 (0.0)
Hodgkin's disease nodular sclerosis	0	1 (0.0)
Hypergammaglobulinaemia benign monoclonal	2 (0.0)	4 (0.0)
Intraductal papilloma of breast	0	1 (0.0)
Intraductal proliferative breast lesion	6 (0.0)	6 (0.0)
Intraocular melanoma	1 (0.0)	1 (0.0)
Invasive breast carcinoma	1 (0.0)	0
Invasive ductal breast carcinoma	2 (0.0)	6 (0.0)
Invasive lobular breast carcinoma	1 (0.0)	0
Iris melanoma	0	1 (0.0)
Juvenile melanoma benign	1 (0.0)	0
Kaposi's sarcoma	0	1 (0.0)
Langerhans' cell histiocytosis	1 (0.0)	0
Large granular lymphocytosis	1 (0.0)	0
Large intestine benign neoplasm	3 (0.0)	1 (0.0)
Laryngeal cancer	4 (0.0)	2 (0.0)
Laryngeal neoplasm	1 (0.0)	0
Laryngeal papilloma	1 (0.0)	0
Leiomyoma	3 (0.0)	4 (0.0)
Leiomyosarcoma	0	1 (0.0)
Lentigo maligna	1 (0.0)	0
Leukaemia	4 (0.0)	2 (0.0)
Lip and/or oral cavity cancer	4 (0.0)	1 (0.0)
Lip neoplasm malignant stage unspecified	0	1 (0.0)
Lip squamous cell carcinoma	3 (0.0)	2 (0.0)
Lipoma	35 (0.2)	39 (0.2)
Lipoma of breast	1 (0.0)	1 (0.0)
Liposarcoma	0	1 (0.0)
Lobular breast carcinoma in situ	4 (0.0)	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Lung adenocarcinoma	1 (0.0)	0
Lung carcinoma cell type unspecified stage IV	1 (0.0)	0
Lung neoplasm malignant	11 (0.1)	10 (0.1)
Lymphangioma	1 (0.0)	0
Lymphoma	5 (0.0)	8 (0.0)
Malignant melanoma	97 (0.5)	85 (0.5)
Malignant melanoma in situ	4 (0.0)	2 (0.0)
Malignant melanoma of eyelid	1 (0.0)	1 (0.0)
Malignant melanoma stage I	2 (0.0)	1 (0.0)
Malignant melanoma stage II	1 (0.0)	0
Mantle cell lymphoma	1 (0.0)	1 (0.0)
Melanocytic naevus	15 (0.1)	12 (0.1)
Melanoma recurrent	1 (0.0)	0
Meningioma	5 (0.0)	12 (0.1)
Meningioma benign	7 (0.0)	3 (0.0)
Metaplastic breast carcinoma	1 (0.0)	0
Metastases to bone	1 (0.0)	0
Metastatic malignant melanoma	0	1 (0.0)
Metastatic neoplasm	1 (0.0)	0
Metastatic squamous cell carcinoma	0	1 (0.0)
Monoclonal gammopathy	1 (0.0)	1 (0.0)
Nasopharyngeal cancer	1 (0.0)	0
Neoplasm	1 (0.0)	3 (0.0)
Neoplasm malignant	3 (0.0)	1 (0.0)
Neoplasm of appendix	1 (0.0)	1 (0.0)
Neoplasm skin	0	1 (0.0)
Nephroblastoma	1 (0.0)	0
Nervous system neoplasm benign	0	1 (0.0)
Neurilemmoma benign	0	2 (0.0)
Neuroendocrine carcinoma	1 (0.0)	0
Neuroendocrine tumour	0	1 (0.0)
Neurofibroma	1 (0.0)	0
Neuroma	11 (0.1)	9 (0.0)
Non-Hodgkin's lymphoma	6 (0.0)	11 (0.1)
Ocular neoplasm	0	1 (0.0)
Oesophageal adenocarcinoma	1 (0.0)	0
Oesophageal carcinoma	1 (0.0)	0
Oesophageal carcinoma stage 0	1 (0.0)	0
Oral neoplasm	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Oral neoplasm benign	0	1 (0.0)
Oropharyngeal cancer	0	1 (0.0)
Osteochondroma	1 (0.0)	4 (0.0)
Osteoma	0	3 (0.0)
Osteosarcoma	0	1 (0.0)
Ovarian adenoma	1 (0.0)	0
Ovarian cancer	10 (0.1)	12 (0.1)
Ovarian cancer metastatic	0	1 (0.0)
Ovarian cancer stage IV	1 (0.0)	0
Ovarian dysgerminoma stage unspecified	1 (0.0)	0
Ovarian fibroma	2 (0.0)	0
Ovarian germ cell teratoma	2 (0.0)	0
Ovarian germ cell teratoma benign	1 (0.0)	5 (0.0)
Ovarian neoplasm	0	2 (0.0)
Paget's disease of nipple	1 (0.0)	0
Pancreatic carcinoma	2 (0.0)	0
Pancreatic neoplasm	0	1 (0.0)
Papillary thyroid cancer	7 (0.0)	6 (0.0)
Papilloma	0	1 (0.0)
Paraganglion neoplasm benign	0	1 (0.0)
Parathyroid tumour	0	1 (0.0)
Parathyroid tumour benign	5 (0.0)	9 (0.0)
Phaeochromocytoma	0	1 (0.0)
Phyllodes tumour	1 (0.0)	0
Pineal germinoma	0	1 (0.0)
Pituitary tumour	0	2 (0.0)
Pituitary tumour benign	12 (0.1)	10 (0.1)
Plasma cell myeloma	4 (0.0)	2 (0.0)
Pleural neoplasm	0	1 (0.0)
Polycythaemia vera	1 (0.0)	0
Prolactin-producing pituitary tumour	1 (0.0)	2 (0.0)
Prostate cancer	165 (0.9)	167 (0.9)
Prostate cancer stage I	1 (0.0)	1 (0.0)
Prostate cancer stage III	1 (0.0)	0
Prostate cancer stage IV	1 (0.0)	0
Prostatic adenoma	0	3 (0.0)
Rectal cancer	2 (0.0)	3 (0.0)
Rectal neoplasm	1 (0.0)	0
Renal adenoma	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Renal cancer	14 (0.1)	10 (0.1)
Renal cell carcinoma	2 (0.0)	4 (0.0)
Renal hamartoma	1 (0.0)	1 (0.0)
Renal neoplasm	1 (0.0)	0
Retinoblastoma	1 (0.0)	2 (0.0)
Round cell liposarcoma	1 (0.0)	0
Salivary gland cancer	0	3 (0.0)
Salivary gland neoplasm	0	1 (0.0)
Sarcoma	0	1 (0.0)
Schwannoma	4 (0.0)	3 (0.0)
Seborrhoeic keratosis	17 (0.1)	23 (0.1)
Seminoma	1 (0.0)	1 (0.0)
Sinonasal papilloma	1 (0.0)	0
Skin cancer	21 (0.1)	20 (0.1)
Skin papilloma	11 (0.1)	4 (0.0)
Small intestine carcinoma	1 (0.0)	2 (0.0)
Soft tissue sarcoma	1 (0.0)	0
Spinal cord neoplasm	0	1 (0.0)
Squamous cell breast carcinoma	1 (0.0)	0
Squamous cell carcinoma	65 (0.3)	69 (0.4)
Squamous cell carcinoma of lung	1 (0.0)	0
Squamous cell carcinoma of skin	42 (0.2)	28 (0.1)
Squamous cell carcinoma of the oral cavity	0	1 (0.0)
Squamous cell carcinoma of the tongue	2 (0.0)	2 (0.0)
Sweat gland tumour	0	2 (0.0)
Synovial sarcoma	0	1 (0.0)
T-cell lymphoma	2 (0.0)	1 (0.0)
Teratoma	0	1 (0.0)
Testis cancer	13 (0.1)	14 (0.1)
Throat cancer	5 (0.0)	5 (0.0)
Thymoma	1 (0.0)	0
Thyroid adenoma	2 (0.0)	1 (0.0)
Thyroid cancer	40 (0.2)	32 (0.2)
Thyroid cancer stage IV	1 (0.0)	0
Thyroid neoplasm	2 (0.0)	3 (0.0)
Tongue neoplasm	0	1 (0.0)
Tongue neoplasm malignant stage unspecified	3 (0.0)	1 (0.0)
Tonsil cancer	3 (0.0)	4 (0.0)
Tonsillar neoplasm benign	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Triple negative breast cancer	1 (0.0)	0
Uterine cancer	20 (0.1)	18 (0.1)
Uterine carcinoma in situ	1 (0.0)	0
Uterine leiomyoma	336 (1.8)	343 (1.8)
Uterine neoplasm	1 (0.0)	0
Vulval cancer	2 (0.0)	0
Vulvovaginal warts	1 (0.0)	0
Xanthogranuloma	1 (0.0)	0
Nervous system disorders	2571 (13.6)	2477 (13.1)
Ageusia	1 (0.0)	1 (0.0)
Akathisia	1 (0.0)	0
Amnesia	13 (0.1)	12 (0.1)
Angiopathic neuropathy	1 (0.0)	1 (0.0)
Anosmia	5 (0.0)	6 (0.0)
Arachnoid cyst	4 (0.0)	2 (0.0)
Arachnoiditis	0	1 (0.0)
Ataxia	3 (0.0)	0
Aura	0	1 (0.0)
Autoimmune encephalopathy	1 (0.0)	0
Autonomic nervous system imbalance	0	2 (0.0)
Autonomic neuropathy	2 (0.0)	0
Balance disorder	1 (0.0)	1 (0.0)
Blood brain barrier defect	1 (0.0)	0
Brachial plexopathy	1 (0.0)	1 (0.0)
Brain injury	3 (0.0)	1 (0.0)
Brain stem stroke	1 (0.0)	0
Carotid arterial embolus	0	1 (0.0)
Carotid arteriosclerosis	3 (0.0)	5 (0.0)
Carotid artery disease	9 (0.0)	3 (0.0)
Carotid artery dissection	2 (0.0)	1 (0.0)
Carotid artery occlusion	6 (0.0)	5 (0.0)
Carotid artery stenosis	13 (0.1)	13 (0.1)
Carotid artery thrombosis	0	1 (0.0)
Carpal tunnel syndrome	200 (1.1)	153 (0.8)
Cataplexy	0	1 (0.0)
Cauda equina syndrome	0	1 (0.0)
Central auditory processing disorder	1 (0.0)	0
Cerebellar ataxia	1 (0.0)	0
Cerebellar atrophy	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Cerebellar infarction	1 (0.0)	0
Cerebellar stroke	2 (0.0)	0
Cerebral atrophy	1 (0.0)	0
Cerebral cyst	1 (0.0)	0
Cerebral haemorrhage	1 (0.0)	1 (0.0)
Cerebral infarction	2 (0.0)	0
Cerebral ischaemia	1 (0.0)	0
Cerebral thrombosis	1 (0.0)	0
Cerebral venous sinus thrombosis	0	1 (0.0)
Cerebrospinal fluid leakage	0	1 (0.0)
Cerebrovascular accident	77 (0.4)	75 (0.4)
Cerebrovascular disorder	2 (0.0)	1 (0.0)
Cervical cord compression	1 (0.0)	0
Cervical radiculopathy	14 (0.1)	17 (0.1)
Cervicobrachial syndrome	0	1 (0.0)
Cervicogenic headache	0	2 (0.0)
Cervicogenic vertigo	0	1 (0.0)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	3 (0.0)
Circadian rhythm sleep disorder	1 (0.0)	1 (0.0)
Cluster headache	14 (0.1)	8 (0.0)
Cognitive disorder	4 (0.0)	6 (0.0)
Colloid brain cyst	0	1 (0.0)
Coma	2 (0.0)	0
Complex regional pain syndrome	1 (0.0)	7 (0.0)
Convulsive threshold lowered	0	1 (0.0)
Cramp-fasciculation syndrome	0	1 (0.0)
Cranial nerve disorder	0	1 (0.0)
Cubital tunnel syndrome	1 (0.0)	5 (0.0)
Dementia	5 (0.0)	7 (0.0)
Dementia Alzheimer's type	1 (0.0)	1 (0.0)
Demyelination	1 (0.0)	0
Depressed level of consciousness	1 (0.0)	0
Diabetic neuropathy	86 (0.5)	103 (0.5)
Disturbance in attention	5 (0.0)	3 (0.0)
Dizziness	19 (0.1)	23 (0.1)
Dizziness postural	0	1 (0.0)
Drug withdrawal headache	1 (0.0)	0
Dural arteriovenous fistula	1 (0.0)	0
Dysaesthesia	0	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Dysgeusia	0	2 (0.0)
Dyslexia	1 (0.0)	2 (0.0)
Dystonia	2 (0.0)	0
Dystonic tremor	0	1 (0.0)
Embolic stroke	1 (0.0)	0
Encephalopathy	0	3 (0.0)
Epilepsy	40 (0.2)	43 (0.2)
Essential tremor	33 (0.2)	37 (0.2)
Extrapyramidal disorder	1 (0.0)	1 (0.0)
Facial nerve disorder	0	2 (0.0)
Facial neuralgia	3 (0.0)	0
Facial paralysis	17 (0.1)	14 (0.1)
Facial paresis	1 (0.0)	0
Facial spasm	0	1 (0.0)
Febrile convulsion	3 (0.0)	1 (0.0)
Fine motor skill dysfunction	1 (0.0)	0
Focal dyscognitive seizures	0	1 (0.0)
Generalised tonic-clonic seizure	2 (0.0)	4 (0.0)
Glossopharyngeal neuralgia	1 (0.0)	0
Guillain-Barre syndrome	1 (0.0)	1 (0.0)
Haemorrhagic stroke	1 (0.0)	5 (0.0)
Hashimoto's encephalopathy	0	1 (0.0)
Head titubation	2 (0.0)	1 (0.0)
Headache	439 (2.3)	434 (2.3)
Hemiparesis	1 (0.0)	4 (0.0)
Hemiplegia	3 (0.0)	3 (0.0)
Hemiplegic migraine	0	2 (0.0)
Horner's syndrome	2 (0.0)	0
Hydrocephalus	2 (0.0)	7 (0.0)
Hypersomnia	9 (0.0)	9 (0.0)
Hypoaesthesia	13 (0.1)	12 (0.1)
Hypogeusia	1 (0.0)	0
Hyporeflexia	1 (0.0)	0
Hyposmia	1 (0.0)	3 (0.0)
Hypotonia	0	1 (0.0)
Hypoxic-ischaemic encephalopathy	0	1 (0.0)
IVth nerve paralysis	2 (0.0)	0
Idiopathic intracranial hypertension	0	3 (0.0)
Incoherent	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Intention tremor	2 (0.0)	1 (0.0)
Intercostal neuralgia	0	1 (0.0)
Intracranial aneurysm	7 (0.0)	9 (0.0)
Intracranial mass	0	1 (0.0)
Intracranial pressure increased	1 (0.0)	2 (0.0)
Irlen syndrome	1 (0.0)	0
Ischaemic stroke	8 (0.0)	8 (0.0)
Juvenile myoclonic epilepsy	0	1 (0.0)
Lacunar infarction	1 (0.0)	0
Lacunar stroke	0	1 (0.0)
Lethargy	1 (0.0)	0
Lumbar radiculopathy	27 (0.1)	33 (0.2)
Lumbosacral radiculopathy	2 (0.0)	4 (0.0)
Medication overuse headache	1 (0.0)	0
Meige's syndrome	0	1 (0.0)
Memory impairment	3 (0.0)	3 (0.0)
Meralgia paraesthetica	1 (0.0)	0
Migraine	851 (4.5)	867 (4.6)
Migraine with aura	25 (0.1)	30 (0.2)
Migraine without aura	22 (0.1)	19 (0.1)
Monoparesis	1 (0.0)	0
Monoplegia	4 (0.0)	1 (0.0)
Morton's neuralgia	10 (0.1)	11 (0.1)
Multiple sclerosis	3 (0.0)	5 (0.0)
Muscle contractions involuntary	2 (0.0)	4 (0.0)
Muscle spasticity	1 (0.0)	0
Myasthenia gravis	2 (0.0)	5 (0.0)
Myelopathy	2 (0.0)	2 (0.0)
Myoclonic epilepsy	0	1 (0.0)
Myoclonus	3 (0.0)	3 (0.0)
Narcolepsy	10 (0.1)	15 (0.1)
Nerve compression	19 (0.1)	27 (0.1)
Nervous system disorder	2 (0.0)	1 (0.0)
Neuralgia	37 (0.2)	26 (0.1)
Neuralgic amyotrophy	1 (0.0)	0
Neuritis	1 (0.0)	2 (0.0)
Neurological symptom	1 (0.0)	0
Neuropathy peripheral	200 (1.1)	188 (1.0)
Neuropathy vitamin B6 deficiency	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Normal pressure hydrocephalus	0	2 (0.0)
Notalgia paraesthetica	1 (0.0)	0
Nystagmus	1 (0.0)	3 (0.0)
Occipital neuralgia	2 (0.0)	2 (0.0)
Olfactory nerve disorder	1 (0.0)	0
Optic neuritis	3 (0.0)	1 (0.0)
Paraesthesia	12 (0.1)	9 (0.0)
Paralysis	1 (0.0)	0
Paraparesis	1 (0.0)	0
Paraplegia	0	2 (0.0)
Parkinson's disease	16 (0.1)	14 (0.1)
Parkinsonism	0	2 (0.0)
Parosmia	0	1 (0.0)
Paroxysmal choreoathetosis	0	1 (0.0)
Partial seizures	1 (0.0)	0
Perineurial cyst	1 (0.0)	0
Periodic limb movement disorder	3 (0.0)	6 (0.0)
Peripheral nerve lesion	1 (0.0)	0
Peripheral sensory neuropathy	1 (0.0)	0
Peroneal nerve palsy	8 (0.0)	5 (0.0)
Petit mal epilepsy	2 (0.0)	4 (0.0)
Phantom limb syndrome	1 (0.0)	0
Pineal gland cyst	1 (0.0)	0
Piriformis syndrome	4 (0.0)	0
Polyneuropathy	3 (0.0)	3 (0.0)
Polyneuropathy alcoholic	1 (0.0)	0
Post herpetic neuralgia	3 (0.0)	9 (0.0)
Post polio syndrome	2 (0.0)	1 (0.0)
Post stroke seizure	1 (0.0)	0
Post-traumatic epilepsy	0	1 (0.0)
Post-traumatic headache	1 (0.0)	3 (0.0)
Post-traumatic neuralgia	1 (0.0)	0
Posterior reversible encephalopathy syndrome	0	2 (0.0)
Postural tremor	1 (0.0)	0
Presyncope	4 (0.0)	1 (0.0)
Psychogenic seizure	1 (0.0)	1 (0.0)
Psychomotor hyperactivity	1 (0.0)	2 (0.0)
Radicular pain	0	1 (0.0)
Radiculitis brachial	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Radiculopathy	8 (0.0)	7 (0.0)
Relapsing multiple sclerosis	1 (0.0)	0
Resting tremor	1 (0.0)	0
Restless legs syndrome	131 (0.7)	151 (0.8)
Ruptured cerebral aneurysm	0	1 (0.0)
Sacral radiculopathy	1 (0.0)	0
Sciatic nerve neuropathy	1 (0.0)	0
Sciatica	118 (0.6)	97 (0.5)
Seizure	46 (0.2)	47 (0.2)
Senile dementia	1 (0.0)	3 (0.0)
Sensory disturbance	0	1 (0.0)
Serotonin syndrome	1 (0.0)	1 (0.0)
Shift work disorder	2 (0.0)	1 (0.0)
Sinus headache	43 (0.2)	33 (0.2)
Sleep deficit	1 (0.0)	1 (0.0)
Small fibre neuropathy	0	2 (0.0)
Somnolence	2 (0.0)	0
Spasmodic dysphonia	1 (0.0)	2 (0.0)
Speech disorder	0	1 (0.0)
Spondylitic myelopathy	2 (0.0)	1 (0.0)
Stiff person syndrome	0	1 (0.0)
Subarachnoid haemorrhage	2 (0.0)	3 (0.0)
Syncope	26 (0.1)	21 (0.1)
Tardive dyskinesia	2 (0.0)	0
Tarsal tunnel syndrome	5 (0.0)	1 (0.0)
Temporal lobe epilepsy	2 (0.0)	1 (0.0)
Tension headache	113 (0.6)	62 (0.3)
Thoracic outlet syndrome	2 (0.0)	3 (0.0)
Thoracic radiculopathy	0	1 (0.0)
Tonic convulsion	0	1 (0.0)
Transient global amnesia	3 (0.0)	2 (0.0)
Transient ischaemic attack	60 (0.3)	46 (0.2)
Tremor	29 (0.2)	27 (0.1)
Trigeminal nerve disorder	0	2 (0.0)
Trigeminal neuralgia	14 (0.1)	11 (0.1)
VIth nerve paralysis	2 (0.0)	0
Vertebral artery dissection	1 (0.0)	0
Vertebral artery occlusion	1 (0.0)	0
Vertebral artery stenosis	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Vestibular migraine	1 (0.0)	3 (0.0)
Visual field defect	0	3 (0.0)
Vocal cord paralysis	2 (0.0)	1 (0.0)
Vocal cord paresis	1 (0.0)	0
Writer's cramp	1 (0.0)	0
Pregnancy, puerperium and perinatal conditions	129 (0.7)	129 (0.7)
Abnormal cord insertion	1 (0.0)	0
Abortion	5 (0.0)	2 (0.0)
Abortion incomplete	0	1 (0.0)
Abortion spontaneous	23 (0.1)	22 (0.1)
Breech delivery	0	1 (0.0)
Breech presentation	1 (0.0)	1 (0.0)
Cephalo-pelvic disproportion	1 (0.0)	1 (0.0)
Complication of pregnancy	2 (0.0)	0
Delivery	51 (0.3)	44 (0.2)
Eclampsia	1 (0.0)	0
Ectopic pregnancy	19 (0.1)	27 (0.1)
Foetal death	0	2 (0.0)
Foetal distress syndrome	0	1 (0.0)
Gestational diabetes	12 (0.1)	10 (0.1)
Gestational hypertension	1 (0.0)	3 (0.0)
HELLP syndrome	0	1 (0.0)
Habitual abortion	0	1 (0.0)
Morning sickness	1 (0.0)	0
Peripartum cardiomyopathy	1 (0.0)	0
Placenta accreta	1 (0.0)	4 (0.0)
Post abortion haemorrhage	0	1 (0.0)
Postpartum haemorrhage	2 (0.0)	3 (0.0)
Pre-eclampsia	8 (0.0)	5 (0.0)
Pregnancy	4 (0.0)	8 (0.0)
Premature baby	0	1 (0.0)
Premature labour	1 (0.0)	0
Premature separation of placenta	0	1 (0.0)
Retained placenta or membranes	1 (0.0)	0
Stillbirth	0	1 (0.0)
Unintended pregnancy	0	1 (0.0)
Product issues	3 (0.0)	2 (0.0)
Device breakage	0	1 (0.0)
Device leakage	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Device malfunction	0	1 (0.0)
Embedded device	1 (0.0)	0
Stent malfunction	1 (0.0)	0
Psychiatric disorders	4042 (21.4)	4127 (21.9)
Abnormal dreams	0	1 (0.0)
Adjustment disorder	4 (0.0)	7 (0.0)
Adjustment disorder with depressed mood	11 (0.1)	5 (0.0)
Adjustment disorder with mixed anxiety and depressed mood	2 (0.0)	3 (0.0)
Aerophobia	0	1 (0.0)
Affect lability	2 (0.0)	1 (0.0)
Affective disorder	10 (0.1)	8 (0.0)
Aggression	0	1 (0.0)
Agitated depression	0	1 (0.0)
Agitation	1 (0.0)	0
Agoraphobia	0	1 (0.0)
Alcohol abuse	17 (0.1)	13 (0.1)
Alcohol problem	0	1 (0.0)
Alcohol use disorder	2 (0.0)	4 (0.0)
Alcohol withdrawal syndrome	0	1 (0.0)
Alcoholism	24 (0.1)	15 (0.1)
Anger	2 (0.0)	2 (0.0)
Anorexia nervosa	2 (0.0)	2 (0.0)
Anxiety	1598 (8.5)	1702 (9.0)
Anxiety disorder	117 (0.6)	109 (0.6)
Attention deficit hyperactivity disorder	465 (2.5)	432 (2.3)
Autism spectrum disorder	13 (0.1)	14 (0.1)
Binge eating	2 (0.0)	6 (0.0)
Bipolar I disorder	3 (0.0)	11 (0.1)
Bipolar II disorder	16 (0.1)	12 (0.1)
Bipolar disorder	146 (0.8)	149 (0.8)
Borderline personality disorder	4 (0.0)	1 (0.0)
Breathing-related sleep disorder	1 (0.0)	0
Bruxism	1 (0.0)	4 (0.0)
Bulimia nervosa	2 (0.0)	3 (0.0)
Cardiovascular somatic symptom disorder	0	1 (0.0)
Chronic tic disorder	1 (0.0)	0
Conversion disorder	0	1 (0.0)
Cyclothymic disorder	2 (0.0)	2 (0.0)
Delirium tremens	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Dependence	1 (0.0)	1 (0.0)
Depressed mood	3 (0.0)	0
Depression	1721 (9.1)	1759 (9.3)
Depressive symptom	1 (0.0)	0
Dissociative disorder	0	1 (0.0)
Drug abuse	18 (0.1)	13 (0.1)
Drug dependence	10 (0.1)	13 (0.1)
Drug use disorder	1 (0.0)	1 (0.0)
Dysphemia	0	2 (0.0)
Eating disorder	4 (0.0)	3 (0.0)
Enuresis	0	1 (0.0)
Gambling disorder	0	1 (0.0)
Gastrointestinal somatic symptom disorder	1 (0.0)	0
Gender dysphoria	4 (0.0)	2 (0.0)
Generalised anxiety disorder	78 (0.4)	82 (0.4)
Grief reaction	0	3 (0.0)
Hallucination	1 (0.0)	2 (0.0)
Initial insomnia	0	2 (0.0)
Insomnia	1039 (5.5)	1031 (5.5)
Intentional self-injury	1 (0.0)	0
Intermittent explosive disorder	1 (0.0)	1 (0.0)
Irritability	1 (0.0)	3 (0.0)
Libido decreased	24 (0.1)	22 (0.1)
Major depression	127 (0.7)	135 (0.7)
Mania	1 (0.0)	3 (0.0)
Menopausal depression	1 (0.0)	0
Mental disorder	3 (0.0)	4 (0.0)
Middle insomnia	1 (0.0)	0
Mood swings	3 (0.0)	1 (0.0)
Nicotine dependence	31 (0.2)	17 (0.1)
Nightmare	1 (0.0)	2 (0.0)
Obsessive-compulsive disorder	38 (0.2)	42 (0.2)
Obsessive-compulsive personality disorder	0	1 (0.0)
Oppositional defiant disorder	0	2 (0.0)
Panic attack	29 (0.2)	33 (0.2)
Panic disorder	15 (0.1)	11 (0.1)
Panic reaction	1 (0.0)	1 (0.0)
Parasomnia	0	1 (0.0)
Performance fear	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Perinatal depression	11 (0.1)	14 (0.1)
Persistent depressive disorder	3 (0.0)	14 (0.1)
Personality disorder	0	1 (0.0)
Post-traumatic amnestic disorder	0	1 (0.0)
Post-traumatic stress disorder	102 (0.5)	92 (0.5)
Postpartum anxiety	1 (0.0)	0
Premature ejaculation	1 (0.0)	5 (0.0)
Psychogenic erectile dysfunction	1 (0.0)	0
Psychosexual disorder	0	1 (0.0)
Psychotic disorder	3 (0.0)	3 (0.0)
Rapid eye movements sleep abnormal	1 (0.0)	1 (0.0)
Restlessness	1 (0.0)	3 (0.0)
Schizoaffective disorder	6 (0.0)	2 (0.0)
Schizophrenia	22 (0.1)	27 (0.1)
Seasonal affective disorder	14 (0.1)	5 (0.0)
Sexual inhibition	0	1 (0.0)
Sleep disorder	18 (0.1)	37 (0.2)
Sleep disorder due to general medical condition, insomnia type	2 (0.0)	0
Sleep terror	2 (0.0)	1 (0.0)
Social anxiety disorder	9 (0.0)	0
Somatic symptom disorder	1 (0.0)	1 (0.0)
Somnambulism	0	2 (0.0)
Stress	6 (0.0)	4 (0.0)
Substance abuse	3 (0.0)	2 (0.0)
Substance dependence	1 (0.0)	1 (0.0)
Substance use disorder	1 (0.0)	0
Suicidal behaviour	1 (0.0)	0
Suicidal ideation	4 (0.0)	3 (0.0)
Suicide attempt	4 (0.0)	2 (0.0)
Tachyphrenia	0	1 (0.0)
Terminal insomnia	1 (0.0)	0
Tic	0	2 (0.0)
Tobacco abuse	8 (0.0)	7 (0.0)
Trichotillomania	2 (0.0)	1 (0.0)
Renal and urinary disorders	916 (4.9)	908 (4.8)
Acute kidney injury	6 (0.0)	1 (0.0)
Albuminuria	1 (0.0)	0
Atonic urinary bladder	0	1 (0.0)
Bladder disorder	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Bladder dysfunction	0	1 (0.0)
Bladder irritation	0	2 (0.0)
Bladder malposition acquired	1 (0.0)	0
Bladder neck obstruction	1 (0.0)	0
Bladder obstruction	0	1 (0.0)
Bladder outlet obstruction	1 (0.0)	2 (0.0)
Bladder perforation	0	2 (0.0)
Bladder prolapse	20 (0.1)	27 (0.1)
Bladder spasm	7 (0.0)	6 (0.0)
Bladder stenosis	1 (0.0)	0
Calculus bladder	3 (0.0)	2 (0.0)
Calculus urinary	1 (0.0)	4 (0.0)
Chronic kidney disease	95 (0.5)	96 (0.5)
Cystitis haemorrhagic	1 (0.0)	0
Cystitis interstitial	13 (0.1)	9 (0.0)
Diabetic nephropathy	4 (0.0)	2 (0.0)
Dysuria	11 (0.1)	4 (0.0)
End stage renal disease	1 (0.0)	0
Focal segmental glomerulosclerosis	2 (0.0)	0
Glomerulonephritis	0	1 (0.0)
Glomerulonephritis membranous	1 (0.0)	2 (0.0)
Haematuria	7 (0.0)	18 (0.1)
Hydronephrosis	8 (0.0)	4 (0.0)
Hypercalciuria	2 (0.0)	4 (0.0)
Hypertensive nephropathy	1 (0.0)	0
Hypertonic bladder	158 (0.8)	157 (0.8)
IgA nephropathy	1 (0.0)	1 (0.0)
Incontinence	13 (0.1)	11 (0.1)
Kidney small	0	1 (0.0)
Lower urinary tract symptoms	1 (0.0)	2 (0.0)
Microalbuminuria	10 (0.1)	5 (0.0)
Micturition disorder	3 (0.0)	5 (0.0)
Micturition urgency	6 (0.0)	12 (0.1)
Mixed incontinence	3 (0.0)	2 (0.0)
Nephritis	1 (0.0)	3 (0.0)
Nephrolithiasis	346 (1.8)	336 (1.8)
Nephropathy	14 (0.1)	14 (0.1)
Nephrotic syndrome	0	3 (0.0)
Neurogenic bladder	2 (0.0)	4 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Nocturia	26 (0.1)	26 (0.1)
Pelvi-ureteric obstruction	1 (0.0)	0
Pollakiuria	24 (0.1)	24 (0.1)
Polyuria	3 (0.0)	4 (0.0)
Proteinuria	4 (0.0)	8 (0.0)
Reflux nephropathy	1 (0.0)	0
Renal artery stenosis	0	3 (0.0)
Renal atrophy	0	1 (0.0)
Renal colic	0	1 (0.0)
Renal cyst	10 (0.1)	15 (0.1)
Renal disorder	3 (0.0)	2 (0.0)
Renal failure	4 (0.0)	10 (0.1)
Renal impairment	4 (0.0)	3 (0.0)
Renal infarct	1 (0.0)	0
Renal injury	1 (0.0)	0
Renal mass	4 (0.0)	3 (0.0)
Single functional kidney	2 (0.0)	5 (0.0)
Stress urinary incontinence	35 (0.2)	28 (0.1)
Trigonitis	1 (0.0)	1 (0.0)
Ureteral disorder	2 (0.0)	0
Ureteric obstruction	0	1 (0.0)
Ureteric stenosis	1 (0.0)	5 (0.0)
Ureterolithiasis	0	1 (0.0)
Urethral cyst	1 (0.0)	0
Urethral dilatation	0	2 (0.0)
Urethral disorder	1 (0.0)	1 (0.0)
Urethral polyp	0	1 (0.0)
Urethral prolapse	0	1 (0.0)
Urethral stenosis	2 (0.0)	5 (0.0)
Urge incontinence	18 (0.1)	12 (0.1)
Urinary bladder polyp	0	1 (0.0)
Urinary hesitation	5 (0.0)	2 (0.0)
Urinary incontinence	78 (0.4)	79 (0.4)
Urinary retention	20 (0.1)	20 (0.1)
Urinary tract obstruction	1 (0.0)	0
Urinary tract pain	0	1 (0.0)
Urine flow decreased	0	3 (0.0)
Urogenital fistula	0	1 (0.0)
Vesicoureteric reflux	1 (0.0)	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Reproductive system and breast disorders	1907 (10.1)	1825 (9.7)
Adenomyosis	8 (0.0)	12 (0.1)
Adnexa uteri cyst	2 (0.0)	0
Adnexa uteri pain	1 (0.0)	0
Adnexal torsion	1 (0.0)	1 (0.0)
Amenorrhoea	17 (0.1)	12 (0.1)
Anisomastia	1 (0.0)	1 (0.0)
Artificial menopause	2 (0.0)	1 (0.0)
Atrophic vulvovaginitis	19 (0.1)	21 (0.1)
Azoospermia	2 (0.0)	1 (0.0)
Balanoposthitis	1 (0.0)	1 (0.0)
Bartholin's cyst	3 (0.0)	1 (0.0)
Benign prostatic hyperplasia	498 (2.6)	486 (2.6)
Breast calcifications	4 (0.0)	2 (0.0)
Breast cyst	17 (0.1)	21 (0.1)
Breast disorder	0	1 (0.0)
Breast enlargement	5 (0.0)	6 (0.0)
Breast fibrosis	2 (0.0)	0
Breast hyperplasia	2 (0.0)	3 (0.0)
Breast mass	16 (0.1)	18 (0.1)
Breast pain	4 (0.0)	1 (0.0)
Breast swelling	1 (0.0)	0
Calculus prostatic	0	2 (0.0)
Cervical cyst	2 (0.0)	0
Cervical discharge	1 (0.0)	0
Cervical dysplasia	17 (0.1)	14 (0.1)
Cervical polyp	3 (0.0)	3 (0.0)
Cervix disorder	0	1 (0.0)
Colpocele	0	1 (0.0)
Cystocele	5 (0.0)	7 (0.0)
Dysfunctional uterine bleeding	12 (0.1)	8 (0.0)
Dysmenorrhoea	52 (0.3)	63 (0.3)
Dyspareunia	7 (0.0)	3 (0.0)
Ectropion of cervix	1 (0.0)	0
Ejaculation disorder	0	1 (0.0)
Endometrial disorder	0	2 (0.0)
Endometrial hyperplasia	8 (0.0)	4 (0.0)
Endometrial hypertrophy	0	1 (0.0)
Endometrial hypoplasia	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Endometrial thickening	1 (0.0)	1 (0.0)
Endometriosis	180 (1.0)	160 (0.8)
Epididymal cyst	1 (0.0)	2 (0.0)
Epididymal enlargement	0	1 (0.0)
Erectile dysfunction	300 (1.6)	345 (1.8)
Fallopian tube cyst	0	3 (0.0)
Fallopian tube disorder	1 (0.0)	2 (0.0)
Fallopian tube obstruction	3 (0.0)	4 (0.0)
Female genital tract fistula	1 (0.0)	1 (0.0)
Fibrocystic breast disease	28 (0.1)	22 (0.1)
Genital cyst	0	1 (0.0)
Genital lesion	0	1 (0.0)
Genital rash	1 (0.0)	0
Genitourinary syndrome of menopause	0	1 (0.0)
Gynaecomastia	5 (0.0)	8 (0.0)
Haematospermia	1 (0.0)	1 (0.0)
Infertility	18 (0.1)	14 (0.1)
Infertility female	4 (0.0)	7 (0.0)
Infertility male	2 (0.0)	1 (0.0)
Mammary duct ectasia	1 (0.0)	0
Mastoptosis	1 (0.0)	0
Menometrorrhagia	2 (0.0)	1 (0.0)
Menopausal disorder	0	1 (0.0)
Menopausal symptoms	44 (0.2)	47 (0.2)
Menorrhagia	170 (0.9)	148 (0.8)
Menstrual discomfort	1 (0.0)	0
Menstrual disorder	25 (0.1)	22 (0.1)
Menstruation irregular	30 (0.2)	19 (0.1)
Metrorrhagia	5 (0.0)	6 (0.0)
Nipple exudate bloody	0	1 (0.0)
Oligomenorrhoea	3 (0.0)	1 (0.0)
Oligospermia	1 (0.0)	0
Organic erectile dysfunction	2 (0.0)	2 (0.0)
Ovarian adhesion	0	1 (0.0)
Ovarian cyst	103 (0.5)	96 (0.5)
Ovarian cyst ruptured	6 (0.0)	0
Ovarian disorder	1 (0.0)	0
Ovarian enlargement	0	1 (0.0)
Ovarian failure	1 (0.0)	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Ovarian fibrosis	1 (0.0)	2 (0.0)
Ovarian haemorrhage	0	1 (0.0)
Ovarian mass	1 (0.0)	1 (0.0)
Ovarian rupture	2 (0.0)	1 (0.0)
Ovulation pain	0	1 (0.0)
Pelvic cyst	1 (0.0)	0
Pelvic floor muscle weakness	1 (0.0)	0
Pelvic pain	8 (0.0)	1 (0.0)
Pelvic prolapse	2 (0.0)	1 (0.0)
Perineal cyst	0	1 (0.0)
Peyronie's disease	2 (0.0)	6 (0.0)
Polycystic ovaries	101 (0.5)	79 (0.4)
Postmenopausal haemorrhage	3 (0.0)	3 (0.0)
Premature menopause	9 (0.0)	5 (0.0)
Premenstrual dysphoric disorder	6 (0.0)	7 (0.0)
Premenstrual headache	0	1 (0.0)
Premenstrual syndrome	4 (0.0)	5 (0.0)
Prostatic disorder	14 (0.1)	7 (0.0)
Prostatic dysplasia	1 (0.0)	0
Prostatic hypoplasia	0	2 (0.0)
Prostatic mass	0	1 (0.0)
Prostatism	8 (0.0)	7 (0.0)
Prostatitis	9 (0.0)	11 (0.1)
Prostatomegaly	101 (0.5)	102 (0.5)
Pruritus genital	0	1 (0.0)
Rectocele	5 (0.0)	4 (0.0)
Scrotal cyst	1 (0.0)	1 (0.0)
Sexual dysfunction	4 (0.0)	4 (0.0)
Spermatocele	1 (0.0)	0
Testicular atrophy	0	1 (0.0)
Testicular cyst	1 (0.0)	0
Testicular mass	0	1 (0.0)
Testicular pain	2 (0.0)	1 (0.0)
Testicular swelling	0	1 (0.0)
Testicular torsion	2 (0.0)	4 (0.0)
Uterine adhesions	0	1 (0.0)
Uterine cervix stenosis	0	1 (0.0)
Uterine cyst	4 (0.0)	7 (0.0)
Uterine disorder	3 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Uterine enlargement	1 (0.0)	1 (0.0)
Uterine haemorrhage	17 (0.1)	15 (0.1)
Uterine inflammation	1 (0.0)	0
Uterine malposition	2 (0.0)	2 (0.0)
Uterine mass	0	1 (0.0)
Uterine polyp	17 (0.1)	9 (0.0)
Uterine prolapse	38 (0.2)	33 (0.2)
Uterine scar	1 (0.0)	2 (0.0)
Vaginal cyst	2 (0.0)	1 (0.0)
Vaginal discharge	0	1 (0.0)
Vaginal disorder	0	1 (0.0)
Vaginal haemorrhage	13 (0.1)	7 (0.0)
Vaginal polyp	0	1 (0.0)
Vaginal prolapse	2 (0.0)	3 (0.0)
Vaginal stricture	1 (0.0)	0
Varicocele	13 (0.1)	9 (0.0)
Varicose veins pelvic	1 (0.0)	0
Vulval disorder	2 (0.0)	0
Vulvar dysplasia	0	1 (0.0)
Vulvovaginal dryness	28 (0.1)	26 (0.1)
Vulvovaginal pain	1 (0.0)	1 (0.0)
Respiratory, thoracic and mediastinal disorders	2831 (15.0)	2883 (15.3)
Acute pulmonary oedema	0	1 (0.0)
Acute respiratory failure	1 (0.0)	0
Adenoidal hypertrophy	10 (0.1)	11 (0.1)
Allergic bronchitis	2 (0.0)	1 (0.0)
Allergic cough	3 (0.0)	4 (0.0)
Allergic pharyngitis	1 (0.0)	0
Allergic sinusitis	25 (0.1)	28 (0.1)
Apnoea	2 (0.0)	3 (0.0)
Aspiration	0	1 (0.0)
Asthma	1169 (6.2)	1148 (6.1)
Asthma exercise induced	53 (0.3)	45 (0.2)
Asthma-chronic obstructive pulmonary disease overlap syndrome	0	1 (0.0)
Asthmatic crisis	1 (0.0)	0
Atelectasis	0	1 (0.0)
Bronchial hyperreactivity	18 (0.1)	20 (0.1)
Bronchiectasis	7 (0.0)	9 (0.0)
Bronchitis chronic	30 (0.2)	24 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Bronchospasm	11 (0.1)	6 (0.0)
Childhood asthma	10 (0.1)	15 (0.1)
Chronic obstructive pulmonary disease	201 (1.1)	206 (1.1)
Chronic respiratory disease	0	1 (0.0)
Chronic respiratory failure	0	2 (0.0)
Cough	28 (0.1)	52 (0.3)
Cough variant asthma	1 (0.0)	3 (0.0)
Cystic lung disease	1 (0.0)	1 (0.0)
Diaphragmatic disorder	1 (0.0)	0
Diaphragmatic paralysis	1 (0.0)	1 (0.0)
Dysphonia	2 (0.0)	5 (0.0)
Dyspnoea	19 (0.1)	20 (0.1)
Dyspnoea exertional	4 (0.0)	5 (0.0)
Emphysema	25 (0.1)	37 (0.2)
Epiglottic oedema	1 (0.0)	0
Epistaxis	8 (0.0)	7 (0.0)
Hypoxia	4 (0.0)	1 (0.0)
Idiopathic pulmonary fibrosis	0	2 (0.0)
Interstitial lung disease	2 (0.0)	1 (0.0)
Laryngeal disorder	1 (0.0)	0
Laryngeal oedema	0	1 (0.0)
Lung cyst	0	1 (0.0)
Lung disorder	1 (0.0)	2 (0.0)
Nasal congestion	13 (0.1)	26 (0.1)
Nasal cyst	1 (0.0)	0
Nasal discomfort	1 (0.0)	0
Nasal disorder	0	1 (0.0)
Nasal obstruction	0	2 (0.0)
Nasal polyps	24 (0.1)	23 (0.1)
Nasal septum deviation	140 (0.7)	136 (0.7)
Nasal turbinate hypertrophy	4 (0.0)	5 (0.0)
Obliterative bronchiolitis	0	1 (0.0)
Obstructive airways disorder	0	1 (0.0)
Organising pneumonia	1 (0.0)	0
Oropharyngeal pain	8 (0.0)	9 (0.0)
Paranasal cyst	1 (0.0)	1 (0.0)
Paranasal sinus discomfort	0	1 (0.0)
Paranasal sinus haemorrhage	1 (0.0)	0
Pharyngeal cyst	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Pharyngeal disorder	1 (0.0)	1 (0.0)
Pharyngeal mass	0	1 (0.0)
Pharyngeal polyp	1 (0.0)	1 (0.0)
Pleural calcification	0	1 (0.0)
Pleural effusion	1 (0.0)	2 (0.0)
Pleurisy	2 (0.0)	3 (0.0)
Pneumonia aspiration	0	1 (0.0)
Pneumonitis	0	2 (0.0)
Pneumothorax	13 (0.1)	13 (0.1)
Pneumothorax spontaneous	8 (0.0)	5 (0.0)
Productive cough	1 (0.0)	0
Pulmonary calcification	1 (0.0)	0
Pulmonary embolism	33 (0.2)	32 (0.2)
Pulmonary fibrosis	5 (0.0)	7 (0.0)
Pulmonary granuloma	2 (0.0)	4 (0.0)
Pulmonary hypertension	4 (0.0)	2 (0.0)
Pulmonary mass	11 (0.1)	15 (0.1)
Pulmonary oedema	1 (0.0)	1 (0.0)
Pulmonary thrombosis	1 (0.0)	2 (0.0)
Rales	0	1 (0.0)
Reflux laryngitis	3 (0.0)	6 (0.0)
Respiratory disorder	0	2 (0.0)
Respiratory distress	0	2 (0.0)
Respiratory failure	0	1 (0.0)
Respiratory tract congestion	0	1 (0.0)
Restrictive pulmonary disease	1 (0.0)	1 (0.0)
Rhinitis allergic	731 (3.9)	689 (3.7)
Rhinitis perennial	37 (0.2)	43 (0.2)
Rhinitis ulcerative	0	1 (0.0)
Rhinorrhoea	6 (0.0)	2 (0.0)
Rhonchi	0	1 (0.0)
Sinus congestion	22 (0.1)	21 (0.1)
Sinus disorder	5 (0.0)	3 (0.0)
Sinus pain	0	1 (0.0)
Sinus polyp	6 (0.0)	8 (0.0)
Sleep apnoea syndrome	536 (2.8)	573 (3.0)
Sneezing	0	1 (0.0)
Snoring	3 (0.0)	4 (0.0)
Throat clearing	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Throat irritation	0	1 (0.0)
Throat tightness	0	1 (0.0)
Tonsillar disorder	1 (0.0)	0
Tonsillar hypertrophy	12 (0.1)	8 (0.0)
Tonsillar inflammation	2 (0.0)	3 (0.0)
Tonsillolith	3 (0.0)	1 (0.0)
Upper airway resistance syndrome	1 (0.0)	0
Upper-airway cough syndrome	12 (0.1)	11 (0.1)
Vasomotor rhinitis	1 (0.0)	0
Vocal cord cyst	0	1 (0.0)
Vocal cord disorder	0	1 (0.0)
Vocal cord leukoplakia	0	1 (0.0)
Vocal cord polyp	6 (0.0)	4 (0.0)
Vocal cord thickening	0	1 (0.0)
Wheezing	3 (0.0)	9 (0.0)
Skin and subcutaneous tissue disorders	1339 (7.1)	1362 (7.2)
Acanthosis	1 (0.0)	0
Acanthosis nigricans	3 (0.0)	1 (0.0)
Acne	232 (1.2)	215 (1.1)
Acne cystic	6 (0.0)	8 (0.0)
Actinic cheilitis	0	1 (0.0)
Actinic keratosis	71 (0.4)	64 (0.3)
Alopecia	79 (0.4)	86 (0.5)
Alopecia areata	3 (0.0)	3 (0.0)
Androgenetic alopecia	8 (0.0)	21 (0.1)
Angioedema	1 (0.0)	2 (0.0)
Angiokeratoma	0	1 (0.0)
Blister	0	1 (0.0)
Brow ptosis	1 (0.0)	0
Cafe au lait spots	1 (0.0)	0
Chloasma	1 (0.0)	3 (0.0)
Chronic pigmented purpura	1 (0.0)	0
Chronic spontaneous urticaria	2 (0.0)	6 (0.0)
Cold urticaria	3 (0.0)	0
Cutaneous amyloidosis	0	1 (0.0)
Cutaneous lupus erythematosus	1 (0.0)	3 (0.0)
Dandruff	3 (0.0)	4 (0.0)
Decubitus ulcer	0	1 (0.0)
Dermal cyst	28 (0.1)	15 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Dermatitis	37 (0.2)	25 (0.1)
Dermatitis acneiform	0	1 (0.0)
Dermatitis allergic	4 (0.0)	12 (0.1)
Dermatitis atopic	37 (0.2)	32 (0.2)
Dermatitis contact	69 (0.4)	86 (0.5)
Dermatomyositis	1 (0.0)	2 (0.0)
Diabetic dermopathy	0	1 (0.0)
Diabetic foot	1 (0.0)	1 (0.0)
Diabetic ulcer	1 (0.0)	0
Drug eruption	36 (0.2)	47 (0.2)
Dry skin	16 (0.1)	12 (0.1)
Dyshidrotic eczema	1 (0.0)	5 (0.0)
Eczema	243 (1.3)	236 (1.3)
Eczema asteatotic	0	1 (0.0)
Eczema nummular	0	1 (0.0)
Eosinophilic cellulitis	0	1 (0.0)
Erythema	0	2 (0.0)
Erythema multiforme	0	1 (0.0)
Excessive skin	0	1 (0.0)
Granuloma annulare	5 (0.0)	4 (0.0)
Guttate psoriasis	0	1 (0.0)
Hair growth abnormal	1 (0.0)	0
Hand dermatitis	12 (0.1)	27 (0.1)
Hidradenitis	4 (0.0)	6 (0.0)
Hirsutism	7 (0.0)	3 (0.0)
Hyperhidrosis	14 (0.1)	10 (0.1)
Hyperkeratosis	7 (0.0)	4 (0.0)
Hypertrichosis	0	1 (0.0)
Hypertrophic scar	1 (0.0)	0
Hypohidrosis	0	1 (0.0)
Hypotrichosis	0	1 (0.0)
Idiopathic guttate hypomelanosis	1 (0.0)	0
Idiopathic urticaria	5 (0.0)	1 (0.0)
Ingrowing nail	3 (0.0)	0
Ingrown hair	1 (0.0)	0
Intertrigo	2 (0.0)	1 (0.0)
Keloid scar	2 (0.0)	7 (0.0)
Keratosis pilaris	8 (0.0)	7 (0.0)
Lentigo	2 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Leukoplakia	0	1 (0.0)
Lichen planopilaris	0	1 (0.0)
Lichen planus	5 (0.0)	6 (0.0)
Lichen sclerosus	8 (0.0)	7 (0.0)
Lichenification	0	2 (0.0)
Lichenoid keratosis	0	1 (0.0)
Lipodystrophy acquired	1 (0.0)	0
Madarosis	0	1 (0.0)
Mechanical urticaria	2 (0.0)	7 (0.0)
Melanocytic hyperplasia	0	1 (0.0)
Miliaria	2 (0.0)	2 (0.0)
Myxoid cyst	1 (0.0)	1 (0.0)
Nail bed disorder	0	1 (0.0)
Nail discolouration	1 (0.0)	0
Nail dystrophy	0	1 (0.0)
Nail growth abnormal	0	1 (0.0)
Necrobiosis lipoidica diabeticorum	1 (0.0)	0
Neurodermatitis	5 (0.0)	2 (0.0)
Night sweats	2 (0.0)	4 (0.0)
Palmoplantar keratoderma	1 (0.0)	0
Panniculitis	1 (0.0)	0
Parapsoriasis	1 (0.0)	0
Peau d'orange	0	1 (0.0)
Perioral dermatitis	1 (0.0)	1 (0.0)
Photodermatosis	1 (0.0)	3 (0.0)
Photosensitivity reaction	1 (0.0)	0
Pigmentation disorder	1 (0.0)	0
Pityriasis	1 (0.0)	0
Pityriasis lichenoides et varioliformis acuta	0	1 (0.0)
Pityriasis rosea	2 (0.0)	0
Polymorphic light eruption	2 (0.0)	0
Precancerous skin lesion	4 (0.0)	3 (0.0)
Pruritus	9 (0.0)	11 (0.1)
Pruritus allergic	10 (0.1)	6 (0.0)
Pseudofolliculitis	1 (0.0)	1 (0.0)
Psoriasis	129 (0.7)	130 (0.7)
Purpura	2 (0.0)	1 (0.0)
Purpura senile	5 (0.0)	2 (0.0)
Rash	26 (0.1)	36 (0.2)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Rash pruritic	0	2 (0.0)
Rosacea	153 (0.8)	130 (0.7)
Scab	0	1 (0.0)
Seborrhoea	2 (0.0)	1 (0.0)
Seborrhoeic dermatitis	34 (0.2)	24 (0.1)
Sensitive skin	1 (0.0)	2 (0.0)
Skin atrophy	4 (0.0)	0
Skin burning sensation	1 (0.0)	0
Skin discolouration	3 (0.0)	3 (0.0)
Skin disorder	1 (0.0)	1 (0.0)
Skin exfoliation	1 (0.0)	1 (0.0)
Skin fissures	0	1 (0.0)
Skin hyperpigmentation	1 (0.0)	1 (0.0)
Skin hypertrophy	2 (0.0)	0
Skin hypopigmentation	1 (0.0)	1 (0.0)
Skin irritation	1 (0.0)	1 (0.0)
Skin lesion	3 (0.0)	8 (0.0)
Skin mass	1 (0.0)	3 (0.0)
Skin ulcer	3 (0.0)	1 (0.0)
Solar lentigo	2 (0.0)	0
Stasis dermatitis	0	1 (0.0)
Stevens-Johnson syndrome	1 (0.0)	1 (0.0)
Telangiectasia	1 (0.0)	0
Transient acantholytic dermatosis	1 (0.0)	2 (0.0)
Urticaria	58 (0.3)	72 (0.4)
Urticaria cholinergic	0	1 (0.0)
Urticaria chronic	1 (0.0)	3 (0.0)
Urticaria papular	1 (0.0)	0
Urticaria thermal	1 (0.0)	0
Vitiligo	23 (0.1)	19 (0.1)
Social circumstances	2576 (13.7)	2558 (13.6)
Alcohol use	21 (0.1)	17 (0.1)
Alcoholic	0	2 (0.0)
Andropause	1 (0.0)	1 (0.0)
Bereavement	2 (0.0)	0
Blood donor	21 (0.1)	28 (0.1)
Corrective lens user	224 (1.2)	232 (1.2)
Denture wearer	8 (0.0)	10 (0.1)
Dependence on oxygen therapy	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Drug abuser	1 (0.0)	1 (0.0)
Electronic cigarette user	3 (0.0)	1 (0.0)
Ex-tobacco user	72 (0.4)	62 (0.3)
Eye prosthesis user	0	2 (0.0)
Familial risk factor	4 (0.0)	2 (0.0)
Hearing aid user	29 (0.2)	19 (0.1)
High risk sexual behaviour	0	2 (0.0)
Limb prosthesis user	1 (0.0)	0
Menarche	0	2 (0.0)
Menopause	377 (2.0)	383 (2.0)
Multigravida	0	1 (0.0)
Multiparous	0	1 (0.0)
Organ donor	8 (0.0)	14 (0.1)
Orthodontic appliance user	1 (0.0)	0
Orthosis user	1 (0.0)	1 (0.0)
Personal relationship issue	1 (0.0)	0
Physical assault	1 (0.0)	1 (0.0)
Postmenopause	1754 (9.3)	1777 (9.4)
Social alcohol drinker	5 (0.0)	3 (0.0)
Substance use	21 (0.1)	14 (0.1)
Tattoo	1 (0.0)	0
Testicular prosthesis user	1 (0.0)	0
Tobacco user	164 (0.9)	136 (0.7)
Trans-sexualism	5 (0.0)	1 (0.0)
Woman of childbearing potential	1 (0.0)	1 (0.0)
Surgical and medical procedures	7281 (38.6)	7278 (38.6)
Abdominal exploration	3 (0.0)	1 (0.0)
Abdominal hernia repair	40 (0.2)	33 (0.2)
Abdominal operation	12 (0.1)	8 (0.0)
Abdominal panniculectomy	1 (0.0)	1 (0.0)
Abdominal wall operation	2 (0.0)	0
Abdominoplasty	60 (0.3)	44 (0.2)
Abortion induced	2 (0.0)	3 (0.0)
Abscess drainage	12 (0.1)	12 (0.1)
Acoustic neuroma removal	4 (0.0)	4 (0.0)
Acupuncture	0	1 (0.0)
Adenoidectomy	94 (0.5)	78 (0.4)
Adenotonsillectomy	24 (0.1)	26 (0.1)
Adhesiolysis	1 (0.0)	3 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Adrenalectomy	4 (0.0)	2 (0.0)
Amblyopia therapy	1 (0.0)	0
Amputation	0	2 (0.0)
Anal fissure excision	1 (0.0)	1 (0.0)
Anal fistula repair	5 (0.0)	4 (0.0)
Anal sphincterotomy	0	1 (0.0)
Aneurysm repair	2 (0.0)	4 (0.0)
Angioplasty	18 (0.1)	14 (0.1)
Ankle arthroplasty	11 (0.1)	12 (0.1)
Ankle operation	53 (0.3)	62 (0.3)
Anorectal operation	6 (0.0)	12 (0.1)
Antibiotic therapy	1 (0.0)	0
Anticoagulant therapy	2 (0.0)	2 (0.0)
Antidepressant therapy	1 (0.0)	0
Antiviral prophylaxis	2 (0.0)	0
Antiviral treatment	1 (0.0)	1 (0.0)
Aortic aneurysm repair	6 (0.0)	3 (0.0)
Aortic stent insertion	1 (0.0)	3 (0.0)
Aortic surgery	2 (0.0)	0
Aortic valve repair	3 (0.0)	2 (0.0)
Aortic valve replacement	20 (0.1)	23 (0.1)
Apicectomy	0	1 (0.0)
Appendicectomy	616 (3.3)	611 (3.2)
Arm amputation	1 (0.0)	0
Arterial aneurysm repair	0	1 (0.0)
Arterial bypass operation	1 (0.0)	0
Arterial graft	0	1 (0.0)
Arterial repair	2 (0.0)	2 (0.0)
Arterial stent insertion	2 (0.0)	3 (0.0)
Arterial therapeutic procedure	2 (0.0)	2 (0.0)
Arteriovenous fistula operation	1 (0.0)	1 (0.0)
Arthrodesis	17 (0.1)	19 (0.1)
Arthroscopic surgery	4 (0.0)	3 (0.0)
Arthrotomy	0	2 (0.0)
Artificial crown procedure	1 (0.0)	2 (0.0)
Artificial insemination	1 (0.0)	0
Artificial urinary sphincter implant	0	2 (0.0)
Astrocytoma surgery	1 (0.0)	0
Atrial appendage closure	1 (0.0)	3 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Atrial septal defect repair	8 (0.0)	11 (0.1)
Axillary lymphadenectomy	2 (0.0)	2 (0.0)
Baker's cyst excision	1 (0.0)	0
Bartholin's cyst removal	3 (0.0)	1 (0.0)
Benign breast lump removal	18 (0.1)	15 (0.1)
Benign tumour excision	6 (0.0)	5 (0.0)
Bilateral orchidectomy	1 (0.0)	2 (0.0)
Bile duct stent insertion	1 (0.0)	0
Bile duct stent removal	1 (0.0)	0
Biliary stent placement	1 (0.0)	0
Birth defect correction	1 (0.0)	0
Bladder calculus removal	3 (0.0)	2 (0.0)
Bladder lesion excision	0	1 (0.0)
Bladder neoplasm surgery	5 (0.0)	4 (0.0)
Bladder operation	4 (0.0)	8 (0.0)
Bladder polypectomy	2 (0.0)	1 (0.0)
Bladder repair	7 (0.0)	12 (0.1)
Blepharoplasty	20 (0.1)	19 (0.1)
Blood donation	0	1 (0.0)
Blood pressure management	1 (0.0)	0
Bone anchored hearing aid implantation	0	2 (0.0)
Bone cyst excision	8 (0.0)	8 (0.0)
Bone debridement	2 (0.0)	1 (0.0)
Bone graft	7 (0.0)	2 (0.0)
Bone lesion excision	27 (0.1)	33 (0.2)
Bone marrow donation	2 (0.0)	2 (0.0)
Bone operation	52 (0.3)	39 (0.2)
Botulinum toxin injection	0	2 (0.0)
Brachytherapy	3 (0.0)	0
Brachytherapy to prostate	3 (0.0)	1 (0.0)
Brain lobectomy	2 (0.0)	0
Brain operation	5 (0.0)	7 (0.0)
Brain stent insertion	1 (0.0)	0
Brain tumour operation	5 (0.0)	5 (0.0)
Breast conserving surgery	118 (0.6)	114 (0.6)
Breast cyst excision	11 (0.1)	12 (0.1)
Breast operation	7 (0.0)	6 (0.0)
Breast prosthesis removal	8 (0.0)	0
Breast reconstruction	16 (0.1)	17 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Breast tumour excision	3 (0.0)	3 (0.0)
Bunion operation	94 (0.5)	101 (0.5)
Burn operation	2 (0.0)	0
Bursa removal	2 (0.0)	2 (0.0)
Bursal operation	0	2 (0.0)
Caecectomy	1 (0.0)	0
Caecopexy	0	1 (0.0)
Caesarean section	520 (2.8)	540 (2.9)
Calcific deposits removal	2 (0.0)	1 (0.0)
Canalith repositioning procedure	0	1 (0.0)
Cancer surgery	58 (0.3)	47 (0.2)
Capsulorrhaphy	1 (0.0)	0
Cardiac ablation	75 (0.4)	73 (0.4)
Cardiac operation	10 (0.1)	11 (0.1)
Cardiac pacemaker insertion	49 (0.3)	57 (0.3)
Cardiac pacemaker removal	0	2 (0.0)
Cardiac pacemaker replacement	1 (0.0)	1 (0.0)
Cardiovascular event prophylaxis	0	1 (0.0)
Cardioversion	8 (0.0)	7 (0.0)
Carotid artery bypass	1 (0.0)	0
Carotid artery stent insertion	4 (0.0)	4 (0.0)
Carotid endarterectomy	7 (0.0)	5 (0.0)
Carotid revascularisation	0	1 (0.0)
Carpal tunnel decompression	128 (0.7)	107 (0.6)
Carpectomy	1 (0.0)	2 (0.0)
Cartilage graft	2 (0.0)	0
Cartilage operation	3 (0.0)	1 (0.0)
Cataract operation	324 (1.7)	323 (1.7)
Catheter placement	0	1 (0.0)
Central venous catheter removal	0	1 (0.0)
Central venous catheterisation	3 (0.0)	1 (0.0)
Cerebral cyst excision	0	1 (0.0)
Cerebral endovascular aneurysm repair	0	1 (0.0)
Cerebrovascular accident prophylaxis	1 (0.0)	0
Cerebrovascular operation	0	1 (0.0)
Cervical conisation	2 (0.0)	1 (0.0)
Cervical laser therapy	2 (0.0)	0
Cervical polypectomy	2 (0.0)	2 (0.0)
Cervicectomy	0	4 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Cervix cautery	1 (0.0)	0
Cervix cryotherapy	3 (0.0)	0
Cervix operation	1 (0.0)	0
Cheilectomy	2 (0.0)	3 (0.0)
Chemical contraception	0	1 (0.0)
Chemotherapy	11 (0.1)	9 (0.0)
Chest tube insertion	4 (0.0)	2 (0.0)
Chest wall operation	0	1 (0.0)
Cholecystectomy	704 (3.7)	692 (3.7)
Cholecystostomy	1 (0.0)	1 (0.0)
Choledocholithotomy	0	1 (0.0)
Cholelithotomy	6 (0.0)	5 (0.0)
Cholesteatoma removal	0	3 (0.0)
Chondrectomy	0	3 (0.0)
Chondroplasty	33 (0.2)	35 (0.2)
Circumcision	7 (0.0)	7 (0.0)
Cleft lip repair	1 (0.0)	0
Cleft palate repair	2 (0.0)	0
Closed fracture manipulation	1 (0.0)	1 (0.0)
Coccygectomy	1 (0.0)	0
Cochlea implant	7 (0.0)	5 (0.0)
Colectomy	53 (0.3)	47 (0.2)
Colectomy total	2 (0.0)	2 (0.0)
Colon operation	10 (0.1)	4 (0.0)
Colostomy	6 (0.0)	5 (0.0)
Colostomy closure	3 (0.0)	1 (0.0)
Colporrhaphy	2 (0.0)	2 (0.0)
Contact lens therapy	1 (0.0)	1 (0.0)
Continuous positive airway pressure	18 (0.1)	11 (0.1)
Contraception	12 (0.1)	16 (0.1)
Contraceptive implant	4 (0.0)	6 (0.0)
Corneal implant	0	1 (0.0)
Corneal operation	3 (0.0)	4 (0.0)
Corneal transplant	14 (0.1)	12 (0.1)
Coronary angioplasty	14 (0.1)	18 (0.1)
Coronary arterial stent insertion	151 (0.8)	151 (0.8)
Coronary artery bypass	98 (0.5)	112 (0.6)
Coronary artery stent removal	1 (0.0)	0
Coronary artery surgery	1 (0.0)	4 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Coronary revascularisation	3 (0.0)	4 (0.0)
Cranial nerve decompression	2 (0.0)	0
Cranial operation	7 (0.0)	5 (0.0)
Craniectomy	0	1 (0.0)
Cranioplasty	1 (0.0)	1 (0.0)
Craniotomy	5 (0.0)	8 (0.0)
Cryotherapy	4 (0.0)	4 (0.0)
Cyst drainage	2 (0.0)	0
Cyst removal	15 (0.1)	11 (0.1)
Cystocele repair	3 (0.0)	2 (0.0)
Cytoreductive surgery	1 (0.0)	1 (0.0)
Dacryocystorhinostomy	3 (0.0)	1 (0.0)
Debridement	7 (0.0)	9 (0.0)
Decompressive craniectomy	0	1 (0.0)
Deep brain stimulation	1 (0.0)	3 (0.0)
Dental care	0	1 (0.0)
Dental cosmetic procedure	1 (0.0)	1 (0.0)
Dental implantation	12 (0.1)	11 (0.1)
Dental operation	3 (0.0)	1 (0.0)
Dental prosthesis placement	3 (0.0)	2 (0.0)
Dermabrasion	1 (0.0)	0
Detoxification	0	1 (0.0)
Diaphragmatic operation	1 (0.0)	1 (0.0)
Diplopia correction	1 (0.0)	0
Diverticulectomy	1 (0.0)	2 (0.0)
Drug delivery device placement	0	2 (0.0)
Drug rehabilitation	1 (0.0)	1 (0.0)
Duodenal operation	1 (0.0)	0
Duodenal switch	0	2 (0.0)
Duodenal ulcer repair	0	1 (0.0)
Duodenectomy	1 (0.0)	0
Dupuytren's contracture operation	4 (0.0)	5 (0.0)
Ear operation	11 (0.1)	7 (0.0)
Ear tube insertion	16 (0.1)	23 (0.1)
Ear tube removal	1 (0.0)	3 (0.0)
Ectopic pregnancy termination	2 (0.0)	1 (0.0)
Elbow operation	20 (0.1)	26 (0.1)
Electrodesiccation	1 (0.0)	0
Endarterectomy	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Endocervical curettage	1 (0.0)	0
Endocrine gland operation	1 (0.0)	0
Endodontic procedure	1 (0.0)	5 (0.0)
Endometrial ablation	105 (0.6)	93 (0.5)
Endometriosis ablation	5 (0.0)	9 (0.0)
Endoscopic sleeve gastroplasty	0	1 (0.0)
Enterorrhaphy	0	1 (0.0)
Enterostomy	1 (0.0)	0
Epidermoid cyst excision	0	1 (0.0)
Epididymal cyst removal	3 (0.0)	0
Epididymal operation	1 (0.0)	0
Epidural injection	1 (0.0)	0
Epiphysiodesis	1 (0.0)	0
Ethmoid sinus surgery	1 (0.0)	0
Eustachian tube operation	1 (0.0)	2 (0.0)
Exeresis	8 (0.0)	9 (0.0)
Explorative laparotomy	6 (0.0)	7 (0.0)
External fixation of fracture	2 (0.0)	0
External nose lesion excision	1 (0.0)	0
Eye excision	3 (0.0)	2 (0.0)
Eye laser surgery	40 (0.2)	20 (0.1)
Eye muscle operation	3 (0.0)	10 (0.1)
Eye operation	22 (0.1)	24 (0.1)
Eyeglasses therapy	1 (0.0)	1 (0.0)
Eyelid cyst removal	0	2 (0.0)
Eyelid operation	7 (0.0)	8 (0.0)
Face lift	12 (0.1)	9 (0.0)
Facet joint block	0	1 (0.0)
Facial lesion excision	0	1 (0.0)
Facial operation	4 (0.0)	1 (0.0)
Fallopian tube operation	4 (0.0)	3 (0.0)
Fascia release	4 (0.0)	4 (0.0)
Fascial operation	2 (0.0)	4 (0.0)
Fasciotomy	8 (0.0)	7 (0.0)
Female genital operation	1 (0.0)	0
Female sterilisation	614 (3.3)	660 (3.5)
Femoral derotation osteotomy	0	1 (0.0)
Femoral hernia repair	1 (0.0)	1 (0.0)
Finger amputation	10 (0.1)	12 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Finger repair operation	6 (0.0)	7 (0.0)
Fistula repair	2 (0.0)	2 (0.0)
Fistulotomy	1 (0.0)	0
Foetal surgery	0	1 (0.0)
Foot amputation	3 (0.0)	1 (0.0)
Foot operation	48 (0.3)	40 (0.2)
Foraminotomy	2 (0.0)	2 (0.0)
Fracture reduction	1 (0.0)	2 (0.0)
Fracture treatment	124 (0.7)	122 (0.6)
Fulguration	0	1 (0.0)
Functional endoscopic sinus surgery	3 (0.0)	4 (0.0)
Gallbladder operation	6 (0.0)	5 (0.0)
Gastrectomy	73 (0.4)	90 (0.5)
Gastric banding	25 (0.1)	28 (0.1)
Gastric banding reversal	3 (0.0)	4 (0.0)
Gastric bypass	124 (0.7)	118 (0.6)
Gastric bypass reversal	0	1 (0.0)
Gastric operation	1 (0.0)	6 (0.0)
Gastric stapling	0	4 (0.0)
Gastric ulcer surgery	0	3 (0.0)
Gastroenterostomy	1 (0.0)	2 (0.0)
Gastrointestinal dilation procedure	0	1 (0.0)
Gastrointestinal surgery	3 (0.0)	1 (0.0)
Gastrointestinal ulcer management	2 (0.0)	1 (0.0)
Gastroplasty	1 (0.0)	4 (0.0)
Gastrostomy	1 (0.0)	0
Gastrostomy tube removal	1 (0.0)	0
Genitourinary operation	1 (0.0)	1 (0.0)
Gingival graft	2 (0.0)	7 (0.0)
Gingival operation	0	2 (0.0)
Glaucoma drainage device placement	1 (0.0)	1 (0.0)
Glaucoma surgery	5 (0.0)	9 (0.0)
Glossectomy	1 (0.0)	1 (0.0)
Haemangioma removal	2 (0.0)	3 (0.0)
Haematoma evacuation	0	2 (0.0)
Haemorrhoid operation	43 (0.2)	48 (0.3)
Haemostasis	2 (0.0)	1 (0.0)
Hair transplant	2 (0.0)	3 (0.0)
Hand amputation	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Hand repair operation	3 (0.0)	5 (0.0)
Hearing aid therapy	0	1 (0.0)
Heart valve replacement	6 (0.0)	8 (0.0)
Hepatectomy	2 (0.0)	2 (0.0)
Hepatitis B immunisation	0	1 (0.0)
Hernia diaphragmatic repair	1 (0.0)	0
Hernia hiatus repair	15 (0.1)	36 (0.2)
Hernia repair	129 (0.7)	123 (0.7)
Herpes zoster immunisation	0	1 (0.0)
High frequency ablation	1 (0.0)	2 (0.0)
Hip arthroplasty	191 (1.0)	181 (1.0)
Hip surgery	26 (0.1)	19 (0.1)
Hormone replacement therapy	11 (0.1)	6 (0.0)
Hormone therapy	1 (0.0)	0
Hospitalisation	1 (0.0)	1 (0.0)
Hydrocele operation	5 (0.0)	4 (0.0)
Hyperbaric oxygen therapy	1 (0.0)	0
Hyperthermic chemotherapy	0	1 (0.0)
Hypophysectomy	1 (0.0)	0
Hysterectomy	1354 (7.2)	1299 (6.9)
Hysteropexy	0	2 (0.0)
Hysterosalpingectomy	0	1 (0.0)
Hysterosalpingo-oophorectomy	14 (0.1)	16 (0.1)
Hysterotomy	0	1 (0.0)
Ileectomy	1 (0.0)	1 (0.0)
Ileostomy	4 (0.0)	1 (0.0)
Ileostomy closure	1 (0.0)	0
Immunoglobulin therapy	1 (0.0)	0
Implantable cardiac monitor insertion	4 (0.0)	5 (0.0)
Implantable defibrillator insertion	12 (0.1)	9 (0.0)
Implantable defibrillator removal	1 (0.0)	1 (0.0)
Implantable defibrillator replacement	2 (0.0)	5 (0.0)
In vitro fertilisation	0	3 (0.0)
Incisional drainage	3 (0.0)	4 (0.0)
Incisional hernia repair	1 (0.0)	8 (0.0)
Infection prophylaxis	0	1 (0.0)
Influenza immunisation	1 (0.0)	4 (0.0)
Infusion	0	1 (0.0)
Inguinal hernia repair	229 (1.2)	240 (1.3)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Injection	0	2 (0.0)
Inner ear operation	2 (0.0)	2 (0.0)
Internal fixation of fracture	8 (0.0)	10 (0.1)
Internal fixation of spine	0	1 (0.0)
Intervertebral disc operation	106 (0.6)	106 (0.6)
Intestinal adhesion lysis	1 (0.0)	0
Intestinal anastomosis	1 (0.0)	1 (0.0)
Intestinal fistula repair	0	1 (0.0)
Intestinal malrotation repair	0	1 (0.0)
Intestinal operation	13 (0.1)	4 (0.0)
Intestinal polypectomy	0	2 (0.0)
Intestinal resection	19 (0.1)	17 (0.1)
Intra-cerebral aneurysm operation	3 (0.0)	1 (0.0)
Intra-thoracic aortic aneurysm repair	0	1 (0.0)
Intra-uterine contraceptive device insertion	26 (0.1)	28 (0.1)
Intracerebral haematoma evacuation	1 (0.0)	0
Intramedullary rod insertion	3 (0.0)	1 (0.0)
Intraocular lens implant	22 (0.1)	36 (0.2)
Intrauterine contraception	22 (0.1)	31 (0.2)
Iridotomy	2 (0.0)	2 (0.0)
Jaw lesion excision	1 (0.0)	0
Jaw operation	24 (0.1)	26 (0.1)
Jejunal operation	0	1 (0.0)
Jejunostomy	0	1 (0.0)
Joint arthroplasty	18 (0.1)	15 (0.1)
Joint debridement	3 (0.0)	4 (0.0)
Joint dislocation reduction	11 (0.1)	10 (0.1)
Joint fluid drainage	1 (0.0)	0
Joint irrigation	0	1 (0.0)
Joint manipulation	0	4 (0.0)
Joint resurfacing surgery	1 (0.0)	0
Joint stabilisation	1 (0.0)	1 (0.0)
Joint surgery	4 (0.0)	7 (0.0)
Keratectomy	1 (0.0)	1 (0.0)
Keratomileusis	108 (0.6)	103 (0.5)
Keratoplasty	2 (0.0)	1 (0.0)
Keratotomy	3 (0.0)	5 (0.0)
Kidney ablation	1 (0.0)	0
Knee arthroplasty	306 (1.6)	303 (1.6)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Knee operation	174 (0.9)	163 (0.9)
Lacrimal duct procedure	3 (0.0)	4 (0.0)
Lacrimal gland operation	0	1 (0.0)
Laparoscopic surgery	4 (0.0)	4 (0.0)
Laparotomy	4 (0.0)	5 (0.0)
Large intestinal polypectomy	52 (0.3)	49 (0.3)
Large intestine anastomosis	1 (0.0)	0
Large intestine operation	1 (0.0)	2 (0.0)
Laryngeal cyst removal	0	1 (0.0)
Laryngeal operation	2 (0.0)	1 (0.0)
Laryngeal polypectomy	0	1 (0.0)
Laryngectomy	1 (0.0)	0
Laser therapy	1 (0.0)	2 (0.0)
Leg amputation	7 (0.0)	7 (0.0)
Lens capsulotomy	4 (0.0)	0
Lens extraction	1 (0.0)	0
Lenticular operation	1 (0.0)	0
Lesion excision	2 (0.0)	1 (0.0)
Ligament operation	145 (0.8)	150 (0.8)
Limb operation	86 (0.5)	94 (0.5)
Limb reattachment surgery	3 (0.0)	1 (0.0)
Limb reconstructive surgery	1 (0.0)	2 (0.0)
Lip operation	1 (0.0)	1 (0.0)
Lipectomy	2 (0.0)	2 (0.0)
Lipoma excision	27 (0.1)	26 (0.1)
Liposuction	10 (0.1)	17 (0.1)
Lithotomy position	0	1 (0.0)
Lithotripsy	34 (0.2)	35 (0.2)
Liver ablation	1 (0.0)	0
Liver operation	0	1 (0.0)
Liver transplant	0	1 (0.0)
Loop electrosurgical excision procedure	12 (0.1)	12 (0.1)
Lower oesophageal sphincter magnetic augmentation	3 (0.0)	3 (0.0)
Lung cyst removal	1 (0.0)	0
Lung lobectomy	6 (0.0)	8 (0.0)
Lung neoplasm surgery	1 (0.0)	0
Lung operation	1 (0.0)	5 (0.0)
Lymphadenectomy	12 (0.1)	21 (0.1)
Lymphoid tissue operation	2 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Lymphoma operation	2 (0.0)	2 (0.0)
Mammary ductectomy	1 (0.0)	1 (0.0)
Mammoplasty	209 (1.1)	187 (1.0)
Manipulation	1 (0.0)	0
Mass excision	2 (0.0)	1 (0.0)
Mastectomy	86 (0.5)	85 (0.5)
Mastoidectomy	2 (0.0)	4 (0.0)
Maxillofacial operation	3 (0.0)	2 (0.0)
Mediastinal operation	0	1 (0.0)
Medical device battery replacement	1 (0.0)	2 (0.0)
Medical device implantation	2 (0.0)	3 (0.0)
Medical device removal	3 (0.0)	4 (0.0)
Meningioma surgery	4 (0.0)	4 (0.0)
Meniscus operation	135 (0.7)	125 (0.7)
Meniscus removal	17 (0.1)	27 (0.1)
Metabolic disorder prophylaxis	0	1 (0.0)
Metabolic surgery	43 (0.2)	35 (0.2)
Metacarpal excision	0	1 (0.0)
Metatarsal excision	1 (0.0)	0
Micrographic skin surgery	37 (0.2)	39 (0.2)
Microsurgery to hand	0	1 (0.0)
Middle ear lesion excision	1 (0.0)	0
Middle ear operation	1 (0.0)	0
Middle ear prosthesis insertion	0	1 (0.0)
Mitral valve repair	10 (0.1)	6 (0.0)
Mitral valve replacement	4 (0.0)	7 (0.0)
Modified radical mastectomy	1 (0.0)	0
Mole excision	14 (0.1)	10 (0.1)
Muscle flap operation	1 (0.0)	0
Muscle graft	0	1 (0.0)
Muscle operation	15 (0.1)	19 (0.1)
Muscle reattachment	2 (0.0)	1 (0.0)
Myectomy	0	3 (0.0)
Myomectomy	24 (0.1)	33 (0.2)
Myopia correction	2 (0.0)	5 (0.0)
Myringotomy	6 (0.0)	12 (0.1)
Nail operation	4 (0.0)	1 (0.0)
Nasal operation	10 (0.1)	13 (0.1)
Nasal polypectomy	14 (0.1)	10 (0.1)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Nasal septal operation	118 (0.6)	115 (0.6)
Nasal sinus irrigation	1 (0.0)	1 (0.0)
Nasopharyngeal surgery	0	1 (0.0)
Neck dissection	3 (0.0)	2 (0.0)
Neck lift	0	1 (0.0)
Neck surgery	19 (0.1)	14 (0.1)
Neoplasm prophylaxis	0	1 (0.0)
Nephrectomy	29 (0.2)	28 (0.1)
Nephrostomy	0	1 (0.0)
Nerve block	5 (0.0)	3 (0.0)
Nerve graft	0	1 (0.0)
Nervous system neoplasm surgery	4 (0.0)	1 (0.0)
Neurectomy	16 (0.1)	12 (0.1)
Neuroprosthesis implantation	2 (0.0)	1 (0.0)
Neurosurgery	1 (0.0)	2 (0.0)
Oesophageal dilation procedure	4 (0.0)	7 (0.0)
Oesophageal lesion excision	0	1 (0.0)
Oesophageal operation	4 (0.0)	3 (0.0)
Oesophagectomy	1 (0.0)	1 (0.0)
Oesophagocardiomyotomy	0	2 (0.0)
Oesophagogastrectomy	1 (0.0)	0
Oesophagogastric fundoplasty	16 (0.1)	12 (0.1)
Oestrogen replacement therapy	1 (0.0)	0
Oestrogen therapy	0	1 (0.0)
Oocyte harvest	2 (0.0)	0
Oophorectomy	64 (0.3)	64 (0.3)
Oophorectomy bilateral	53 (0.3)	40 (0.2)
Open reduction of fracture	42 (0.2)	43 (0.2)
Oral cavity neoplasm surgery	1 (0.0)	2 (0.0)
Oral contraception	1 (0.0)	0
Oral surgery	2 (0.0)	2 (0.0)
Orbit plastic repair	1 (0.0)	0
Orbital decompression	0	1 (0.0)
Orchidectomy	14 (0.1)	14 (0.1)
Orchidopexy	4 (0.0)	3 (0.0)
Orthognathic surgery	8 (0.0)	9 (0.0)
Orthopaedic procedure	6 (0.0)	6 (0.0)
Ossicular operation	0	2 (0.0)
Ossiculoplasty	1 (0.0)	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Ostectomy	9 (0.0)	8 (0.0)
Osteotomy	13 (0.1)	7 (0.0)
Otoplasty	6 (0.0)	5 (0.0)
Ovarian cystectomy	22 (0.1)	34 (0.2)
Ovarian lesion excision	2 (0.0)	2 (0.0)
Ovarian neoplasm surgery	3 (0.0)	1 (0.0)
Ovarian operation	1 (0.0)	2 (0.0)
Ovariocentesis	0	1 (0.0)
Oxygen therapy	0	1 (0.0)
Pain management	0	1 (0.0)
Palatal operation	3 (0.0)	0
Palatoplasty	0	1 (0.0)
Pancreatectomy	1 (0.0)	1 (0.0)
Pancreatic operation	0	1 (0.0)
Pancreatic stent placement	0	1 (0.0)
Pancreatic stent removal	0	1 (0.0)
Pancreaticoduodenectomy	3 (0.0)	4 (0.0)
Papilloma excision	6 (0.0)	2 (0.0)
Paranasal sinus polypectomy	4 (0.0)	8 (0.0)
Paraovarian cystectomy	0	1 (0.0)
Parathyroid gland operation	2 (0.0)	3 (0.0)
Parathyroidectomy	25 (0.1)	14 (0.1)
Parotidectomy	7 (0.0)	1 (0.0)
Patellectomy	0	2 (0.0)
Patent ductus arteriosus repair	1 (0.0)	0
Pelvic floor repair	3 (0.0)	2 (0.0)
Pelvic operation	2 (0.0)	0
Penile prosthesis insertion	7 (0.0)	7 (0.0)
Percutaneous coronary intervention	2 (0.0)	4 (0.0)
Pericardial excision	0	1 (0.0)
Peripheral artery bypass	1 (0.0)	3 (0.0)
Peripheral artery stent insertion	1 (0.0)	0
Peripheral artery surgery	1 (0.0)	0
Peripheral nerve decompression	7 (0.0)	12 (0.1)
Peripheral nerve destruction	0	2 (0.0)
Peripheral nerve neurostimulation	0	2 (0.0)
Peripheral nerve operation	4 (0.0)	16 (0.1)
Peripheral nerve transposition	6 (0.0)	5 (0.0)
Permanent contraceptive tubal implant	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Pharyngeal operation	4 (0.0)	5 (0.0)
Phlebectomy	3 (0.0)	11 (0.1)
Photorefractive keratectomy	6 (0.0)	9 (0.0)
Physiotherapy	1 (0.0)	2 (0.0)
Pilonidal sinus repair	16 (0.1)	16 (0.1)
Pituitary tumour removal	4 (0.0)	4 (0.0)
Plastic surgery	4 (0.0)	2 (0.0)
Plastic surgery to the face	6 (0.0)	11 (0.1)
Platelet rich plasma therapy	1 (0.0)	0
Pleural operation	0	4 (0.0)
Pleurectomy	0	1 (0.0)
Pleurodesis	1 (0.0)	0
Pneumocentesis	0	1 (0.0)
Pneumonectomy	2 (0.0)	4 (0.0)
Polypectomy	21 (0.1)	16 (0.1)
Portal shunt procedure	0	1 (0.0)
Postoperative care	0	1 (0.0)
Precancerous lesion excision	3 (0.0)	2 (0.0)
Preventive surgery	1 (0.0)	0
Proctectomy	0	2 (0.0)
Proctocolectomy	1 (0.0)	0
Prophylaxis	2 (0.0)	1 (0.0)
Prophylaxis against HIV infection	6 (0.0)	2 (0.0)
Prostate ablation	2 (0.0)	4 (0.0)
Prostate cryoablation	1 (0.0)	1 (0.0)
Prostatectomy	76 (0.4)	92 (0.5)
Prostatic operation	11 (0.1)	16 (0.1)
Prostatic urethral lift procedure	2 (0.0)	7 (0.0)
Prosthesis implantation	0	1 (0.0)
Pterygium operation	3 (0.0)	2 (0.0)
Ptosis repair	3 (0.0)	2 (0.0)
Pulmonary bullectomy	1 (0.0)	1 (0.0)
Pulmonary resection	3 (0.0)	2 (0.0)
Pulmonary valve repair	1 (0.0)	0
Pulmonary valve replacement	0	1 (0.0)
Punctal plug insertion	1 (0.0)	0
Pyeloplasty	1 (0.0)	1 (0.0)
Pyloromyotomy	2 (0.0)	2 (0.0)
Pyloroplasty	2 (0.0)	7 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Pylorus dilation procedure	0	1 (0.0)
Rabies immunisation	0	1 (0.0)
Rachiotomy	1 (0.0)	0
Radiation therapy to ear, nose, or throat	1 (0.0)	0
Radical cystectomy	1 (0.0)	0
Radical hysterectomy	3 (0.0)	6 (0.0)
Radical mastectomy	1 (0.0)	0
Radical prostatectomy	13 (0.1)	9 (0.0)
Radiculotomy	1 (0.0)	1 (0.0)
Radioactive iodine therapy	6 (0.0)	3 (0.0)
Radiotherapy	10 (0.1)	6 (0.0)
Radiotherapy to breast	4 (0.0)	4 (0.0)
Radiotherapy to eye	0	1 (0.0)
Radiotherapy to prostate	5 (0.0)	4 (0.0)
Radiotherapy to skin	1 (0.0)	0
Radiotherapy to thyroid	0	3 (0.0)
Rectal fistula repair	1 (0.0)	2 (0.0)
Rectal lesion excision	2 (0.0)	0
Rectal polypectomy	1 (0.0)	0
Rectal prolapse repair	3 (0.0)	2 (0.0)
Rectocele repair	6 (0.0)	4 (0.0)
Reduction of increased intracranial pressure	1 (0.0)	0
Rehabilitation therapy	1 (0.0)	0
Removal of foreign body	6 (0.0)	6 (0.0)
Removal of foreign body from eye	0	2 (0.0)
Removal of foreign body from gastrointestinal tract	1 (0.0)	1 (0.0)
Removal of foreign body from joint	1 (0.0)	0
Removal of foreign body from rectum	1 (0.0)	0
Removal of foreign body from throat	1 (0.0)	0
Renal artery stent placement	0	2 (0.0)
Renal cyst excision	2 (0.0)	2 (0.0)
Renal stone removal	48 (0.3)	52 (0.3)
Renal surgery	2 (0.0)	10 (0.1)
Renal tumour excision	2 (0.0)	1 (0.0)
Retinal operation	17 (0.1)	19 (0.1)
Retinopexy	22 (0.1)	16 (0.1)
Rhinoplasty	62 (0.3)	78 (0.4)
Rib excision	4 (0.0)	1 (0.0)
Rotator cuff repair	174 (0.9)	152 (0.8)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Salivary gland operation	3 (0.0)	5 (0.0)
Salivary gland resection	4 (0.0)	1 (0.0)
Salpingectomy	85 (0.5)	82 (0.4)
Salpingo-oophorectomy	2 (0.0)	1 (0.0)
Salpingo-oophorectomy bilateral	13 (0.1)	5 (0.0)
Salpingo-oophorectomy unilateral	4 (0.0)	1 (0.0)
Salpingoplasty	2 (0.0)	1 (0.0)
Salpingostomy	1 (0.0)	2 (0.0)
Sarcoma excision	1 (0.0)	2 (0.0)
Scar excision	2 (0.0)	7 (0.0)
Scleral buckling surgery	3 (0.0)	0
Sclerotherapy	2 (0.0)	1 (0.0)
Scoliosis surgery	5 (0.0)	3 (0.0)
Scrotal cystectomy	0	1 (0.0)
Scrotal operation	2 (0.0)	0
Sebaceous cyst excision	3 (0.0)	6 (0.0)
Seizure prophylaxis	1 (0.0)	0
Septal myectomy	0	1 (0.0)
Sesamoidectomy	1 (0.0)	2 (0.0)
Shoulder arthroplasty	40 (0.2)	37 (0.2)
Shoulder operation	129 (0.7)	89 (0.5)
Sigmoidectomy	6 (0.0)	6 (0.0)
Simple mastectomy	2 (0.0)	2 (0.0)
Sinuplasty	12 (0.1)	12 (0.1)
Sinus antrostomy	2 (0.0)	0
Sinus operation	74 (0.4)	61 (0.3)
Skin cosmetic procedure	3 (0.0)	5 (0.0)
Skin cryotherapy	1 (0.0)	0
Skin cyst excision	6 (0.0)	1 (0.0)
Skin graft	12 (0.1)	16 (0.1)
Skin lesion removal	18 (0.1)	14 (0.1)
Skin neoplasm excision	161 (0.9)	175 (0.9)
Skin operation	6 (0.0)	5 (0.0)
Skin ulcer excision	0	1 (0.0)
Skull fracture treatment	1 (0.0)	2 (0.0)
Small intestinal resection	7 (0.0)	4 (0.0)
Small intestine operation	4 (0.0)	2 (0.0)
Soft tissue flap operation	0	1 (0.0)
Spermatic cord operation	1 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Sphenoid sinus operation	1 (0.0)	1 (0.0)
Spinal cord operation	1 (0.0)	1 (0.0)
Spinal corpectomy	3 (0.0)	1 (0.0)
Spinal decompression	12 (0.1)	9 (0.0)
Spinal deformity correction	0	1 (0.0)
Spinal fracture treatment	4 (0.0)	2 (0.0)
Spinal fusion surgery	173 (0.9)	168 (0.9)
Spinal laminectomy	77 (0.4)	86 (0.5)
Spinal nerve stimulator implantation	13 (0.1)	12 (0.1)
Spinal nerve stimulator removal	0	1 (0.0)
Spinal operation	110 (0.6)	99 (0.5)
Spinal rod insertion	2 (0.0)	1 (0.0)
Spleen operation	0	1 (0.0)
Splenectomy	19 (0.1)	20 (0.1)
Splenic artery embolisation	1 (0.0)	1 (0.0)
Stapedectomy	4 (0.0)	3 (0.0)
Stem cell therapy	2 (0.0)	1 (0.0)
Stem cell transplant	2 (0.0)	2 (0.0)
Stent placement	19 (0.1)	27 (0.1)
Sterilisation	15 (0.1)	4 (0.0)
Sterilisation reversal	2 (0.0)	3 (0.0)
Sternotomy	0	1 (0.0)
Steroid therapy	1 (0.0)	0
Stomach lesion excision	2 (0.0)	0
Strabismus correction	18 (0.1)	26 (0.1)
Stricturoplasty	1 (0.0)	0
Subdural haematoma evacuation	1 (0.0)	0
Surgery	8 (0.0)	11 (0.1)
Surgical fixation of rib fracture	1 (0.0)	0
Suture insertion	2 (0.0)	2 (0.0)
Suture removal	0	1 (0.0)
Sympathectomy	0	3 (0.0)
Synovectomy	0	1 (0.0)
Synovial cyst removal	31 (0.2)	23 (0.1)
Talipes correction	1 (0.0)	5 (0.0)
Tarsal tunnel decompression	0	1 (0.0)
Temporomandibular joint surgery	6 (0.0)	2 (0.0)
Tendon graft	3 (0.0)	0
Tendon operation	5 (0.0)	9 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Tendon sheath incision	35 (0.2)	24 (0.1)
Tendon transfer	2 (0.0)	2 (0.0)
Tenodesis	1 (0.0)	1 (0.0)
Tenolysis	2 (0.0)	3 (0.0)
Tenonectomy	1 (0.0)	0
Tenoplasty	79 (0.4)	88 (0.5)
Tenotomy	6 (0.0)	17 (0.1)
Testes exploration	1 (0.0)	3 (0.0)
Testicular operation	0	3 (0.0)
Tetralogy of Fallot repair	0	1 (0.0)
Therapeutic aspiration	0	1 (0.0)
Therapeutic embolisation	5 (0.0)	1 (0.0)
Therapeutic nerve ablation	5 (0.0)	1 (0.0)
Therapeutic procedure	4 (0.0)	0
Thermal ablation	1 (0.0)	0
Thoracic operation	3 (0.0)	0
Thoracic outlet surgery	1 (0.0)	0
Thoracoplasty	2 (0.0)	2 (0.0)
Thoracotomy	5 (0.0)	3 (0.0)
Thrombectomy	4 (0.0)	1 (0.0)
Thromboembolectomy	0	1 (0.0)
Thymectomy	1 (0.0)	2 (0.0)
Thyroglossal cyst excision	0	3 (0.0)
Thyroid cystectomy	0	1 (0.0)
Thyroid nodule removal	4 (0.0)	6 (0.0)
Thyroid operation	4 (0.0)	6 (0.0)
Thyroidectomy	139 (0.7)	151 (0.8)
Toe amputation	15 (0.1)	11 (0.1)
Toe operation	24 (0.1)	24 (0.1)
Tongue operation	0	2 (0.0)
Tongue tie operation	0	2 (0.0)
Tonsillectomy	740 (3.9)	687 (3.6)
Tooth extraction	15 (0.1)	15 (0.1)
Tooth repair	0	1 (0.0)
Trabeculectomy	4 (0.0)	4 (0.0)
Trabeculoplasty	0	2 (0.0)
Tracheal fistula repair	1 (0.0)	0
Tracheostomy	3 (0.0)	4 (0.0)
Tracheostomy tube removal	0	1 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Transcatheter aortic valve implantation	1 (0.0)	0
Transfusion	10 (0.1)	9 (0.0)
Transgender hormonal therapy	2 (0.0)	2 (0.0)
Transgender operation	3 (0.0)	1 (0.0)
Transplant	3 (0.0)	1 (0.0)
Transurethral bladder resection	3 (0.0)	0
Transurethral incision of prostate	1 (0.0)	0
Transurethral prostatectomy	16 (0.1)	28 (0.1)
Trapeziectomy	0	2 (0.0)
Tumour excision	6 (0.0)	3 (0.0)
Turbinectomy	9 (0.0)	9 (0.0)
Turbinoplasty	1 (0.0)	1 (0.0)
Tympanoplasty	10 (0.1)	13 (0.1)
Umbilical hernia repair	91 (0.5)	112 (0.6)
Umbilicoplasty	0	1 (0.0)
Ureteral stent insertion	6 (0.0)	9 (0.0)
Ureteral stent removal	1 (0.0)	0
Ureterectomy	0	1 (0.0)
Ureteric calculus removal	1 (0.0)	0
Ureteric operation	2 (0.0)	1 (0.0)
Ureteric repair	1 (0.0)	3 (0.0)
Ureterolithotomy	0	1 (0.0)
Urethral bulking agent injection	1 (0.0)	0
Urethral dilation procedure	1 (0.0)	1 (0.0)
Urethral operation	6 (0.0)	5 (0.0)
Urethral repair	0	4 (0.0)
Urethrectomy	0	1 (0.0)
Urethrotomy	0	1 (0.0)
Urinary bladder suspension	52 (0.3)	47 (0.2)
Urinary control neurostimulator implantation	2 (0.0)	3 (0.0)
Urinary incontinence surgery	2 (0.0)	1 (0.0)
Urinary tract operation	2 (0.0)	3 (0.0)
Urogenital fistula repair	0	1 (0.0)
Uterine cystectomy	1 (0.0)	3 (0.0)
Uterine dilation and curettage	46 (0.2)	57 (0.3)
Uterine irrigation	1 (0.0)	0
Uterine leiomyoma embolisation	2 (0.0)	1 (0.0)
Uterine operation	6 (0.0)	2 (0.0)
Uterine polypectomy	10 (0.1)	3 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Uterine prolapse repair	2 (0.0)	0
Uterine repair	1 (0.0)	0
Uterine tumour excision	1 (0.0)	2 (0.0)
Uvulectomy	4 (0.0)	6 (0.0)
Uvulopalatopharyngoplasty	5 (0.0)	10 (0.1)
Vagal nerve stimulator implantation	1 (0.0)	0
Vaginal fistula repair	0	1 (0.0)
Vaginal operation	5 (0.0)	1 (0.0)
Vaginal pessary insertion	0	1 (0.0)
Vaginal prolapse repair	3 (0.0)	0
Vaginal ring	1 (0.0)	0
Valvuloplasty cardiac	1 (0.0)	1 (0.0)
Varicocele repair	10 (0.1)	11 (0.1)
Varicose vein operation	18 (0.1)	19 (0.1)
Vascular graft	3 (0.0)	7 (0.0)
Vascular operation	1 (0.0)	3 (0.0)
Vascular stent insertion	10 (0.1)	14 (0.1)
Vasectomy	704 (3.7)	663 (3.5)
Vasectomy reversal	3 (0.0)	2 (0.0)
Vena cava filter insertion	5 (0.0)	0
Venous ligation	1 (0.0)	1 (0.0)
Venous operation	2 (0.0)	2 (0.0)
Venous reconstruction	0	1 (0.0)
Venous stent insertion	2 (0.0)	0
Ventricular drainage	1 (0.0)	0
Ventricular septal defect repair	1 (0.0)	1 (0.0)
Ventriculo-peritoneal shunt	1 (0.0)	5 (0.0)
Vertebroplasty	4 (0.0)	5 (0.0)
Vesicoureteral reflux surgery	0	1 (0.0)
Vessel harvesting	1 (0.0)	0
Vision correction operation	5 (0.0)	3 (0.0)
Vitamin supplementation	2 (0.0)	0
Vitrectomy	10 (0.1)	10 (0.1)
Vocal cord nodule removal	0	1 (0.0)
Vocal cord operation	0	2 (0.0)
Vocal cord polypectomy	2 (0.0)	3 (0.0)
Vulval operation	1 (0.0)	0
Vulvectomy	2 (0.0)	2 (0.0)
Weight control	2 (0.0)	0

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Wisdom teeth removal	120 (0.6)	133 (0.7)
Wound closure	6 (0.0)	6 (0.0)
Wound treatment	2 (0.0)	1 (0.0)
Wrist surgery	37 (0.2)	48 (0.3)
Vascular disorders	4978 (26.4)	5025 (26.7)
Aneurysm	4 (0.0)	2 (0.0)
Aneurysm ruptured	0	1 (0.0)
Angiopathy	3 (0.0)	2 (0.0)
Aortic aneurysm	25 (0.1)	27 (0.1)
Aortic arteriosclerosis	39 (0.2)	32 (0.2)
Aortic dilatation	7 (0.0)	7 (0.0)
Aortic disorder	2 (0.0)	2 (0.0)
Aortic stenosis	7 (0.0)	7 (0.0)
Arterial occlusive disease	4 (0.0)	5 (0.0)
Arterial stenosis	1 (0.0)	0
Arterial thrombosis	1 (0.0)	1 (0.0)
Arteriosclerosis	14 (0.1)	16 (0.1)
Arteriovenous fistula	1 (0.0)	0
Capillary fragility	0	1 (0.0)
Collateral circulation	0	1 (0.0)
Deep vein thrombosis	66 (0.3)	71 (0.4)
Diabetic vascular disorder	1 (0.0)	2 (0.0)
Embolism	0	1 (0.0)
Embolism arterial	1 (0.0)	0
Embolism venous	2 (0.0)	1 (0.0)
Endocrine hypertension	0	1 (0.0)
Essential hypertension	89 (0.5)	74 (0.4)
Fibromuscular dysplasia	0	2 (0.0)
Giant cell arteritis	0	1 (0.0)
Haematoma	1 (0.0)	2 (0.0)
Haemorrhage	1 (0.0)	1 (0.0)
Hot flush	119 (0.6)	133 (0.7)
Hypertension	4601 (24.4)	4638 (24.6)
Hypotension	19 (0.1)	10 (0.1)
Infarction	1 (0.0)	2 (0.0)
Intermittent claudication	7 (0.0)	3 (0.0)
Ischaemia	1 (0.0)	0
Lymphoedema	8 (0.0)	8 (0.0)
May-Thurner syndrome	2 (0.0)	2 (0.0)

14.287. Medical History – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18860) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=18846) n[b] (%)
Microangiopathy	1 (0.0)	0
Orthostatic hypotension	2 (0.0)	5 (0.0)
Peripheral arterial occlusive disease	13 (0.1)	11 (0.1)
Peripheral artery aneurysm	2 (0.0)	5 (0.0)
Peripheral artery thrombosis	1 (0.0)	0
Peripheral vascular disorder	17 (0.1)	20 (0.1)
Peripheral venous disease	15 (0.1)	22 (0.1)
Phlebitis	4 (0.0)	0
Phlebosclerosis	1 (0.0)	0
Poor peripheral circulation	1 (0.0)	4 (0.0)
Post thrombotic syndrome	0	1 (0.0)
Prehypertension	1 (0.0)	5 (0.0)
Raynaud's phenomenon	24 (0.1)	37 (0.2)
Spider vein	1 (0.0)	0
Subclavian artery aneurysm	1 (0.0)	0
Subclavian artery occlusion	1 (0.0)	0
Subclavian vein thrombosis	1 (0.0)	1 (0.0)
Thrombophlebitis	1 (0.0)	4 (0.0)
Thrombosis	22 (0.1)	14 (0.1)
Varicose vein	61 (0.3)	71 (0.4)
Vasculitis	1 (0.0)	0
Vena cava thrombosis	2 (0.0)	0
Venous haemorrhage	0	1 (0.0)
Venous thrombosis	3 (0.0)	1 (0.0)
Venous thrombosis limb	1 (0.0)	1 (0.0)
White coat hypertension	9 (0.0)	4 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:04) Source Data: admh Table Generation: 24NOV2020 (11:16)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 EUA FAEF RR/admh s002 p3 saf

14.288. Baseline Charlson Comorbidities – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18860)	Placebo (N[a]=18846)	Total (N[a]=37706)
Charlson Comorbidity Index Category	n[b] (%)	n[b] (%)	n[b] (%)
Subjects with any Charlson comorbidity	3934 (20.9)	3809 (20.2)	7743 (20.5)
AIDS/HIV	59 (0.3)	62 (0.3)	121 (0.3)
Any Malignancy	733 (3.9)	662 (3.5)	1395 (3.7)
Cerebrovascular Disease	195 (1.0)	166 (0.9)	361 (1.0)
Chronic Pulmonary Disease	1478 (7.8)	1453 (7.7)	2931 (7.8)
Congestive Heart Failure	88 (0.5)	83 (0.4)	171 (0.5)
Dementia	7 (0.0)	11 (0.1)	18 (0.0)
Diabetes With Chronic Complication	99 (0.5)	113 (0.6)	212 (0.6)
Diabetes Without Chronic Complication	1473 (7.8)	1478 (7.8)	2951 (7.8)
Hemiplegia or Paraplegia	13 (0.1)	21 (0.1)	34 (0.1)
Leukemia	12 (0.1)	10 (0.1)	22 (0.1)
Lymphoma	22 (0.1)	32 (0.2)	54 (0.1)
Metastatic Solid Tumor	4 (0.0)	3 (0.0)	7 (0.0)
Mild Liver Disease	125 (0.7)	89 (0.5)	214 (0.6)
Moderate or Severe Liver Disease	1 (0.0)	2 (0.0)	3 (0.0)
Myocardial Infarction	194 (1.0)	188 (1.0)	382 (1.0)
Peptic Ulcer Disease	52 (0.3)	71 (0.4)	123 (0.3)
Peripheral Vascular Disease	124 (0.7)	117 (0.6)	241 (0.6)
Renal Disease	123 (0.7)	133 (0.7)	256 (0.7)
Rheumatic Disease	62 (0.3)	56 (0.3)	118 (0.3)

Note: MedDRA (v23.1) coding dictionary applied.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. 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: 17NOV2020 (10:04) Source Data: admh Table Generation: 17NOV2020 (16:21)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/admh_s002_risk_p3_saf

14.289. Baseline Charlson Comorbidities, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=10889)	Placebo (N[a]=10896)	Total (N[a]=21785)
Charlson Comorbidity Index Category	n[b] (%)	n[b] (%)	n[b] (%)
Subjects with any Charlson comorbidity	1424 (13.1)	1369 (12.6)	2793 (12.8)
AIDS/HIV	48 (0.4)	46 (0.4)	94 (0.4)
Any Malignancy	121 (1.1)	102 (0.9)	223 (1.0)
Cerebrovascular Disease	36 (0.3)	33 (0.3)	69 (0.3)
Chronic Pulmonary Disease	792 (7.3)	741 (6.8)	1533 (7.0)
Congestive Heart Failure	19 (0.2)	15 (0.1)	34 (0.2)
Diabetes With Chronic Complication	17 (0.2)	15 (0.1)	32 (0.1)
Diabetes Without Chronic Complication	394 (3.6)	406 (3.7)	800 (3.7)
Hemiplegia or Paraplegia	3 (0.0)	13 (0.1)	16 (0.1)
Leukemia	4 (0.0)	3 (0.0)	7 (0.0)
Lymphoma	3 (0.0)	10 (0.1)	13 (0.1)
Metastatic Solid Tumor	1 (0.0)	0	1 (0.0)
Mild Liver Disease	47 (0.4)	47 (0.4)	94 (0.4)
Myocardial Infarction	29 (0.3)	22 (0.2)	51 (0.2)
Peptic Ulcer Disease	17 (0.2)	24 (0.2)	41 (0.2)
Peripheral Vascular Disease	7 (0.1)	8 (0.1)	15 (0.1)
Renal Disease	18 (0.2)	16 (0.1)	34 (0.2)
Rheumatic Disease	22 (0.2)	21 (0.2)	43 (0.2)

Note: MedDRA (v23.1) coding dictionary applied.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. 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: 17NOV2020 (10:04) Source Data: admh Table Generation: 17NOV2020 (16:25)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/admh s002 risk age p3 saf

14.290. Baseline Charlson Comorbidities, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
Charlson Comorbidity Index Category	BNT162b2 (30 µg) (N[a]=7971) n[b] (%)	Placebo (N[a]=7950) n[b] (%)	Total (N[a]=15921) n[b] (%)
Subjects with any Charlson comorbidity	2510 (31.5)	2440 (30.7)	4950 (31.1)
AIDS/HIV	11 (0.1)	16 (0.2)	27 (0.2)
Any Malignancy	612 (7.7)	560 (7.0)	1172 (7.4)
Cerebrovascular Disease	159 (2.0)	133 (1.7)	292 (1.8)
Chronic Pulmonary Disease	686 (8.6)	712 (9.0)	1398 (8.8)
Congestive Heart Failure	69 (0.9)	68 (0.9)	137 (0.9)
Dementia	7 (0.1)	11 (0.1)	18 (0.1)
Diabetes With Chronic Complication	82 (1.0)	98 (1.2)	180 (1.1)
Diabetes Without Chronic Complication	1079 (13.5)	1072 (13.5)	2151 (13.5)
Hemiplegia or Paraplegia	10 (0.1)	8 (0.1)	18 (0.1)
Leukemia	8 (0.1)	7 (0.1)	15 (0.1)
Lymphoma	19 (0.2)	22 (0.3)	41 (0.3)
Metastatic Solid Tumor	3 (0.0)	3 (0.0)	6 (0.0)
Mild Liver Disease	78 (1.0)	42 (0.5)	120 (0.8)
Moderate or Severe Liver Disease	1 (0.0)	2 (0.0)	3 (0.0)
Myocardial Infarction	165 (2.1)	166 (2.1)	331 (2.1)
Peptic Ulcer Disease	35 (0.4)	47 (0.6)	82 (0.5)
Peripheral Vascular Disease	117 (1.5)	109 (1.4)	226 (1.4)
Renal Disease	105 (1.3)	117 (1.5)	222 (1.4)
Rheumatic Disease	40 (0.5)	35 (0.4)	75 (0.5)

Note: MedDRA (v23.1) coding dictionary applied.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. 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: 17NOV2020 (10:04) Source Data: admh Table Generation: 17NOV2020 (16:25)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/admh s002 risk age p3 saf

14.291. Demographic Characteristics – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Placebo (N[a]=21728) n[b] (%)	Total (N[a]=43448) n[b] (%)
Sex			
Male	11183 (51.5)	10942 (50.4)	22125 (50.9)
Female	10537 (48.5)	10786 (49.6)	21323 (49.1)
Race			
White	17839 (82.1)	17857 (82.2)	35696 (82.2)
Black or African American	2091 (9.6)	2107 (9.7)	4198 (9.7)
American Indian or Alaska native	160 (0.7)	159 (0.7)	319 (0.7)
Asian	934 (4.3)	930 (4.3)	1864 (4.3)
Native Hawaiian or other Pacific Islander	57 (0.3)	31 (0.1)	88 (0.2)
Multiracial	536 (2.5)	514 (2.4)	1050 (2.4)
Not reported	103 (0.5)	130 (0.6)	233 (0.5)
Ethnicity			
Hispanic/Latino	5672 (26.1)	5668 (26.1)	11340 (26.1)
Non-Hispanic/non-Latino	15928 (73.3)	15940 (73.4)	31868 (73.3)
Not reported	120 (0.6)	120 (0.6)	240 (0.6)
Country			
Argentina	2883 (13.3)	2881 (13.3)	5764 (13.3)
Brazil	1452 (6.7)	1448 (6.7)	2900 (6.7)
Germany	249 (1.1)	250 (1.2)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	16486 (75.9)	16501 (75.9)	32987 (75.9)
Age group			
16-55 Years	12780 (58.8)	12822 (59.0)	25602 (58.9)
>55 Years	8940 (41.2)	8906 (41.0)	17846 (41.1)
Age at vaccination (years)			
Mean (SD)	50.1 (15.68)	49.9 (15.78)	50.0 (15.73)
Median	51.0	51.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	247 (1.1)	275 (1.3)	522 (1.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	6363 (29.3)	6357 (29.3)	12720 (29.3)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	7614 (35.1)	7513 (34.6)	15127 (34.8)
Obese (≥30.0 kg/m^2)	7488 (34.5)	7575 (34.9)	15063 (34.7)
Missing	8 (0.0)	8 (0.0)	16 (0.0)

14.291. Demographic Characteristics – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Placebo (N[a]=21728) n[b] (%)	Total (N[a]=43448) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (16:23)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s005_demo_all_p3_saf

14.292. Demographic Characteristics, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=12780) n[b] (%)	Placebo (N[a]=12822) n[b] (%)	Total (N[a]=25602) n[b] (%)
Sex			
Male	6509 (50.9)	6266 (48.9)	12775 (49.9)
Female	6271 (49.1)	6556 (51.1)	12827 (50.1)
Race			
White	10009 (78.3)	10050 (78.4)	20059 (78.3)
Black or African American	1420 (11.1)	1424 (11.1)	2844 (11.1)
American Indian or Alaska native	118 (0.9)	111 (0.9)	229 (0.9)
Asian	686 (5.4)	700 (5.5)	1386 (5.4)
Native Hawaiian or other Pacific Islander	42 (0.3)	20 (0.2)	62 (0.2)
Multiracial	424 (3.3)	420 (3.3)	844 (3.3)
Not reported	81 (0.6)	97 (0.8)	178 (0.7)
Ethnicity			
Hispanic/Latino	4017 (31.4)	3996 (31.2)	8013 (31.3)
Non-Hispanic/non-Latino	8699 (68.1)	8761 (68.3)	17460 (68.2)
Not reported	64 (0.5)	65 (0.5)	129 (0.5)
Country			
Argentina	1975 (15.5)	1973 (15.4)	3948 (15.4)
Brazil	1191 (9.3)	1189 (9.3)	2380 (9.3)
Germany	134 (1.0)	139 (1.1)	273 (1.1)
South Africa	328 (2.6)	330 (2.6)	658 (2.6)
Turkey	190 (1.5)	197 (1.5)	387 (1.5)
USA	8962 (70.1)	8994 (70.1)	17956 (70.1)
Age at vaccination (years)			
Mean (SD)	39.4 (10.40)	39.1 (10.43)	39.3 (10.42)
Median	40.5	40.0	40.0
Min, max	(16, 55)	(16, 55)	(16, 55)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	175 (1.4)	194 (1.5)	369 (1.4)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	4044 (31.6)	4105 (32.0)	8149 (31.8)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	4205 (32.9)	4141 (32.3)	8346 (32.6)
Obese (≥30.0 kg/m^2)	4352 (34.1)	4376 (34.1)	8728 (34.1)
Missing	4 (0.0)	6 (0.0)	10 (0.0)

14.292. Demographic Characteristics, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=12780) n^b (%)	Placebo (N^a=12822) n^b (%)	Total (N^a=25602) n^b (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s005_demo_all_age_p3_saf

14.293. Demographic Characteristics, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=8940) n[b] (%)	Placebo (N[a]=8906) n[b] (%)	Total (N[a]=17846) n[b] (%)
Sex			
Male	4674 (52.3)	4676 (52.5)	9350 (52.4)
Female	4266 (47.7)	4230 (47.5)	8496 (47.6)
Race			
White	7830 (87.6)	7807 (87.7)	15637 (87.6)
Black or African American	671 (7.5)	683 (7.7)	1354 (7.6)
American Indian or Alaska native	42 (0.5)	48 (0.5)	90 (0.5)
Asian	248 (2.8)	230 (2.6)	478 (2.7)
Native Hawaiian or other Pacific Islander	15 (0.2)	11 (0.1)	26 (0.1)
Multiracial	112 (1.3)	94 (1.1)	206 (1.2)
Not reported	22 (0.2)	33 (0.4)	55 (0.3)
Ethnicity			
Hispanic/Latino	1655 (18.5)	1672 (18.8)	3327 (18.6)
Non-Hispanic/non-Latino	7229 (80.9)	7179 (80.6)	14408 (80.7)
Not reported	56 (0.6)	55 (0.6)	111 (0.6)
Country			
Argentina	908 (10.2)	908 (10.2)	1816 (10.2)
Brazil	261 (2.9)	259 (2.9)	520 (2.9)
Germany	115 (1.3)	111 (1.2)	226 (1.3)
South Africa	73 (0.8)	69 (0.8)	142 (0.8)
Turkey	59 (0.7)	52 (0.6)	111 (0.6)
USA	7524 (84.2)	7507 (84.3)	15031 (84.2)
Age at vaccination (years)			
Mean (SD)	65.5 (6.52)	65.4 (6.51)	65.5 (6.52)
Median	65.0	65.0	65.0
Min, max	(56, 89)	(56, 91)	(56, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	72 (0.8)	81 (0.9)	153 (0.9)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	2319 (25.9)	2252 (25.3)	4571 (25.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	3409 (38.1)	3372 (37.9)	6781 (38.0)
Obese (≥30.0 kg/m^2)	3136 (35.1)	3199 (35.9)	6335 (35.5)
Missing	4 (0.0)	2 (0.0)	6 (0.0)

14.293. Demographic Characteristics, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=8940) n[b] (%)	Placebo (N[a]=8906) n[b] (%)	Total (N[a]=17846) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:32)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adsl_s005_demo_all_age_p3_saf

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Any medical history	17656 (81.3)	17758 (81.7)
**Uncoded Body System or Organ Class	12 (0.1)	8 (0.0)
ALLERGY, AZITHROMYCIN	0	1 (0.0)
ALLERGY, ENVIRONMENTAL	0	1 (0.0)
Allergic Rhinitis	1 (0.0)	0
BENIGN PROSTATE HYPERPLASIA	0	1 (0.0)
Benign prostatic hyperplasia	1 (0.0)	0
Childhood seizure	1 (0.0)	0
EPICONDYLOTOMY, ELBOW, RIGHT	0	1 (0.0)
Elevated Prostate-Specific Antigen	1 (0.0)	0
Erectile Dysfunction	1 (0.0)	0
GLAUCOMA, BILATERAL	0	1 (0.0)
HYPERLIPIDEMIA	0	1 (0.0)
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	0	1 (0.0)
IRRATATABLE BOWEL SYNDROME, CONSTIPATION TYPE	0	1 (0.0)
Implantable Cardioverter Defibrillator	1 (0.0)	0
Isoniazid treatment	0	1 (0.0)
MACULAR DEGENERATION, AGE RELATED, BILATERAL	0	1 (0.0)
Neurologic Injury associated with moderate motor and coordination deficit.	1 (0.0)	0
Nodular Prostate	1 (0.0)	0
OSTEOARTHRITIS	0	1 (0.0)
OSTEOPOROSIS, HIP, RIGHT	1 (0.0)	0
PLANTAR NERVE NEUROMA, LEFT	0	1 (0.0)
POSTIONAL VERTIGO, BENIGN	0	1 (0.0)
Seasonal allergies	1 (0.0)	0
Surgical Repair of Foot Drop	0	1 (0.0)
Testicular Hypofunction	1 (0.0)	0
Testicular Hypogonadism	1 (0.0)	0
VASCULAR CIRCULATION LEG, LEFT, WORSENING	0	1 (0.0)
VESTIBULOPATHY, RIGHT EAR	0	1 (0.0)
bilateral tympanostomy tubes	0	1 (0.0)
intermittent headaches	1 (0.0)	0
menorrhagia	1 (0.0)	0
migraine headaches with aura	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
migraines	1 (0.0)	0
tramadol allergy	1 (0.0)	0
trazadone allergy	1 (0.0)	0
Blood and lymphatic system disorders	330 (1.5)	337 (1.6)
Activated protein C resistance	1 (0.0)	0
Anaemia	196 (0.9)	215 (1.0)
Anaemia macrocytic	2 (0.0)	0
Anaemia vitamin B12 deficiency	2 (0.0)	0
Antiphospholipid syndrome	4 (0.0)	5 (0.0)
Blood loss anaemia	1 (0.0)	1 (0.0)
Coagulopathy	2 (0.0)	3 (0.0)
Eosinophilia	1 (0.0)	0
Haemolytic anaemia	0	3 (0.0)
Haemolytic uraemic syndrome	1 (0.0)	0
Hypercoagulation	4 (0.0)	2 (0.0)
Hypochromic anaemia	1 (0.0)	0
Immune thrombocytopenia	6 (0.0)	6 (0.0)
Increased tendency to bruise	2 (0.0)	2 (0.0)
Iron deficiency anaemia	53 (0.2)	55 (0.3)
Leukocytosis	3 (0.0)	0
Leukopenia	5 (0.0)	6 (0.0)
Lymphadenitis	0	1 (0.0)
Lymphadenopathy	10 (0.0)	9 (0.0)
Lymphatic disorder	1 (0.0)	0
Lymphocytosis	0	1 (0.0)
Lymphoid tissue hyperplasia	1 (0.0)	0
Macrocytosis	0	2 (0.0)
Mast cell activation syndrome	1 (0.0)	0
Mastocytosis	2 (0.0)	0
Microcytic anaemia	1 (0.0)	1 (0.0)
Microcytosis	0	1 (0.0)
Monoclonal B-cell lymphocytosis	0	1 (0.0)
Neutropenia	1 (0.0)	4 (0.0)
Normocytic anaemia	0	1 (0.0)
Pancytopenia	0	2 (0.0)
Pernicious anaemia	7 (0.0)	2 (0.0)
Polycythaemia	5 (0.0)	3 (0.0)
Pseudolymphoma	0	1 (0.0)
Spherocytic anaemia	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Splenic lesion	1 (0.0)	0
Splenomegaly	1 (0.0)	2 (0.0)
Thrombocytopenia	17 (0.1)	15 (0.1)
Thrombocytosis	3 (0.0)	2 (0.0)
Thrombotic thrombocytopenic purpura	0	1 (0.0)
Thymic cyst	1 (0.0)	0
Cardiac disorders	1264 (5.8)	1222 (5.6)
Acute cardiac event	0	1 (0.0)
Acute coronary syndrome	0	2 (0.0)
Acute myocardial infarction	41 (0.2)	23 (0.1)
Adams-Stokes syndrome	1 (0.0)	0
Angina pectoris	49 (0.2)	41 (0.2)
Angina unstable	2 (0.0)	3 (0.0)
Aortic valve disease	2 (0.0)	2 (0.0)
Aortic valve incompetence	12 (0.1)	13 (0.1)
Aortic valve prolapse	1 (0.0)	0
Aortic valve sclerosis	1 (0.0)	0
Aortic valve stenosis	9 (0.0)	7 (0.0)
Arrhythmia	76 (0.3)	82 (0.4)
Arrhythmia supraventricular	1 (0.0)	2 (0.0)
Arteriosclerosis coronary artery	22 (0.1)	24 (0.1)
Arteriospasm coronary	2 (0.0)	4 (0.0)
Atrial fibrillation	246 (1.1)	237 (1.1)
Atrial flutter	17 (0.1)	17 (0.1)
Atrial tachycardia	9 (0.0)	3 (0.0)
Atrioventricular block	3 (0.0)	5 (0.0)
Atrioventricular block complete	3 (0.0)	5 (0.0)
Atrioventricular block first degree	5 (0.0)	5 (0.0)
Atrioventricular block second degree	1 (0.0)	0
Bifascicular block	0	1 (0.0)
Bradyarrhythmia	0	1 (0.0)
Bradycardia	24 (0.1)	22 (0.1)
Bundle branch block	0	2 (0.0)
Bundle branch block left	12 (0.1)	11 (0.1)
Bundle branch block right	11 (0.1)	16 (0.1)
Cardiac amyloidosis	1 (0.0)	0
Cardiac aneurysm	0	2 (0.0)
Cardiac arrest	2 (0.0)	2 (0.0)
Cardiac disorder	7 (0.0)	7 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Cardiac failure	14 (0.1)	8 (0.0)
Cardiac failure acute	1 (0.0)	1 (0.0)
Cardiac failure chronic	5 (0.0)	3 (0.0)
Cardiac failure congestive	59 (0.3)	49 (0.2)
Cardiac flutter	0	2 (0.0)
Cardiac septal hypertrophy	1 (0.0)	0
Cardiac valve disease	3 (0.0)	1 (0.0)
Cardiac ventricular thrombosis	1 (0.0)	0
Cardio-respiratory arrest	0	1 (0.0)
Cardiomegaly	3 (0.0)	3 (0.0)
Cardiomyopathy	18 (0.1)	14 (0.1)
Cardiomyopathy alcoholic	0	1 (0.0)
Cardiovascular disorder	5 (0.0)	9 (0.0)
Chronic left ventricular failure	1 (0.0)	2 (0.0)
Congestive cardiomyopathy	3 (0.0)	3 (0.0)
Coronary artery aneurysm	0	1 (0.0)
Coronary artery disease	291 (1.3)	305 (1.4)
Coronary artery dissection	2 (0.0)	0
Coronary artery insufficiency	2 (0.0)	5 (0.0)
Coronary artery occlusion	21 (0.1)	12 (0.1)
Coronary artery stenosis	2 (0.0)	2 (0.0)
Diastolic dysfunction	0	3 (0.0)
Extrasystoles	4 (0.0)	1 (0.0)
Heart valve incompetence	2 (0.0)	1 (0.0)
Hypertensive heart disease	0	4 (0.0)
Ischaemic cardiomyopathy	2 (0.0)	1 (0.0)
Left ventricular dysfunction	0	1 (0.0)
Left ventricular failure	1 (0.0)	8 (0.0)
Left ventricular hypertrophy	8 (0.0)	7 (0.0)
Microvascular coronary artery disease	1 (0.0)	0
Mitral valve disease	6 (0.0)	2 (0.0)
Mitral valve incompetence	22 (0.1)	16 (0.1)
Mitral valve prolapse	74 (0.3)	52 (0.2)
Mitral valve stenosis	3 (0.0)	0
Myocardial infarction	157 (0.7)	181 (0.8)
Myocardial ischaemia	6 (0.0)	6 (0.0)
Myocarditis	1 (0.0)	0
Palpitations	58 (0.3)	49 (0.2)
Pericardial effusion	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Pericarditis	5 (0.0)	5 (0.0)
Postural orthostatic tachycardia syndrome	5 (0.0)	2 (0.0)
Prinzmetal angina	1 (0.0)	2 (0.0)
Pulmonary valve incompetence	1 (0.0)	0
Pulmonary valve stenosis	2 (0.0)	2 (0.0)
Rheumatic heart disease	1 (0.0)	0
Right atrial enlargement	0	1 (0.0)
Right ventricular failure	1 (0.0)	0
Silent myocardial infarction	1 (0.0)	0
Sinus arrhythmia	6 (0.0)	3 (0.0)
Sinus bradycardia	4 (0.0)	8 (0.0)
Sinus node dysfunction	9 (0.0)	2 (0.0)
Sinus tachycardia	8 (0.0)	13 (0.1)
Stress cardiomyopathy	3 (0.0)	2 (0.0)
Supraventricular extrasystoles	9 (0.0)	9 (0.0)
Supraventricular tachycardia	60 (0.3)	46 (0.2)
Tachyarrhythmia	3 (0.0)	1 (0.0)
Tachycardia	32 (0.1)	37 (0.2)
Tachycardia paroxysmal	3 (0.0)	3 (0.0)
Tricuspid valve disease	1 (0.0)	1 (0.0)
Tricuspid valve incompetence	1 (0.0)	3 (0.0)
Ventricular arrhythmia	1 (0.0)	1 (0.0)
Ventricular extrasystoles	48 (0.2)	53 (0.2)
Ventricular fibrillation	2 (0.0)	1 (0.0)
Ventricular tachycardia	10 (0.0)	7 (0.0)
Wolff-Parkinson-White syndrome	9 (0.0)	13 (0.1)
Congenital, familial and genetic disorders	397 (1.8)	405 (1.9)
Acrocephalosyndactyly	1 (0.0)	0
Adrenogenital syndrome	1 (0.0)	0
Alpha-1 antitrypsin deficiency	3 (0.0)	0
Amniotic band syndrome	1 (0.0)	0
Aniridia	0	1 (0.0)
Ankyloglossia congenital	0	1 (0.0)
Anomalous pulmonary venous connection	1 (0.0)	1 (0.0)
Anomaly of external ear congenital	0	1 (0.0)
Antithrombin III deficiency	0	2 (0.0)
Arnold-Chiari malformation	7 (0.0)	4 (0.0)
Arterial tortuosity syndrome	1 (0.0)	0
Arteriovenous malformation	5 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Asplenia	1 (0.0)	0
Asymptomatic gene carrier	1 (0.0)	0
Ataxia telangiectasia	0	1 (0.0)
Atrial septal defect	9 (0.0)	16 (0.1)
BRCA1 gene mutation	0	1 (0.0)
BRCA2 gene mutation	0	2 (0.0)
Benign familial pemphigus	1 (0.0)	0
Bicuspid aortic valve	12 (0.1)	4 (0.0)
Bicuspid pulmonary valve	0	1 (0.0)
Blindness congenital	2 (0.0)	0
Brachymetatarsia	0	1 (0.0)
Branchial cyst	1 (0.0)	0
Breast malformation	1 (0.0)	0
Cancer gene carrier	1 (0.0)	3 (0.0)
Carpus curvus	0	1 (0.0)
Cataract congenital	2 (0.0)	1 (0.0)
Cerebral palsy	2 (0.0)	10 (0.0)
Cerebrovascular arteriovenous malformation	0	3 (0.0)
Checkpoint kinase 2 gene mutation	1 (0.0)	0
Chediak-Higashi syndrome	1 (0.0)	0
Cleft lip	0	2 (0.0)
Cleft palate	4 (0.0)	4 (0.0)
Coarctation of the aorta	1 (0.0)	1 (0.0)
Colour blindness	2 (0.0)	1 (0.0)
Congenital absence of vertebra	1 (0.0)	0
Congenital anomaly	1 (0.0)	1 (0.0)
Congenital aortic anomaly	0	1 (0.0)
Congenital aortic stenosis	2 (0.0)	1 (0.0)
Congenital benign neoplasm	0	1 (0.0)
Congenital cerebrovascular anomaly	1 (0.0)	1 (0.0)
Congenital coronary artery malformation	0	1 (0.0)
Congenital cystic kidney disease	11 (0.1)	4 (0.0)
Congenital cystic lung	2 (0.0)	0
Congenital ectodermal dysplasia	0	1 (0.0)
Congenital eye disorder	1 (0.0)	1 (0.0)
Congenital flat feet	1 (0.0)	0
Congenital foot malformation	0	2 (0.0)
Congenital hand malformation	0	1 (0.0)
Congenital hearing disorder	2 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Congenital heart valve disorder	0	2 (0.0)
Congenital hydronephrosis	0	1 (0.0)
Congenital hypothyroidism	1 (0.0)	1 (0.0)
Congenital intestinal malformation	0	2 (0.0)
Congenital jaw malformation	4 (0.0)	2 (0.0)
Congenital joint malformation	2 (0.0)	1 (0.0)
Congenital lymphoedema	0	2 (0.0)
Congenital multiplex arthrogryposis	2 (0.0)	0
Congenital musculoskeletal anomaly	2 (0.0)	1 (0.0)
Congenital myopathy	0	1 (0.0)
Congenital myopia	1 (0.0)	0
Congenital neoplasm	0	1 (0.0)
Congenital osteodystrophy	1 (0.0)	0
Congenital pulmonary valve disorder	1 (0.0)	0
Congenital renal disorder	1 (0.0)	1 (0.0)
Congenital scoliosis	1 (0.0)	0
Congenital skin disorder	0	1 (0.0)
Congenital small intestinal atresia	0	1 (0.0)
Congenital spinal cord anomaly	1 (0.0)	0
Congenital spinal stenosis	1 (0.0)	0
Congenital spondylolisthesis	1 (0.0)	0
Congenital toxoplasmosis	1 (0.0)	0
Congenital ureteric anomaly	0	1 (0.0)
Congenital urethral anomaly	0	1 (0.0)
Congenital uterine anomaly	1 (0.0)	3 (0.0)
Congenital vas deferens absence	1 (0.0)	0
Corneal dystrophy	13 (0.1)	9 (0.0)
Cornelia de Lange syndrome	0	1 (0.0)
Craniosynostosis	0	1 (0.0)
Cryptorchism	3 (0.0)	4 (0.0)
Cystic fibrosis	0	2 (0.0)
Deafness congenital	2 (0.0)	2 (0.0)
Dermoid cyst	1 (0.0)	1 (0.0)
Developmental glaucoma	0	1 (0.0)
Developmental hip dysplasia	4 (0.0)	9 (0.0)
Dextrocardia	0	1 (0.0)
Diverticulitis Meckel's	1 (0.0)	0
Dolichocolon	2 (0.0)	1 (0.0)
Dopa-responsive dystonia	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Duodenal atresia	1 (0.0)	0
Dysmorphism	2 (0.0)	1 (0.0)
Dysplastic naevus syndrome	1 (0.0)	0
Eagle Barrett syndrome	1 (0.0)	0
Ear malformation	2 (0.0)	0
Ectopic kidney	1 (0.0)	0
Ectrodactyly	1 (0.0)	0
Ehlers-Danlos syndrome	13 (0.1)	7 (0.0)
Factor II deficiency	0	1 (0.0)
Factor II mutation	2 (0.0)	1 (0.0)
Factor V Leiden carrier	3 (0.0)	4 (0.0)
Factor V Leiden mutation	15 (0.1)	20 (0.1)
Factor V deficiency	4 (0.0)	1 (0.0)
Factor VII deficiency	0	1 (0.0)
Factor VIII deficiency	1 (0.0)	1 (0.0)
Factor XI deficiency	2 (0.0)	1 (0.0)
Factor XII deficiency	1 (0.0)	2 (0.0)
Factor XIII deficiency	1 (0.0)	0
Fallot's tetralogy	1 (0.0)	2 (0.0)
Familial hypertriglyceridaemia	1 (0.0)	0
Familial mediterranean fever	2 (0.0)	2 (0.0)
Familial polycythaemia	1 (0.0)	0
Familial tremor	4 (0.0)	3 (0.0)
Gallbladder anomaly congenital	0	1 (0.0)
Gastrointestinal arteriovenous malformation	0	1 (0.0)
Gaucher's disease	0	1 (0.0)
Gene mutation	2 (0.0)	1 (0.0)
Gilbert's syndrome	13 (0.1)	10 (0.0)
Glucose-6-phosphate dehydrogenase deficiency	2 (0.0)	7 (0.0)
Haemangioma congenital	1 (0.0)	0
Haemoglobin C trait	0	1 (0.0)
Haemoglobinopathy	3 (0.0)	3 (0.0)
Haemophilia	0	1 (0.0)
Hamartoma	0	1 (0.0)
Heart disease congenital	4 (0.0)	3 (0.0)
Hepato-lenticular degeneration	0	1 (0.0)
Hereditary haemochromatosis	2 (0.0)	2 (0.0)
Hereditary motor and sensory neuropathy	2 (0.0)	1 (0.0)
Hereditary non-polyposis colorectal cancer syndrome	0	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Hereditary pancreatitis	0	1 (0.0)
Hereditary spherocytosis	3 (0.0)	1 (0.0)
Heterotaxia	1 (0.0)	0
Hydrocele	9 (0.0)	4 (0.0)
Hypertrophic cardiomyopathy	2 (0.0)	6 (0.0)
Hypochondroplasia	0	1 (0.0)
Hypophosphatasia	1 (0.0)	0
Ichthyosis	2 (0.0)	1 (0.0)
Imperforate hymen	0	1 (0.0)
Intestinal malrotation	0	1 (0.0)
Intracranial lipoma	0	1 (0.0)
Keratosis follicular	2 (0.0)	0
Kidney malformation	0	1 (0.0)
Klinefelter's syndrome	1 (0.0)	0
Klippel-Feil syndrome	2 (0.0)	2 (0.0)
Kyphosis congenital	1 (0.0)	0
Leptin receptor deficiency	0	1 (0.0)
Limb malformation	0	2 (0.0)
Limb reduction defect	1 (0.0)	1 (0.0)
Malformation venous	0	1 (0.0)
Marfan's syndrome	2 (0.0)	1 (0.0)
Methylenetetrahydrofolate reductase gene mutation	0	5 (0.0)
Micrognathia	0	2 (0.0)
Microphthalmos	1 (0.0)	0
Morton's syndrome	0	1 (0.0)
Myocardial bridging	0	1 (0.0)
Myoclonic dystonia	0	1 (0.0)
Myotonia congenita	0	1 (0.0)
Myotonic dystrophy	0	1 (0.0)
Naevus flammeus	1 (0.0)	0
Neurofibromatosis	6 (0.0)	6 (0.0)
Non-compaction cardiomyopathy	1 (0.0)	0
Oesophageal cyst	0	1 (0.0)
Olfacto genital dysplasia	0	1 (0.0)
Osteogenesis imperfecta	0	1 (0.0)
Otospondylomegaepiphyseal dysplasia	1 (0.0)	0
PTEN gene mutation	0	1 (0.0)
Pancreas divisum	1 (0.0)	0
Patent ductus arteriosus	0	3 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Pectus carinatum	0	1 (0.0)
Pectus excavatum	4 (0.0)	3 (0.0)
Pelvic kidney	0	1 (0.0)
Phenylketonuria	0	1 (0.0)
Phimosis	3 (0.0)	4 (0.0)
Poland's syndrome	2 (0.0)	0
Polycystic liver disease	2 (0.0)	1 (0.0)
Polydactyly	0	1 (0.0)
Porokeratosis	1 (0.0)	1 (0.0)
Porphyria	1 (0.0)	0
Primary familial brain calcification	0	1 (0.0)
Protein C deficiency	0	1 (0.0)
Protein S deficiency	4 (0.0)	2 (0.0)
Pseudoxanthoma elasticum	1 (0.0)	0
Pulmonary hypoplasia	1 (0.0)	0
Pulmonary malformation	1 (0.0)	0
Pyloric stenosis	3 (0.0)	11 (0.1)
Renal aplasia	4 (0.0)	3 (0.0)
Renal dysplasia	1 (0.0)	0
Renal fusion anomaly	2 (0.0)	1 (0.0)
Renal hypoplasia	0	1 (0.0)
Retinal anomaly congenital	1 (0.0)	0
Retinitis pigmentosa	1 (0.0)	2 (0.0)
Schizencephaly	0	1 (0.0)
Schmid Fraccaro syndrome	1 (0.0)	0
Scimitar syndrome	0	1 (0.0)
Sebaceous naevus	0	1 (0.0)
Sickle cell anaemia	1 (0.0)	1 (0.0)
Sickle cell trait	5 (0.0)	8 (0.0)
Spina bifida	2 (0.0)	4 (0.0)
Spina bifida occulta	0	2 (0.0)
Spine malformation	1 (0.0)	2 (0.0)
Stargardt's disease	1 (0.0)	4 (0.0)
Supernumerary nipple	1 (0.0)	0
Syndactyly	1 (0.0)	1 (0.0)
Syringomyelia	1 (0.0)	0
Talipes	4 (0.0)	4 (0.0)
Thalassaemia	11 (0.1)	8 (0.0)
Thalassaemia alpha	1 (0.0)	3 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Thalassaemia beta	3 (0.0)	8 (0.0)
Thalassaemia minor	10 (0.0)	11 (0.1)
Thyroglossal cyst	1 (0.0)	2 (0.0)
Tourette's disorder	3 (0.0)	3 (0.0)
Tracheo-oesophageal fistula	1 (0.0)	0
Transitional vertebrae	1 (0.0)	0
Tuberous sclerosis complex	1 (0.0)	2 (0.0)
Type II hyperlipidaemia	0	1 (0.0)
Type IIa hyperlipidaemia	16 (0.1)	14 (0.1)
Type V hyperlipidaemia	42 (0.2)	26 (0.1)
Umbilical malformation	0	1 (0.0)
Urethral valves	1 (0.0)	0
Venous angioma of brain	1 (0.0)	0
Ventricular septal defect	2 (0.0)	9 (0.0)
Vitello-intestinal duct remnant	3 (0.0)	0
Von Willebrand's disease	3 (0.0)	4 (0.0)
Wolff-Parkinson-White syndrome congenital	1 (0.0)	0
Ear and labyrinth disorders	630 (2.9)	638 (2.9)
Auditory disorder	5 (0.0)	8 (0.0)
Aural polyp	0	1 (0.0)
Cerumen impaction	7 (0.0)	7 (0.0)
Conductive deafness	1 (0.0)	1 (0.0)
Deafness	102 (0.5)	102 (0.5)
Deafness bilateral	110 (0.5)	126 (0.6)
Deafness neurosensory	21 (0.1)	14 (0.1)
Deafness transitory	1 (0.0)	0
Deafness unilateral	52 (0.2)	61 (0.3)
Ear congestion	1 (0.0)	0
Ear deformity acquired	1 (0.0)	0
Ear disorder	2 (0.0)	3 (0.0)
Ear pain	1 (0.0)	7 (0.0)
Ear pruritus	1 (0.0)	1 (0.0)
Endolymphatic hydrops	0	3 (0.0)
Eustachian tube dysfunction	4 (0.0)	6 (0.0)
Eustachian tube patulous	1 (0.0)	0
Eustachian tube stenosis	0	1 (0.0)
Excessive cerumen production	1 (0.0)	1 (0.0)
Exostosis of external ear canal	2 (0.0)	1 (0.0)
Hyperacusis	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Hypoacusis	50 (0.2)	60 (0.3)
Inner ear disorder	2 (0.0)	0
Meniere's disease	43 (0.2)	30 (0.1)
Middle ear effusion	1 (0.0)	0
Mixed deafness	1 (0.0)	1 (0.0)
Motion sickness	5 (0.0)	3 (0.0)
Otosclerosis	8 (0.0)	8 (0.0)
Presbyacusis	6 (0.0)	1 (0.0)
Sudden hearing loss	2 (0.0)	1 (0.0)
Superior semicircular canal dehiscence	1 (0.0)	0
Tinnitus	148 (0.7)	143 (0.7)
Tympanic membrane perforation	11 (0.1)	9 (0.0)
Tympanic membrane scarring	1 (0.0)	0
Vertigo	90 (0.4)	102 (0.5)
Vertigo positional	14 (0.1)	11 (0.1)
Vestibular disorder	1 (0.0)	2 (0.0)
Endocrine disorders	2086 (9.6)	2146 (9.9)
Acromegaly	0	1 (0.0)
Addison's disease	1 (0.0)	1 (0.0)
Adrenal cyst	2 (0.0)	0
Adrenal disorder	0	1 (0.0)
Adrenal insufficiency	2 (0.0)	0
Adrenal mass	1 (0.0)	2 (0.0)
Androgen deficiency	5 (0.0)	6 (0.0)
Anovulatory cycle	1 (0.0)	1 (0.0)
Autoimmune hypothyroidism	2 (0.0)	2 (0.0)
Autoimmune thyroiditis	71 (0.3)	57 (0.3)
Basedow's disease	27 (0.1)	23 (0.1)
Diabetes insipidus	0	3 (0.0)
Empty sella syndrome	1 (0.0)	0
Endocrine disorder	1 (0.0)	1 (0.0)
Goitre	45 (0.2)	62 (0.3)
Gonadotrophin deficiency	1 (0.0)	1 (0.0)
Growth hormone deficiency	2 (0.0)	0
Hyperaldosteronism	1 (0.0)	5 (0.0)
Hyperandrogenism	0	1 (0.0)
Hypergonadism	2 (0.0)	1 (0.0)
Hyperparathyroidism	20 (0.1)	9 (0.0)
Hyperparathyroidism primary	1 (0.0)	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Hyperplasia adrenal	1 (0.0)	0
Hyperprolactinaemia	5 (0.0)	2 (0.0)
Hyperthyroidism	95 (0.4)	86 (0.4)
Hypogonadism	80 (0.4)	75 (0.3)
Hypogonadism male	12 (0.1)	7 (0.0)
Hypoparathyroidism	4 (0.0)	3 (0.0)
Hypopituitarism	1 (0.0)	0
Hypoprogesteronism	1 (0.0)	0
Hypothalamo-pituitary disorder	0	1 (0.0)
Hypothyroidism	1726 (7.9)	1796 (8.3)
Immune-mediated thyroiditis	0	1 (0.0)
Oestrogen deficiency	6 (0.0)	7 (0.0)
Parathyroid disorder	2 (0.0)	0
Pituitary enlargement	1 (0.0)	0
Pituitary-dependent Cushing's syndrome	1 (0.0)	0
Primary hypogonadism	1 (0.0)	1 (0.0)
Secondary hypogonadism	1 (0.0)	1 (0.0)
Secondary hypothyroidism	0	1 (0.0)
Testicular failure	5 (0.0)	5 (0.0)
Thyroid atrophy	0	1 (0.0)
Thyroid calcification	1 (0.0)	0
Thyroid cyst	10 (0.0)	7 (0.0)
Thyroid disorder	12 (0.1)	5 (0.0)
Thyroid mass	46 (0.2)	58 (0.3)
Thyroid stimulating hormone deficiency	0	1 (0.0)
Thyroiditis	5 (0.0)	3 (0.0)
Thyroiditis subacute	0	2 (0.0)
Toxic nodular goitre	0	2 (0.0)
Eye disorders	2272 (10.5)	2264 (10.4)
Age-related macular degeneration	3 (0.0)	2 (0.0)
Amaurosis	1 (0.0)	1 (0.0)
Amaurosis fugax	1 (0.0)	0
Amblyopia	16 (0.1)	17 (0.1)
Amblyopia strabismic	0	1 (0.0)
Angle closure glaucoma	5 (0.0)	2 (0.0)
Anisometropia	2 (0.0)	1 (0.0)
Arcus lipoides	1 (0.0)	0
Asthenopia	0	1 (0.0)
Astigmatism	73 (0.3)	75 (0.3)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Binocular eye movement disorder	1 (0.0)	0
Blepharitis	7 (0.0)	3 (0.0)
Blepharospasm	2 (0.0)	2 (0.0)
Blindness	4 (0.0)	1 (0.0)
Blindness unilateral	26 (0.1)	14 (0.1)
Borderline glaucoma	5 (0.0)	3 (0.0)
Cataract	502 (2.3)	506 (2.3)
Cataract cortical	0	2 (0.0)
Cataract diabetic	1 (0.0)	0
Cataract nuclear	7 (0.0)	6 (0.0)
Central vision loss	0	1 (0.0)
Chalazion	3 (0.0)	2 (0.0)
Chorioretinopathy	9 (0.0)	2 (0.0)
Cogan's syndrome	0	1 (0.0)
Conjunctival haemorrhage	1 (0.0)	1 (0.0)
Conjunctivitis allergic	15 (0.1)	12 (0.1)
Conjunctivochalasis	0	1 (0.0)
Corneal degeneration	1 (0.0)	1 (0.0)
Corneal disorder	1 (0.0)	2 (0.0)
Corneal epithelium defect	0	1 (0.0)
Corneal oedema	1 (0.0)	0
Corneal opacity	2 (0.0)	0
Corneal scar	2 (0.0)	1 (0.0)
Dacryostenosis acquired	3 (0.0)	5 (0.0)
Dermatochalasis	6 (0.0)	0
Diabetic eye disease	1 (0.0)	0
Diabetic retinopathy	13 (0.1)	12 (0.1)
Diplopia	1 (0.0)	2 (0.0)
Dry age-related macular degeneration	8 (0.0)	1 (0.0)
Dry eye	120 (0.6)	110 (0.5)
Endocrine ophthalmopathy	0	2 (0.0)
Entropion	1 (0.0)	1 (0.0)
Exfoliation glaucoma	0	1 (0.0)
Exfoliation syndrome	0	1 (0.0)
Exophthalmos	0	1 (0.0)
Extraocular muscle disorder	0	1 (0.0)
Extraocular muscle paresis	0	1 (0.0)
Eye allergy	1 (0.0)	3 (0.0)
Eye disorder	2 (0.0)	5 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Eye haemorrhage	1 (0.0)	1 (0.0)
Eye inflammation	2 (0.0)	1 (0.0)
Eye irritation	1 (0.0)	2 (0.0)
Eye movement disorder	1 (0.0)	1 (0.0)
Eye pruritus	1 (0.0)	1 (0.0)
Eye swelling	1 (0.0)	1 (0.0)
Eyelid cyst	1 (0.0)	2 (0.0)
Eyelid ptosis	21 (0.1)	9 (0.0)
Fuchs' syndrome	0	1 (0.0)
Giant papillary conjunctivitis	0	1 (0.0)
Glaucoma	225 (1.0)	230 (1.1)
Heterophoria	0	1 (0.0)
Holmes-Adie pupil	1 (0.0)	0
Hyalosis asteroid	0	1 (0.0)
Hypermetropia	268 (1.2)	252 (1.2)
Idiopathic orbital inflammation	1 (0.0)	0
Iridocorneal endothelial syndrome	1 (0.0)	0
Iridocyclitis	0	1 (0.0)
Iris disorder	1 (0.0)	1 (0.0)
Iritis	3 (0.0)	5 (0.0)
Keratitis	3 (0.0)	1 (0.0)
Keratoconus	9 (0.0)	10 (0.0)
Keratomalacia	1 (0.0)	0
Lacrimal disorder	0	1 (0.0)
Lenticular opacities	1 (0.0)	0
Macular degeneration	54 (0.2)	48 (0.2)
Macular fibrosis	5 (0.0)	9 (0.0)
Macular hole	1 (0.0)	5 (0.0)
Macular oedema	2 (0.0)	2 (0.0)
Macular scar	0	1 (0.0)
Macular telangiectasia	1 (0.0)	0
Maculopathy	6 (0.0)	4 (0.0)
Meibomian gland dysfunction	3 (0.0)	1 (0.0)
Mydriasis	2 (0.0)	1 (0.0)
Myopia	817 (3.8)	826 (3.8)
Myopic chorioretinal degeneration	2 (0.0)	2 (0.0)
Narrow anterior chamber angle	0	1 (0.0)
Necrotising retinitis	1 (0.0)	0
Neovascular age-related macular degeneration	4 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Non-proliferative retinopathy	0	1 (0.0)
Normal tension glaucoma	1 (0.0)	3 (0.0)
Ocular discomfort	1 (0.0)	1 (0.0)
Ocular fistula	0	1 (0.0)
Ocular hypertension	4 (0.0)	9 (0.0)
Ocular ischaemic syndrome	0	1 (0.0)
Ocular pemphigoid	1 (0.0)	0
Ocular rosacea	2 (0.0)	1 (0.0)
Ocular vascular disorder	2 (0.0)	2 (0.0)
Open angle glaucoma	7 (0.0)	8 (0.0)
Optic atrophy	1 (0.0)	1 (0.0)
Optic disc drusen	1 (0.0)	0
Optic ischaemic neuropathy	1 (0.0)	3 (0.0)
Optic nerve cupping	0	1 (0.0)
Optic neuropathy	1 (0.0)	1 (0.0)
Oscillopsia	0	2 (0.0)
Photophobia	1 (0.0)	1 (0.0)
Pigment dispersion syndrome	1 (0.0)	0
Pigmentary glaucoma	1 (0.0)	0
Pinguecula	1 (0.0)	0
Posterior capsule opacification	1 (0.0)	0
Presbyopia	289 (1.3)	298 (1.4)
Pterygium	8 (0.0)	5 (0.0)
Punctate keratitis	2 (0.0)	0
Pupils unequal	0	2 (0.0)
Refraction disorder	3 (0.0)	4 (0.0)
Refractive amblyopia	0	1 (0.0)
Retinal artery occlusion	1 (0.0)	1 (0.0)
Retinal artery thrombosis	1 (0.0)	0
Retinal degeneration	4 (0.0)	2 (0.0)
Retinal detachment	39 (0.2)	36 (0.2)
Retinal disorder	4 (0.0)	3 (0.0)
Retinal drusen	1 (0.0)	0
Retinal dystrophy	0	1 (0.0)
Retinal haemorrhage	1 (0.0)	0
Retinal oedema	0	1 (0.0)
Retinal scar	2 (0.0)	1 (0.0)
Retinal tear	11 (0.1)	12 (0.1)
Retinal vascular disorder	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Retinal vein occlusion	3 (0.0)	3 (0.0)
Retinal vein thrombosis	0	1 (0.0)
Retinopathy	2 (0.0)	1 (0.0)
Retinopathy proliferative	2 (0.0)	1 (0.0)
Scintillating scotoma	0	1 (0.0)
Strabismus	28 (0.1)	33 (0.2)
Subretinal fluid	1 (0.0)	0
Ulcerative keratitis	0	1 (0.0)
Uveitis	4 (0.0)	5 (0.0)
Vision blurred	6 (0.0)	3 (0.0)
Visual acuity reduced	115 (0.5)	131 (0.6)
Visual impairment	27 (0.1)	40 (0.2)
Vitreous degeneration	2 (0.0)	2 (0.0)
Vitreous detachment	9 (0.0)	8 (0.0)
Vitreous disorder	0	1 (0.0)
Vitreous floaters	4 (0.0)	2 (0.0)
Vitreous haemorrhage	1 (0.0)	3 (0.0)
Gastrointestinal disorders	3833 (17.6)	3770 (17.4)
Abdominal adhesions	3 (0.0)	2 (0.0)
Abdominal discomfort	0	4 (0.0)
Abdominal distension	5 (0.0)	7 (0.0)
Abdominal fat apron	1 (0.0)	0
Abdominal hernia	62 (0.3)	58 (0.3)
Abdominal mass	1 (0.0)	1 (0.0)
Abdominal migraine	1 (0.0)	1 (0.0)
Abdominal pain	21 (0.1)	18 (0.1)
Abdominal pain lower	2 (0.0)	2 (0.0)
Abdominal pain upper	10 (0.0)	7 (0.0)
Abdominal wall mass	1 (0.0)	0
Acquired oesophageal web	4 (0.0)	2 (0.0)
Anal fissure	6 (0.0)	12 (0.1)
Anal fistula	5 (0.0)	8 (0.0)
Anal haemorrhage	0	1 (0.0)
Anal incontinence	1 (0.0)	3 (0.0)
Anal prolapse	0	1 (0.0)
Anal skin tags	1 (0.0)	0
Angular cheilitis	1 (0.0)	0
Anogenital dysplasia	1 (0.0)	1 (0.0)
Aphthous ulcer	6 (0.0)	4 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Appendiceal mucocoele	0	1 (0.0)
Appendicitis noninfective	1 (0.0)	1 (0.0)
Appendix disorder	1 (0.0)	1 (0.0)
Barrett's oesophagus	42 (0.2)	42 (0.2)
Bile acid malabsorption	1 (0.0)	2 (0.0)
Cannabinoid hyperemesis syndrome	0	1 (0.0)
Chronic gastritis	13 (0.1)	13 (0.1)
Coeliac artery stenosis	0	1 (0.0)
Coeliac disease	42 (0.2)	47 (0.2)
Colitis	9 (0.0)	10 (0.0)
Colitis ischaemic	1 (0.0)	5 (0.0)
Colitis microscopic	6 (0.0)	7 (0.0)
Colitis ulcerative	24 (0.1)	28 (0.1)
Constipation	213 (1.0)	213 (1.0)
Crohn's disease	15 (0.1)	16 (0.1)
Cyclic vomiting syndrome	1 (0.0)	0
Defaecation disorder	1 (0.0)	0
Dental caries	10 (0.0)	10 (0.0)
Dental plaque	1 (0.0)	0
Diaphragmatic hernia	1 (0.0)	1 (0.0)
Diarrhoea	60 (0.3)	58 (0.3)
Diverticular perforation	1 (0.0)	0
Diverticulum	114 (0.5)	97 (0.4)
Diverticulum intestinal	23 (0.1)	29 (0.1)
Diverticulum oesophageal	0	2 (0.0)
Dry mouth	8 (0.0)	7 (0.0)
Dumping syndrome	0	1 (0.0)
Duodenal stenosis	0	1 (0.0)
Duodenal ulcer	7 (0.0)	10 (0.0)
Duodenogastric reflux	5 (0.0)	9 (0.0)
Dyspepsia	346 (1.6)	316 (1.5)
Dysphagia	12 (0.1)	11 (0.1)
Encapsulating peritoneal sclerosis	0	1 (0.0)
Enlarged uvula	0	1 (0.0)
Enteritis	1 (0.0)	0
Enterovesical fistula	2 (0.0)	2 (0.0)
Eosinophilic oesophagitis	10 (0.0)	9 (0.0)
Epigastric discomfort	1 (0.0)	0
Epiploic appendagitis	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Erosive oesophagitis	1 (0.0)	0
Eructation	0	1 (0.0)
Faeces hard	0	1 (0.0)
Faeces soft	2 (0.0)	1 (0.0)
Femoral hernia	2 (0.0)	4 (0.0)
Flatulence	3 (0.0)	3 (0.0)
Food poisoning	1 (0.0)	5 (0.0)
Functional gastrointestinal disorder	1 (0.0)	0
Gastric disorder	3 (0.0)	2 (0.0)
Gastric fistula	0	1 (0.0)
Gastric haemorrhage	1 (0.0)	1 (0.0)
Gastric ileus	1 (0.0)	0
Gastric mucosal lesion	1 (0.0)	0
Gastric ulcer	39 (0.2)	50 (0.2)
Gastric ulcer haemorrhage	1 (0.0)	0
Gastric ulcer perforation	1 (0.0)	1 (0.0)
Gastritis	78 (0.4)	71 (0.3)
Gastritis erosive	3 (0.0)	1 (0.0)
Gastroenteritis eosinophilic	1 (0.0)	0
Gastrointestinal disorder	7 (0.0)	4 (0.0)
Gastrointestinal fistula	0	1 (0.0)
Gastrointestinal haemorrhage	10 (0.0)	11 (0.1)
Gastrointestinal hypomotility	2 (0.0)	2 (0.0)
Gastrointestinal inflammation	0	2 (0.0)
Gastrointestinal necrosis	1 (0.0)	0
Gastrointestinal pain	4 (0.0)	1 (0.0)
Gastrointestinal perforation	2 (0.0)	1 (0.0)
Gastrointestinal polyp	1 (0.0)	2 (0.0)
Gastrointestinal scarring	0	1 (0.0)
Gastrointestinal ulcer	2 (0.0)	1 (0.0)
Gastrointestinal ulcer haemorrhage	2 (0.0)	0
Gastrooesophageal reflux disease	2083 (9.6)	2061 (9.5)
Gingival blister	0	1 (0.0)
Gingival discomfort	0	1 (0.0)
Gingival disorder	1 (0.0)	1 (0.0)
Gingival pain	0	1 (0.0)
Gingival recession	1 (0.0)	4 (0.0)
Haematochezia	2 (0.0)	4 (0.0)
Haemorrhoids	176 (0.8)	175 (0.8)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Haemorrhoids thrombosed	1 (0.0)	0
Hiatus hernia	103 (0.5)	129 (0.6)
Hyperaesthesia teeth	1 (0.0)	0
Hyperchlorhydria	1 (0.0)	0
Ileus	0	1 (0.0)
Impaired gastric emptying	17 (0.1)	14 (0.1)
Inflammatory bowel disease	2 (0.0)	5 (0.0)
Inguinal hernia	274 (1.3)	287 (1.3)
Internal hernia	1 (0.0)	0
Intestinal cyst	2 (0.0)	1 (0.0)
Intestinal obstruction	17 (0.1)	11 (0.1)
Intestinal perforation	3 (0.0)	2 (0.0)
Intestinal polyp	6 (0.0)	3 (0.0)
Intestinal prolapse	0	1 (0.0)
Intestinal pseudo-obstruction	1 (0.0)	0
Intestinal strangulation	1 (0.0)	0
Intussusception	1 (0.0)	1 (0.0)
Irritable bowel syndrome	302 (1.4)	289 (1.3)
Large intestinal obstruction	3 (0.0)	1 (0.0)
Large intestinal stenosis	0	1 (0.0)
Large intestinal ulcer	1 (0.0)	0
Large intestine perforation	5 (0.0)	2 (0.0)
Large intestine polyp	111 (0.5)	104 (0.5)
Leukoplakia oral	1 (0.0)	1 (0.0)
Lower gastrointestinal haemorrhage	1 (0.0)	1 (0.0)
Lumbar hernia	8 (0.0)	4 (0.0)
Lymphangiectasia intestinal	0	1 (0.0)
Malabsorption	3 (0.0)	2 (0.0)
Malocclusion	4 (0.0)	5 (0.0)
Mouth cyst	1 (0.0)	0
Mouth ulceration	4 (0.0)	5 (0.0)
Nausea	24 (0.1)	32 (0.1)
Necrotising colitis	1 (0.0)	0
Noninfective gingivitis	0	1 (0.0)
Noninfective sialoadenitis	2 (0.0)	0
Obstruction gastric	0	2 (0.0)
Obstructive pancreatitis	0	1 (0.0)
Odynophagia	1 (0.0)	0
Oesophageal achalasia	3 (0.0)	5 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Oesophageal dilatation	1 (0.0)	0
Oesophageal disorder	1 (0.0)	1 (0.0)
Oesophageal fistula	1 (0.0)	0
Oesophageal haemorrhage	1 (0.0)	0
Oesophageal motility disorder	0	1 (0.0)
Oesophageal perforation	1 (0.0)	2 (0.0)
Oesophageal spasm	6 (0.0)	4 (0.0)
Oesophageal stenosis	9 (0.0)	5 (0.0)
Oesophageal ulcer	5 (0.0)	1 (0.0)
Oesophagitis	17 (0.1)	15 (0.1)
Oral disorder	0	1 (0.0)
Oral lichen planus	1 (0.0)	1 (0.0)
Oral mucosal blistering	1 (0.0)	1 (0.0)
Pancreatic cyst	8 (0.0)	3 (0.0)
Pancreatic failure	1 (0.0)	5 (0.0)
Pancreatic mass	0	1 (0.0)
Pancreatic pseudocyst	1 (0.0)	0
Pancreatitis	27 (0.1)	18 (0.1)
Pancreatitis acute	5 (0.0)	2 (0.0)
Pancreatitis chronic	5 (0.0)	6 (0.0)
Pancreatitis necrotising	0	1 (0.0)
Pelvic floor dysfunction	4 (0.0)	1 (0.0)
Peptic ulcer	14 (0.1)	21 (0.1)
Peptic ulcer haemorrhage	0	1 (0.0)
Periodontal disease	2 (0.0)	2 (0.0)
Peritoneal cyst	0	1 (0.0)
Pharyngo-oesophageal diverticulum	2 (0.0)	0
Precancerous lesion of digestive tract	1 (0.0)	0
Proctalgia	0	2 (0.0)
Proctitis	0	1 (0.0)
Proctitis ulcerative	2 (0.0)	3 (0.0)
Rectal fissure	4 (0.0)	3 (0.0)
Rectal haemorrhage	6 (0.0)	6 (0.0)
Rectal polyp	1 (0.0)	1 (0.0)
Rectal prolapse	3 (0.0)	5 (0.0)
Rectal spasm	1 (0.0)	0
Reflux gastritis	1 (0.0)	1 (0.0)
Salivary gland calculus	1 (0.0)	1 (0.0)
Salivary gland cyst	3 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Short-bowel syndrome	2 (0.0)	1 (0.0)
Small intestinal obstruction	14 (0.1)	3 (0.0)
Small intestinal perforation	1 (0.0)	1 (0.0)
Small intestinal stenosis	1 (0.0)	1 (0.0)
Small intestine ulcer	1 (0.0)	0
Spigelian hernia	1 (0.0)	0
Splenic artery aneurysm	0	3 (0.0)
Steatorrhoea	1 (0.0)	0
Stomatitis	1 (0.0)	5 (0.0)
Superior mesenteric artery syndrome	0	1 (0.0)
Swollen tongue	1 (0.0)	1 (0.0)
Tongue coated	0	1 (0.0)
Tongue discomfort	0	1 (0.0)
Tongue geographic	0	1 (0.0)
Tooth disorder	2 (0.0)	0
Tooth impacted	34 (0.2)	27 (0.1)
Tooth loss	3 (0.0)	3 (0.0)
Toothache	6 (0.0)	12 (0.1)
Umbilical hernia	145 (0.7)	130 (0.6)
Upper gastrointestinal haemorrhage	1 (0.0)	0
Uvulitis	1 (0.0)	0
Varices oesophageal	1 (0.0)	2 (0.0)
Volvulus	1 (0.0)	5 (0.0)
Vomiting	6 (0.0)	6 (0.0)
General disorders and administration site conditions	465 (2.1)	450 (2.1)
Adverse drug reaction	16 (0.1)	15 (0.1)
Adverse food reaction	1 (0.0)	0
Application site vesicles	0	1 (0.0)
Asthenia	1 (0.0)	2 (0.0)
Atrophy	1 (0.0)	3 (0.0)
Axillary pain	0	1 (0.0)
Calcinosis	2 (0.0)	1 (0.0)
Chest discomfort	1 (0.0)	2 (0.0)
Chest pain	23 (0.1)	13 (0.1)
Chronic fatigue syndrome	5 (0.0)	3 (0.0)
Complication associated with device	0	1 (0.0)
Cyst	18 (0.1)	25 (0.1)
Cyst rupture	1 (0.0)	1 (0.0)
Device intolerance	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Discomfort	0	2 (0.0)
Disease susceptibility	0	1 (0.0)
Drug intolerance	55 (0.3)	58 (0.3)
Dysplasia	2 (0.0)	0
Face oedema	1 (0.0)	0
Facial pain	0	1 (0.0)
Fat tissue increased	1 (0.0)	1 (0.0)
Fatigue	30 (0.1)	33 (0.2)
Fibrosis	0	1 (0.0)
Gait disturbance	6 (0.0)	1 (0.0)
Generalised oedema	1 (0.0)	1 (0.0)
Granuloma	0	1 (0.0)
Gravitational oedema	1 (0.0)	1 (0.0)
Hernia	42 (0.2)	40 (0.2)
Hyperplasia	4 (0.0)	1 (0.0)
Hyperthermia malignant	1 (0.0)	0
Inflammation	2 (0.0)	3 (0.0)
Inflammatory pain	1 (0.0)	0
Injection site erythema	0	1 (0.0)
Injection site swelling	0	1 (0.0)
Injury associated with device	1 (0.0)	0
Lithiasis	0	1 (0.0)
Localised oedema	1 (0.0)	1 (0.0)
Malaise	0	2 (0.0)
Medical device site scar	0	1 (0.0)
Necrosis	1 (0.0)	0
Nodule	0	1 (0.0)
Non-cardiac chest pain	1 (0.0)	2 (0.0)
Oedema	24 (0.1)	15 (0.1)
Oedema peripheral	131 (0.6)	120 (0.6)
Pain	72 (0.3)	82 (0.4)
Pelvic mass	1 (0.0)	1 (0.0)
Perforated ulcer	2 (0.0)	0
Peripheral swelling	12 (0.1)	12 (0.1)
Polyp	2 (0.0)	1 (0.0)
Pre-existing condition improved	1 (0.0)	0
Precancerous condition	5 (0.0)	3 (0.0)
Procedural failure	0	1 (0.0)
Pyrexia	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Stenosis	2 (0.0)	1 (0.0)
Surgical failure	0	2 (0.0)
Swelling face	1 (0.0)	0
Temperature intolerance	1 (0.0)	0
Therapeutic response unexpected	0	1 (0.0)
Therapy responder	0	1 (0.0)
Treatment noncompliance	1 (0.0)	2 (0.0)
Ulcer	4 (0.0)	1 (0.0)
Ulcer haemorrhage	0	1 (0.0)
Vaccination site reaction	0	1 (0.0)
Vaccination site swelling	2 (0.0)	0
Vascular stent occlusion	0	2 (0.0)
Xerosis	3 (0.0)	0
Hepatobiliary disorders	797 (3.7)	773 (3.6)
Bile duct stone	6 (0.0)	4 (0.0)
Biliary colic	7 (0.0)	1 (0.0)
Biliary cyst	0	1 (0.0)
Biliary dyskinesia	4 (0.0)	1 (0.0)
Biliary obstruction	0	1 (0.0)
Biliary polyp	0	1 (0.0)
Biliary tract disorder	4 (0.0)	1 (0.0)
Cholangitis sclerosing	2 (0.0)	0
Cholecystitis	144 (0.7)	172 (0.8)
Cholecystitis acute	2 (0.0)	6 (0.0)
Cholecystitis chronic	2 (0.0)	1 (0.0)
Cholelithiasis	446 (2.1)	426 (2.0)
Cholelithiasis obstructive	1 (0.0)	1 (0.0)
Cholestasis	2 (0.0)	2 (0.0)
Cirrhosis alcoholic	4 (0.0)	0
Drug-induced liver injury	1 (0.0)	1 (0.0)
Fatty liver alcoholic	1 (0.0)	0
Gallbladder cholesterolosis	1 (0.0)	0
Gallbladder disorder	57 (0.3)	48 (0.2)
Gallbladder enlargement	0	1 (0.0)
Gallbladder hypofunction	4 (0.0)	5 (0.0)
Gallbladder obstruction	1 (0.0)	1 (0.0)
Gallbladder oedema	2 (0.0)	0
Gallbladder polyp	2 (0.0)	5 (0.0)
Gallbladder rupture	2 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Hepatic artery stenosis	0	1 (0.0)
Hepatic atrophy	0	1 (0.0)
Hepatic cirrhosis	9 (0.0)	4 (0.0)
Hepatic cyst	4 (0.0)	9 (0.0)
Hepatic fibrosis	0	1 (0.0)
Hepatic function abnormal	0	1 (0.0)
Hepatic lesion	2 (0.0)	0
Hepatic mass	0	4 (0.0)
Hepatic steatosis	87 (0.4)	64 (0.3)
Hepatitis	0	4 (0.0)
Hepatobiliary disease	0	1 (0.0)
Hepatomegaly	5 (0.0)	1 (0.0)
Hyperbilirubinaemia	1 (0.0)	0
Jaundice	1 (0.0)	1 (0.0)
Liver disorder	1 (0.0)	5 (0.0)
Non-alcoholic steatohepatitis	14 (0.1)	8 (0.0)
Nonalcoholic fatty liver disease	10 (0.0)	14 (0.1)
Portal vein thrombosis	0	1 (0.0)
Primary biliary cholangitis	1 (0.0)	1 (0.0)
Immune system disorders	5863 (27.0)	5856 (27.0)
Allergic oedema	7 (0.0)	5 (0.0)
Allergic reaction to excipient	0	1 (0.0)
Allergy to animal	130 (0.6)	133 (0.6)
Allergy to arthropod bite	3 (0.0)	5 (0.0)
Allergy to arthropod sting	75 (0.3)	71 (0.3)
Allergy to chemicals	18 (0.1)	15 (0.1)
Allergy to metals	24 (0.1)	20 (0.1)
Allergy to plants	25 (0.1)	32 (0.1)
Allergy to silk	0	1 (0.0)
Allergy to surgical sutures	0	4 (0.0)
Allergy to synthetic fabric	1 (0.0)	0
Allergy to vaccine	13 (0.1)	11 (0.1)
Allergy to venom	0	2 (0.0)
Amyloidosis	1 (0.0)	1 (0.0)
Anaphylactic reaction	14 (0.1)	22 (0.1)
Anaphylactic shock	1 (0.0)	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	1 (0.0)	0
Atopy	2 (0.0)	3 (0.0)
Autoinflammatory disease	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Cockroach allergy	1 (0.0)	1 (0.0)
Contrast media allergy	38 (0.2)	39 (0.2)
Contrast media reaction	1 (0.0)	1 (0.0)
Device allergy	1 (0.0)	0
Drug hypersensitivity	2773 (12.8)	2647 (12.2)
Dust allergy	32 (0.1)	47 (0.2)
Food allergy	386 (1.8)	369 (1.7)
Hypersensitivity	219 (1.0)	204 (0.9)
Iodine allergy	48 (0.2)	57 (0.3)
Milk allergy	18 (0.1)	22 (0.1)
Mite allergy	23 (0.1)	24 (0.1)
Multiple allergies	22 (0.1)	25 (0.1)
Mycotic allergy	31 (0.1)	24 (0.1)
Oral allergy syndrome	1 (0.0)	0
Perennial allergy	32 (0.1)	37 (0.2)
Perfume sensitivity	2 (0.0)	5 (0.0)
Reaction to colouring	6 (0.0)	7 (0.0)
Reaction to food additive	9 (0.0)	10 (0.0)
Reaction to preservatives	2 (0.0)	2 (0.0)
Rubber sensitivity	125 (0.6)	127 (0.6)
Sarcoidosis	12 (0.1)	14 (0.1)
Seasonal allergy	3222 (14.8)	3293 (15.2)
Serum sickness	0	2 (0.0)
Smoke sensitivity	3 (0.0)	2 (0.0)
Sunscreen sensitivity	0	2 (0.0)
Infections and infestations	2389 (11.0)	2269 (10.4)
Abdominal infection	0	1 (0.0)
Abscess limb	2 (0.0)	1 (0.0)
Abscess neck	2 (0.0)	0
Abscess soft tissue	0	1 (0.0)
Acarodermatitis	0	1 (0.0)
Acquired immunodeficiency syndrome	0	1 (0.0)
Actinomycosis	0	1 (0.0)
Acute hepatitis B	0	1 (0.0)
Acute pulmonary histoplasmosis	1 (0.0)	0
Acute sinusitis	2 (0.0)	6 (0.0)
Adenoiditis	16 (0.1)	12 (0.1)
American trypanosomiasis	2 (0.0)	1 (0.0)
Anal abscess	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Appendiceal abscess	1 (0.0)	0
Appendicitis	484 (2.2)	465 (2.1)
Appendicitis perforated	16 (0.1)	9 (0.0)
Arthritis bacterial	3 (0.0)	3 (0.0)
Arthritis infective	1 (0.0)	3 (0.0)
Asymptomatic HIV infection	1 (0.0)	1 (0.0)
Atypical pneumonia	2 (0.0)	0
Babesiosis	0	1 (0.0)
Bacterial allergy	0	1 (0.0)
Bacterial infection	2 (0.0)	0
Bacterial toxaemia	1 (0.0)	0
Bacterial tracheitis	1 (0.0)	0
Bacterial vaginosis	3 (0.0)	4 (0.0)
Bacterial vulvovaginitis	1 (0.0)	0
Bartonellosis	0	1 (0.0)
Beta haemolytic streptococcal infection	0	1 (0.0)
Body tinea	1 (0.0)	1 (0.0)
Bone abscess	1 (0.0)	0
Brain abscess	0	2 (0.0)
Breast abscess	2 (0.0)	0
Bronchitis	39 (0.2)	35 (0.2)
Bronchitis bacterial	1 (0.0)	0
Bronchopulmonary aspergillosis allergic	1 (0.0)	0
Candida infection	2 (0.0)	3 (0.0)
Carbuncle	1 (0.0)	0
Cat scratch disease	3 (0.0)	3 (0.0)
Cellulitis	15 (0.1)	11 (0.1)
Cellulitis orbital	0	1 (0.0)
Central nervous system viral infection	0	1 (0.0)
Cervicitis human papilloma virus	2 (0.0)	2 (0.0)
Chikungunya virus infection	5 (0.0)	4 (0.0)
Chlamydial cervicitis	0	1 (0.0)
Chlamydial infection	13 (0.1)	10 (0.0)
Cholecystitis infective	2 (0.0)	1 (0.0)
Cholera	1 (0.0)	0
Chronic hepatitis B	1 (0.0)	0
Chronic hepatitis C	1 (0.0)	1 (0.0)
Chronic pulmonary histoplasmosis	0	1 (0.0)
Chronic sinusitis	68 (0.3)	73 (0.3)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Chronic tonsillitis	11 (0.1)	8 (0.0)
Clostridial infection	1 (0.0)	0
Clostridium difficile colitis	2 (0.0)	1 (0.0)
Clostridium difficile infection	9 (0.0)	4 (0.0)
Coccidioidomycosis	2 (0.0)	0
Conjunctivitis	4 (0.0)	4 (0.0)
Conjunctivitis viral	1 (0.0)	1 (0.0)
Croup infectious	0	1 (0.0)
Cyclosporidium infection	0	1 (0.0)
Cystitis	7 (0.0)	6 (0.0)
Cytomegalovirus hepatitis	0	1 (0.0)
Cytomegalovirus infection	1 (0.0)	2 (0.0)
Dengue fever	5 (0.0)	7 (0.0)
Dermatophytosis	0	1 (0.0)
Device related infection	2 (0.0)	0
Diverticulitis	105 (0.5)	90 (0.4)
Ear infection	35 (0.2)	30 (0.1)
Ear infection viral	1 (0.0)	0
Eczema infected	1 (0.0)	0
Eczema vaccinatum	0	1 (0.0)
Empyema	1 (0.0)	1 (0.0)
Encephalitis	4 (0.0)	2 (0.0)
Encephalitis eastern equine	0	1 (0.0)
Encephalomyelitis	1 (0.0)	0
Endocarditis	1 (0.0)	2 (0.0)
Endometritis	0	1 (0.0)
Enterobiasis	1 (0.0)	0
Epidemic typhus	1 (0.0)	0
Epididymitis	3 (0.0)	1 (0.0)
Epiglottitis	0	1 (0.0)
Epstein-Barr virus infection	1 (0.0)	2 (0.0)
Erysipelas	0	2 (0.0)
Escherichia bacteraemia	0	1 (0.0)
Escherichia infection	2 (0.0)	1 (0.0)
Escherichia sepsis	0	1 (0.0)
Extradural abscess	0	1 (0.0)
Eye infection toxoplasmal	0	2 (0.0)
Eyelid infection	1 (0.0)	1 (0.0)
Folliculitis	5 (0.0)	7 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Fracture infection	1 (0.0)	0
Fungal infection	13 (0.1)	2 (0.0)
Fungal skin infection	9 (0.0)	16 (0.1)
Furuncle	1 (0.0)	3 (0.0)
Gangrene	1 (0.0)	0
Gastroenteritis	4 (0.0)	6 (0.0)
Gastroenteritis norovirus	1 (0.0)	0
Gastroenteritis salmonella	0	1 (0.0)
Gastroenteritis viral	0	1 (0.0)
Gastrointestinal bacterial overgrowth	1 (0.0)	1 (0.0)
Gastrointestinal infection	0	2 (0.0)
Genital herpes	49 (0.2)	47 (0.2)
Genital herpes simplex	17 (0.1)	12 (0.1)
Giardiasis	1 (0.0)	0
Gingivitis	0	2 (0.0)
Gonorrhoea	3 (0.0)	3 (0.0)
Groin abscess	1 (0.0)	0
Groin infection	1 (0.0)	0
HIV infection	21 (0.1)	23 (0.1)
Hand-foot-and-mouth disease	0	1 (0.0)
Helicobacter gastritis	5 (0.0)	1 (0.0)
Helicobacter infection	7 (0.0)	10 (0.0)
Hepatitis A	43 (0.2)	33 (0.2)
Hepatitis B	14 (0.1)	13 (0.1)
Hepatitis C	31 (0.1)	41 (0.2)
Herpes dermatitis	1 (0.0)	2 (0.0)
Herpes ophthalmic	1 (0.0)	3 (0.0)
Herpes simplex	176 (0.8)	149 (0.7)
Herpes simplex meningitis	1 (0.0)	0
Herpes virus infection	18 (0.1)	20 (0.1)
Herpes zoster	119 (0.5)	113 (0.5)
Herpes zoster oticus	1 (0.0)	0
Histoplasmosis	6 (0.0)	0
Hordeolum	2 (0.0)	3 (0.0)
Human ehrlichiosis	0	1 (0.0)
Impetigo	1 (0.0)	2 (0.0)
Infected bite	1 (0.0)	0
Infected cyst	0	2 (0.0)
Infected dermal cyst	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Infection	2 (0.0)	1 (0.0)
Infectious mononucleosis	9 (0.0)	7 (0.0)
Infective myositis	0	1 (0.0)
Infective tenosynovitis	1 (0.0)	0
Influenza	4 (0.0)	5 (0.0)
Joint abscess	0	2 (0.0)
Kidney infection	4 (0.0)	9 (0.0)
Labyrinthitis	11 (0.1)	9 (0.0)
Large intestine infection	0	2 (0.0)
Laryngitis	5 (0.0)	0
Latent tuberculosis	9 (0.0)	6 (0.0)
Liver abscess	0	1 (0.0)
Localised infection	5 (0.0)	3 (0.0)
Ludwig angina	1 (0.0)	0
Lung abscess	1 (0.0)	0
Lyme disease	8 (0.0)	22 (0.1)
Lymph gland infection	0	1 (0.0)
Lymph node abscess	1 (0.0)	0
Malaria	3 (0.0)	2 (0.0)
Mastitis	0	4 (0.0)
Mastoiditis	0	2 (0.0)
Measles	0	1 (0.0)
Mediastinitis	1 (0.0)	0
Meningitis	7 (0.0)	7 (0.0)
Meningitis aseptic	1 (0.0)	0
Meningitis viral	4 (0.0)	3 (0.0)
Mycobacterium avium complex infection	1 (0.0)	1 (0.0)
Myiasis	0	1 (0.0)
Myocarditis infectious	0	1 (0.0)
Myringitis	1 (0.0)	1 (0.0)
Nasopharyngitis	2 (0.0)	2 (0.0)
Nocardiosis	1 (0.0)	0
Oesophageal candidiasis	1 (0.0)	0
Oesophagitis bacterial	1 (0.0)	0
Onychomycosis	60 (0.3)	67 (0.3)
Ophthalmic herpes simplex	0	2 (0.0)
Ophthalmic herpes zoster	1 (0.0)	3 (0.0)
Oral candidiasis	1 (0.0)	1 (0.0)
Oral herpes	96 (0.4)	117 (0.5)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Oral infection	1 (0.0)	0
Orchitis	0	1 (0.0)
Osteomyelitis	12 (0.1)	11 (0.1)
Otitis externa	1 (0.0)	3 (0.0)
Otitis media	8 (0.0)	13 (0.1)
Otitis media acute	1 (0.0)	1 (0.0)
Otitis media chronic	5 (0.0)	4 (0.0)
Otosalpingitis	1 (0.0)	0
Overgrowth bacterial	0	1 (0.0)
Papilloma viral infection	11 (0.1)	6 (0.0)
Parasite allergy	1 (0.0)	0
Paronychia	0	3 (0.0)
Parotitis	0	1 (0.0)
Pelvic infection	0	1 (0.0)
Pelvic inflammatory disease	3 (0.0)	3 (0.0)
Periodontal destruction	1 (0.0)	0
Periodontitis	2 (0.0)	1 (0.0)
Perirectal abscess	1 (0.0)	2 (0.0)
Peritonitis	6 (0.0)	5 (0.0)
Peritonsillar abscess	2 (0.0)	1 (0.0)
Pertussis	2 (0.0)	3 (0.0)
Pharyngitis	7 (0.0)	3 (0.0)
Pharyngitis streptococcal	22 (0.1)	15 (0.1)
Pharyngotonsillitis	0	2 (0.0)
Pilonidal cyst	15 (0.1)	19 (0.1)
Plasmodium falciparum infection	1 (0.0)	0
Pleurisy viral	0	1 (0.0)
Pneumocystis jirovecii pneumonia	0	1 (0.0)
Pneumonia	95 (0.4)	83 (0.4)
Pneumonia adenoviral	0	1 (0.0)
Pneumonia bacterial	3 (0.0)	1 (0.0)
Pneumonia legionella	0	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0
Pneumonia viral	0	1 (0.0)
Poliomyelitis	7 (0.0)	10 (0.0)
Post procedural infection	0	2 (0.0)
Post procedural sepsis	0	1 (0.0)
Post treatment Lyme disease syndrome	0	1 (0.0)
Postoperative wound infection	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Presumed ocular histoplasmosis syndrome	0	1 (0.0)
Prostate infection	1 (0.0)	0
Pulmonary mycosis	0	1 (0.0)
Pulmonary sepsis	0	1 (0.0)
Pulmonary tuberculosis	5 (0.0)	3 (0.0)
Pyelonephritis	2 (0.0)	4 (0.0)
Rectal abscess	1 (0.0)	1 (0.0)
Renal abscess	1 (0.0)	0
Renal tuberculosis	0	1 (0.0)
Respiratory syncytial virus infection	0	1 (0.0)
Respiratory tract infection	1 (0.0)	0
Rhinitis	39 (0.2)	34 (0.2)
Rocky mountain spotted fever	2 (0.0)	1 (0.0)
Root canal infection	0	1 (0.0)
Rubella	0	1 (0.0)
Salmonellosis	0	1 (0.0)
Salpingitis	2 (0.0)	2 (0.0)
Scarlet fever	3 (0.0)	3 (0.0)
Scrotal infection	1 (0.0)	0
Sepsis	6 (0.0)	10 (0.0)
Sepsis syndrome	1 (0.0)	0
Septic arthritis staphylococcal	4 (0.0)	0
Septic shock	1 (0.0)	1 (0.0)
Sinobronchitis	0	1 (0.0)
Sinusitis	116 (0.5)	104 (0.5)
Sinusitis bacterial	1 (0.0)	0
Sinusitis fungal	2 (0.0)	1 (0.0)
Skin bacterial infection	2 (0.0)	0
Skin candida	0	1 (0.0)
Skin infection	0	3 (0.0)
Soft tissue infection	1 (0.0)	0
Staphylococcal bacteraemia	0	1 (0.0)
Staphylococcal infection	21 (0.1)	18 (0.1)
Staphylococcal skin infection	3 (0.0)	2 (0.0)
Streptococcal infection	7 (0.0)	1 (0.0)
Subacute endocarditis	1 (0.0)	0
Subcutaneous abscess	2 (0.0)	1 (0.0)
Syphilis	8 (0.0)	5 (0.0)
Tinea capitis	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Tinea cruris	2 (0.0)	1 (0.0)
Tinea infection	1 (0.0)	1 (0.0)
Tinea pedis	13 (0.1)	5 (0.0)
Tinea versicolour	16 (0.1)	13 (0.1)
Tonsillitis	487 (2.2)	436 (2.0)
Tonsillitis streptococcal	1 (0.0)	1 (0.0)
Tooth abscess	2 (0.0)	4 (0.0)
Tooth infection	1 (0.0)	5 (0.0)
Toxic shock syndrome	2 (0.0)	2 (0.0)
Trichomoniasis	2 (0.0)	0
Tropical ulcer	0	1 (0.0)
Tuberculosis	13 (0.1)	8 (0.0)
Tuberculous pleurisy	1 (0.0)	2 (0.0)
Tubo-ovarian abscess	0	1 (0.0)
Typhoid fever	1 (0.0)	1 (0.0)
Typhus	1 (0.0)	1 (0.0)
Upper respiratory tract infection	7 (0.0)	10 (0.0)
Urethritis	0	2 (0.0)
Urinary tract infection	119 (0.5)	116 (0.5)
Urinary tract infection bacterial	1 (0.0)	1 (0.0)
Urosepsis	1 (0.0)	1 (0.0)
Uterine infection	2 (0.0)	0
Vaginal infection	5 (0.0)	5 (0.0)
Vaginitis chlamydial	1 (0.0)	1 (0.0)
Vaginitis gardnerella	1 (0.0)	0
Varicella	13 (0.1)	7 (0.0)
Varicella zoster virus infection	1 (0.0)	0
Vestibular neuronitis	0	2 (0.0)
Viral cardiomyopathy	0	1 (0.0)
Viral infection	2 (0.0)	0
Viral myocarditis	0	1 (0.0)
Vulval abscess	1 (0.0)	0
Vulvitis	1 (0.0)	0
Vulvovaginal candidiasis	1 (0.0)	5 (0.0)
Vulvovaginal mycotic infection	4 (0.0)	4 (0.0)
West Nile viral infection	0	1 (0.0)
Injury, poisoning and procedural complications	1552 (7.1)	1557 (7.2)
Abdominal injury	4 (0.0)	1 (0.0)
Accident	4 (0.0)	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Accident at work	0	1 (0.0)
Accidental poisoning	1 (0.0)	0
Acetabulum fracture	1 (0.0)	1 (0.0)
Alcohol poisoning	0	1 (0.0)
Anaemia postoperative	0	1 (0.0)
Animal bite	3 (0.0)	2 (0.0)
Animal scratch	1 (0.0)	0
Ankle fracture	117 (0.5)	102 (0.5)
Arterial injury	1 (0.0)	3 (0.0)
Arthropod bite	8 (0.0)	5 (0.0)
Arthropod sting	2 (0.0)	1 (0.0)
Asbestosis	0	1 (0.0)
Avulsion fracture	0	2 (0.0)
Back injury	21 (0.1)	15 (0.1)
Bite	1 (0.0)	0
Bladder injury	1 (0.0)	1 (0.0)
Blindness traumatic	1 (0.0)	1 (0.0)
Brachial plexus injury	1 (0.0)	0
Burns second degree	2 (0.0)	0
Burns third degree	1 (0.0)	3 (0.0)
Bursa injury	0	1 (0.0)
Cardiac valve rupture	1 (0.0)	0
Cartilage injury	46 (0.2)	40 (0.2)
Cataract traumatic	0	1 (0.0)
Cervical vertebral fracture	17 (0.1)	11 (0.1)
Chemical poisoning	0	1 (0.0)
Chest injury	2 (0.0)	2 (0.0)
Clavicle fracture	28 (0.1)	42 (0.2)
Colon injury	0	1 (0.0)
Compression fracture	1 (0.0)	1 (0.0)
Concussion	19 (0.1)	12 (0.1)
Contusion	4 (0.0)	3 (0.0)
Corneal abrasion	0	2 (0.0)
Craniocerebral injury	13 (0.1)	11 (0.1)
Craniofacial fracture	0	1 (0.0)
Deafness traumatic	0	2 (0.0)
Decompression sickness	1 (0.0)	1 (0.0)
Dermatitis artefacta	1 (0.0)	0
Dislocation of vertebra	2 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Donor site complication	0	1 (0.0)
Epicondylitis	18 (0.1)	14 (0.1)
Exposure to communicable disease	1 (0.0)	3 (0.0)
Exposure to radiation	1 (0.0)	0
Eye injury	2 (0.0)	9 (0.0)
Eyeball avulsion	1 (0.0)	0
Eyelid contusion	1 (0.0)	0
Face injury	2 (0.0)	2 (0.0)
Facial bones fracture	38 (0.2)	45 (0.2)
Fall	14 (0.1)	10 (0.0)
Fascial rupture	2 (0.0)	0
Femoral neck fracture	0	2 (0.0)
Femur fracture	40 (0.2)	30 (0.1)
Fibula fracture	17 (0.1)	19 (0.1)
Flail chest	0	1 (0.0)
Foot fracture	73 (0.3)	69 (0.3)
Forearm fracture	11 (0.1)	10 (0.0)
Foreign body	3 (0.0)	1 (0.0)
Foreign body in ear	0	1 (0.0)
Foreign body in eye	0	2 (0.0)
Foreign body in gastrointestinal tract	1 (0.0)	0
Fracture	4 (0.0)	3 (0.0)
Fractured coccyx	2 (0.0)	4 (0.0)
Gastrointestinal injury	0	1 (0.0)
Gastrointestinal procedural complication	0	1 (0.0)
Glaucoma traumatic	1 (0.0)	0
Gun shot wound	11 (0.1)	17 (0.1)
Hand fracture	74 (0.3)	69 (0.3)
Head injury	12 (0.1)	25 (0.1)
Hepatic rupture	0	1 (0.0)
Hip fracture	20 (0.1)	24 (0.1)
Humerus fracture	17 (0.1)	16 (0.1)
Iatrogenic injury	1 (0.0)	0
Iliotibial band syndrome	0	9 (0.0)
Ilium fracture	0	1 (0.0)
Incisional hernia	8 (0.0)	10 (0.0)
Injury	1 (0.0)	5 (0.0)
Injury corneal	0	2 (0.0)
Injury to brachial plexus due to birth trauma	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Intentional overdose	0	1 (0.0)
Intentional product misuse	0	1 (0.0)
Intervertebral disc injury	4 (0.0)	1 (0.0)
Iris injury	0	1 (0.0)
Jaw fracture	14 (0.1)	10 (0.0)
Joint dislocation	49 (0.2)	49 (0.2)
Joint injury	50 (0.2)	60 (0.3)
Kidney rupture	0	1 (0.0)
Lacrimal structure injury	1 (0.0)	0
Laryngeal injury	0	1 (0.0)
Ligament injury	17 (0.1)	13 (0.1)
Ligament rupture	153 (0.7)	121 (0.6)
Ligament sprain	15 (0.1)	16 (0.1)
Limb crushing injury	2 (0.0)	2 (0.0)
Limb fracture	2 (0.0)	2 (0.0)
Limb injury	59 (0.3)	55 (0.3)
Limb traumatic amputation	3 (0.0)	3 (0.0)
Lisfranc fracture	1 (0.0)	1 (0.0)
Lower limb fracture	55 (0.3)	49 (0.2)
Lumbar vertebral fracture	13 (0.1)	9 (0.0)
Mallet finger	1 (0.0)	2 (0.0)
Maternal drugs affecting foetus	1 (0.0)	0
Meniscus injury	212 (1.0)	211 (1.0)
Multiple fractures	0	5 (0.0)
Muscle injury	4 (0.0)	8 (0.0)
Muscle rupture	26 (0.1)	18 (0.1)
Muscle strain	18 (0.1)	15 (0.1)
Musculoskeletal foreign body	1 (0.0)	2 (0.0)
Nail injury	0	1 (0.0)
Nasal injury	3 (0.0)	5 (0.0)
Neck injury	8 (0.0)	8 (0.0)
Nerve injury	12 (0.1)	15 (0.1)
Nerve root injury lumbar	0	1 (0.0)
Neurological procedural complication	0	1 (0.0)
Oesophageal injury	1 (0.0)	0
Optic nerve injury	1 (0.0)	0
Overdose	2 (0.0)	0
Pancreatic injury	1 (0.0)	0
Paranasal sinus injury	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Patella fracture	12 (0.1)	7 (0.0)
Pelvic fracture	11 (0.1)	7 (0.0)
Penetrating abdominal trauma	2 (0.0)	0
Penis injury	0	1 (0.0)
Periorbital haematoma	1 (0.0)	0
Periorbital haemorrhage	1 (0.0)	0
Peripheral nerve injury	3 (0.0)	7 (0.0)
Persistent corneal epithelial defect	0	1 (0.0)
Pneumothorax traumatic	1 (0.0)	0
Post ablation tubal sterilisation syndrome	1 (0.0)	0
Post concussion syndrome	1 (0.0)	3 (0.0)
Post procedural complication	1 (0.0)	2 (0.0)
Post procedural diarrhoea	1 (0.0)	2 (0.0)
Post procedural haemorrhage	1 (0.0)	0
Post procedural hypothyroidism	10 (0.0)	10 (0.0)
Post procedural pulmonary embolism	0	1 (0.0)
Post-traumatic neck syndrome	2 (0.0)	1 (0.0)
Post-traumatic pain	1 (0.0)	0
Postoperative adhesion	1 (0.0)	0
Postoperative thrombosis	2 (0.0)	0
Procedural intestinal perforation	1 (0.0)	0
Procedural pain	4 (0.0)	4 (0.0)
Procedural pneumothorax	1 (0.0)	0
Radiation proctitis	0	1 (0.0)
Radius fracture	16 (0.1)	15 (0.1)
Repetitive strain injury	3 (0.0)	0
Respiratory fume inhalation disorder	0	2 (0.0)
Retinal injury	0	1 (0.0)
Rib fracture	17 (0.1)	25 (0.1)
Road traffic accident	28 (0.1)	46 (0.2)
Scapula fracture	0	4 (0.0)
Scar	51 (0.2)	54 (0.2)
Sciatic nerve injury	2 (0.0)	0
Scrotal injury	1 (0.0)	0
Seroma	0	1 (0.0)
Silicosis	1 (0.0)	2 (0.0)
Sinus barotrauma	0	1 (0.0)
Skeletal injury	8 (0.0)	9 (0.0)
Skin abrasion	3 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Skin injury	0	2 (0.0)
Skin laceration	15 (0.1)	17 (0.1)
Skull fracture	3 (0.0)	5 (0.0)
Skull fractured base	2 (0.0)	1 (0.0)
Snake bite	3 (0.0)	1 (0.0)
Soft tissue injury	1 (0.0)	0
Spinal column injury	8 (0.0)	3 (0.0)
Spinal compression fracture	9 (0.0)	13 (0.1)
Spinal cord injury	3 (0.0)	2 (0.0)
Spinal cord injury cervical	2 (0.0)	0
Spinal cord injury thoracic	0	1 (0.0)
Spinal fracture	12 (0.1)	13 (0.1)
Splenic injury	1 (0.0)	2 (0.0)
Splenic rupture	5 (0.0)	6 (0.0)
Sports injury	4 (0.0)	2 (0.0)
Stab wound	4 (0.0)	1 (0.0)
Sternal fracture	2 (0.0)	1 (0.0)
Stress fracture	7 (0.0)	6 (0.0)
Subarachnoid haematoma	1 (0.0)	0
Subdural haematoma	4 (0.0)	5 (0.0)
Subdural haemorrhage	0	1 (0.0)
Superficial injury of eye	0	1 (0.0)
Suture related complication	1 (0.0)	0
Suture rupture	1 (0.0)	0
Tendon dislocation	1 (0.0)	0
Tendon injury	14 (0.1)	11 (0.1)
Tendon rupture	68 (0.3)	72 (0.3)
Testicular injury	0	1 (0.0)
Thermal burn	3 (0.0)	3 (0.0)
Thermal burns of eye	1 (0.0)	1 (0.0)
Thoracic vertebral fracture	2 (0.0)	5 (0.0)
Tibia fracture	39 (0.2)	33 (0.2)
Tooth fracture	2 (0.0)	0
Tooth injury	0	1 (0.0)
Traumatic arthritis	2 (0.0)	1 (0.0)
Traumatic ear amputation	1 (0.0)	0
Traumatic haematoma	1 (0.0)	1 (0.0)
Traumatic liver injury	0	1 (0.0)
Traumatic lung injury	0	7 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Traumatic renal injury	2 (0.0)	1 (0.0)
Ulna fracture	7 (0.0)	12 (0.1)
Ulnar nerve injury	0	3 (0.0)
Upper limb fracture	81 (0.4)	86 (0.4)
Ureteric injury	1 (0.0)	0
Urethral stricture traumatic	0	1 (0.0)
Uterine perforation	1 (0.0)	0
Uterine rupture	2 (0.0)	0
Vascular pseudoaneurysm	2 (0.0)	2 (0.0)
Venomous sting	0	1 (0.0)
Vitreous injury	1 (0.0)	0
Vth nerve injury	1 (0.0)	1 (0.0)
Wound	1 (0.0)	2 (0.0)
Wrist fracture	78 (0.4)	96 (0.4)
Investigations	1677 (7.7)	1677 (7.7)
Alanine aminotransferase increased	2 (0.0)	1 (0.0)
Androgens abnormal	0	1 (0.0)
Angiocardiogram	3 (0.0)	7 (0.0)
Angiogram	1 (0.0)	2 (0.0)
Angiogram peripheral	0	1 (0.0)
Anti-platelet antibody positive	1 (0.0)	0
Anti-thyroid antibody positive	1 (0.0)	0
Anticoagulation drug level	1 (0.0)	0
Antinuclear antibody positive	0	1 (0.0)
Aortic bruit	0	1 (0.0)
Apnoea test	0	1 (0.0)
Apolipoprotein E	1 (0.0)	0
Arteriogram	1 (0.0)	0
Arthroscopy	139 (0.6)	142 (0.7)
Aspartate aminotransferase increased	1 (0.0)	0
Aspiration bone marrow	1 (0.0)	0
Aspiration breast	1 (0.0)	0
Aspiration bursa	0	1 (0.0)
Aspiration joint	0	2 (0.0)
Aspiration pleural cavity	0	3 (0.0)
Bacterial test positive	0	1 (0.0)
Biopsy	5 (0.0)	7 (0.0)
Biopsy bone	1 (0.0)	0
Biopsy bone marrow	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Biopsy breast	34 (0.2)	30 (0.1)
Biopsy breast normal	15 (0.1)	13 (0.1)
Biopsy cervix	3 (0.0)	7 (0.0)
Biopsy cervix abnormal	1 (0.0)	0
Biopsy cervix normal	2 (0.0)	0
Biopsy colon	4 (0.0)	5 (0.0)
Biopsy colon normal	1 (0.0)	0
Biopsy endometrium normal	1 (0.0)	1 (0.0)
Biopsy larynx normal	1 (0.0)	0
Biopsy liver	2 (0.0)	2 (0.0)
Biopsy liver normal	1 (0.0)	1 (0.0)
Biopsy lung	1 (0.0)	4 (0.0)
Biopsy lymph gland	3 (0.0)	4 (0.0)
Biopsy lymph gland normal	1 (0.0)	0
Biopsy pharynx normal	1 (0.0)	0
Biopsy prostate	9 (0.0)	9 (0.0)
Biopsy prostate normal	1 (0.0)	3 (0.0)
Biopsy salivary gland	0	1 (0.0)
Biopsy site unspecified normal	2 (0.0)	0
Biopsy skin	6 (0.0)	10 (0.0)
Biopsy skin normal	0	1 (0.0)
Biopsy small intestine normal	0	1 (0.0)
Biopsy soft tissue	0	1 (0.0)
Biopsy testes	0	1 (0.0)
Biopsy thyroid gland	2 (0.0)	2 (0.0)
Biopsy thyroid gland normal	0	1 (0.0)
Biopsy uterus	1 (0.0)	0
Biopsy vulva	0	1 (0.0)
Blood bilirubin increased	1 (0.0)	3 (0.0)
Blood calcium abnormal	0	1 (0.0)
Blood calcium decreased	2 (0.0)	0
Blood calcium increased	1 (0.0)	3 (0.0)
Blood cholesterol	4 (0.0)	4 (0.0)
Blood cholesterol increased	683 (3.1)	698 (3.2)
Blood cholinesterase decreased	0	1 (0.0)
Blood chromium increased	1 (0.0)	0
Blood cobalt increased	1 (0.0)	0
Blood creatine phosphokinase increased	0	1 (0.0)
Blood creatinine abnormal	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Blood glucose	2 (0.0)	0
Blood glucose abnormal	3 (0.0)	0
Blood glucose increased	8 (0.0)	8 (0.0)
Blood iron decreased	2 (0.0)	2 (0.0)
Blood magnesium decreased	1 (0.0)	1 (0.0)
Blood oestrogen	0	1 (0.0)
Blood oestrogen decreased	3 (0.0)	2 (0.0)
Blood oestrogen increased	2 (0.0)	1 (0.0)
Blood parathyroid hormone abnormal	0	1 (0.0)
Blood parathyroid hormone increased	0	1 (0.0)
Blood potassium decreased	8 (0.0)	7 (0.0)
Blood pressure diastolic increased	1 (0.0)	1 (0.0)
Blood pressure increased	14 (0.1)	15 (0.1)
Blood pressure measurement	1 (0.0)	1 (0.0)
Blood prolactin increased	1 (0.0)	1 (0.0)
Blood testosterone	0	1 (0.0)
Blood testosterone decreased	130 (0.6)	134 (0.6)
Blood testosterone increased	1 (0.0)	0
Blood thyroid stimulating hormone abnormal	1 (0.0)	0
Blood thyroid stimulating hormone decreased	1 (0.0)	1 (0.0)
Blood thyroid stimulating hormone increased	0	1 (0.0)
Blood triglycerides	1 (0.0)	0
Blood triglycerides increased	48 (0.2)	43 (0.2)
Blood uric acid increased	2 (0.0)	5 (0.0)
Blood urine present	1 (0.0)	0
Blood zinc decreased	1 (0.0)	0
Body mass index decreased	0	1 (0.0)
Bone density abnormal	1 (0.0)	0
Bone density decreased	2 (0.0)	0
Bronchoscopy	2 (0.0)	2 (0.0)
Bronchoscopy abnormal	1 (0.0)	0
C-reactive protein increased	1 (0.0)	2 (0.0)
Carbon dioxide increased	0	1 (0.0)
Cardiac murmur	113 (0.5)	122 (0.6)
Cardiac murmur functional	2 (0.0)	1 (0.0)
Cardiac stress test	0	2 (0.0)
Cardiac stress test abnormal	0	1 (0.0)
Carotid bruit	0	3 (0.0)
Catheterisation cardiac	29 (0.1)	27 (0.1)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Chlamydia test positive	0	1 (0.0)
Coagulation factor V level	1 (0.0)	2 (0.0)
Colonoscopy	138 (0.6)	118 (0.5)
Colonoscopy abnormal	0	1 (0.0)
Colonoscopy normal	3 (0.0)	1 (0.0)
Colposcopy	4 (0.0)	2 (0.0)
Colposcopy normal	0	1 (0.0)
Computerised tomogram coronary artery	1 (0.0)	0
Continuous glucose monitoring	0	2 (0.0)
Cortisol increased	0	1 (0.0)
Cystoscopy	7 (0.0)	5 (0.0)
Cystoscopy normal	0	1 (0.0)
Cytology abnormal	1 (0.0)	0
Dehydroepiandrosterone increased	1 (0.0)	0
Diagnostic aspiration	1 (0.0)	0
Diagnostic procedure	3 (0.0)	0
Discogram	1 (0.0)	0
Echocardiogram	2 (0.0)	1 (0.0)
Ejection fraction decreased	2 (0.0)	1 (0.0)
Electrocardiogram PR shortened	1 (0.0)	0
Electrocardiogram QT prolonged	2 (0.0)	1 (0.0)
Electrocardiogram ST segment abnormal	0	1 (0.0)
Electrocardiogram ST segment depression	1 (0.0)	0
Electrocardiogram T wave inversion	2 (0.0)	0
Electrocardiogram abnormal	2 (0.0)	4 (0.0)
Endoscopic retrograde cholangiopancreatography	1 (0.0)	1 (0.0)
Endoscopy	14 (0.1)	11 (0.1)
Endoscopy gastrointestinal	0	1 (0.0)
Endoscopy upper gastrointestinal tract	9 (0.0)	7 (0.0)
Eosinophil count increased	1 (0.0)	0
Epinephrine	0	1 (0.0)
Epstein-Barr virus test positive	0	1 (0.0)
False positive investigation result	1 (0.0)	1 (0.0)
Full blood count	0	1 (0.0)
Gamma-glutamyltransferase abnormal	0	1 (0.0)
Gastrointestinal tract biopsy	0	1 (0.0)
Gene mutation identification test positive	1 (0.0)	1 (0.0)
Glomerular filtration rate	1 (0.0)	0
Glomerular filtration rate decreased	2 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Glycosylated haemoglobin	0	1 (0.0)
Glycosylated haemoglobin increased	3 (0.0)	1 (0.0)
HIV test positive	77 (0.4)	73 (0.3)
HLA marker study	0	3 (0.0)
HLA-B*27 positive	0	1 (0.0)
Haemoglobin decreased	0	2 (0.0)
Haemoglobin increased	1 (0.0)	0
Heart rate decreased	3 (0.0)	1 (0.0)
Heart rate increased	1 (0.0)	4 (0.0)
Heart rate irregular	28 (0.1)	44 (0.2)
Helicobacter test positive	2 (0.0)	0
Hepatic enzyme abnormal	1 (0.0)	0
Hepatic enzyme increased	13 (0.1)	4 (0.0)
Hepatitis A antibody positive	1 (0.0)	0
Hepatitis B antibody positive	1 (0.0)	1 (0.0)
Hepatitis B surface antibody positive	1 (0.0)	1 (0.0)
Hepatitis B test negative	0	1 (0.0)
Hepatitis C antibody positive	3 (0.0)	0
Hepatitis C core antibody negative	0	1 (0.0)
Hepatitis C test negative	0	1 (0.0)
High density lipoprotein decreased	6 (0.0)	4 (0.0)
Hormone level abnormal	7 (0.0)	5 (0.0)
Human papilloma virus test	0	1 (0.0)
Human papilloma virus test positive	29 (0.1)	26 (0.1)
Hysteroscopy	8 (0.0)	5 (0.0)
Intraocular pressure decreased	0	1 (0.0)
Intraocular pressure increased	4 (0.0)	10 (0.0)
Intraocular pressure test	1 (0.0)	0
Investigation	1 (0.0)	0
Laparoscopy	26 (0.1)	18 (0.1)
Lipids	0	1 (0.0)
Lipids increased	8 (0.0)	7 (0.0)
Lipoprotein (a) abnormal	1 (0.0)	0
Lipoprotein (a) increased	0	2 (0.0)
Liver function test abnormal	1 (0.0)	1 (0.0)
Liver function test increased	10 (0.0)	5 (0.0)
Low density lipoprotein increased	2 (0.0)	7 (0.0)
Lumbar puncture	0	1 (0.0)
Lumbar puncture normal	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Magnetic resonance imaging	0	1 (0.0)
Magnetic resonance imaging joint	0	1 (0.0)
Mammogram	1 (0.0)	2 (0.0)
Mammogram abnormal	5 (0.0)	1 (0.0)
Mean cell volume increased	0	1 (0.0)
Mediastinoscopy	0	2 (0.0)
Medical observation	1 (0.0)	0
Metabolic function test	0	1 (0.0)
Mumps antibody test positive	1 (0.0)	0
Mycobacterium tuberculosis complex test negative	1 (0.0)	0
Mycobacterium tuberculosis complex test positive	3 (0.0)	1 (0.0)
Nasoendoscopy	2 (0.0)	1 (0.0)
Occult blood positive	0	1 (0.0)
Oesophageal manometry	0	1 (0.0)
Oesophageal pH	0	1 (0.0)
Oesophagogastroduodenoscopy	6 (0.0)	4 (0.0)
Oesophagoscopy	1 (0.0)	0
Oestradiol decreased	1 (0.0)	0
Oestrogen receptor assay negative	0	1 (0.0)
Pelvic laparoscopy	5 (0.0)	1 (0.0)
Plasminogen activator inhibitor increased	0	1 (0.0)
Platelet count decreased	0	2 (0.0)
Precancerous cells present	9 (0.0)	14 (0.1)
Proctoscopy	0	1 (0.0)
Progesterone decreased	1 (0.0)	5 (0.0)
Prostatic specific antigen abnormal	1 (0.0)	0
Prostatic specific antigen increased	17 (0.1)	20 (0.1)
Pulmonary function test decreased	0	2 (0.0)
Red blood cell count increased	0	1 (0.0)
Rheumatoid factor	1 (0.0)	0
Scan myocardial perfusion	0	1 (0.0)
Seroconversion test positive	0	1 (0.0)
Serum ferritin decreased	1 (0.0)	1 (0.0)
Serum ferritin increased	0	1 (0.0)
Sigmoidoscopy	1 (0.0)	1 (0.0)
Sleep study	1 (0.0)	0
Smear cervix abnormal	22 (0.1)	15 (0.1)
Smooth muscle antibody	1 (0.0)	0
Staphylococcus test positive	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Stool analysis abnormal	1 (0.0)	0
Streptococcus test positive	0	1 (0.0)
Thyroid function test normal	0	1 (0.0)
Total bile acids increased	0	1 (0.0)
Transaminases increased	3 (0.0)	1 (0.0)
Tuberculin test	0	1 (0.0)
Tuberculin test positive	8 (0.0)	9 (0.0)
Ureteroscopy	2 (0.0)	1 (0.0)
Urogram	1 (0.0)	0
Vitamin B12 decreased	4 (0.0)	1 (0.0)
Vitamin D abnormal	0	1 (0.0)
Vitamin D decreased	10 (0.0)	12 (0.1)
Weight decreased	4 (0.0)	2 (0.0)
Weight increased	4 (0.0)	3 (0.0)
White blood cell count decreased	3 (0.0)	1 (0.0)
White blood cell count increased	2 (0.0)	0
X-ray	1 (0.0)	0
Metabolism and nutrition disorders	6497 (29.9)	6346 (29.2)
Abnormal loss of weight	0	1 (0.0)
Abnormal weight gain	0	1 (0.0)
Acidosis	1 (0.0)	0
Calcium deficiency	1 (0.0)	2 (0.0)
Central obesity	2 (0.0)	0
Cholesterosis	2 (0.0)	0
Dairy intolerance	3 (0.0)	1 (0.0)
Decreased appetite	1 (0.0)	5 (0.0)
Dehydration	4 (0.0)	5 (0.0)
Diabetes mellitus	27 (0.1)	19 (0.1)
Diabetes mellitus inadequate control	1 (0.0)	0
Diabetic complication	1 (0.0)	0
Diabetic dyslipidaemia	2 (0.0)	0
Diabetic ketoacidosis	1 (0.0)	3 (0.0)
Disaccharide metabolism disorder	1 (0.0)	0
Dyslipidaemia	534 (2.5)	504 (2.3)
Electrolyte imbalance	1 (0.0)	0
Fluid retention	23 (0.1)	14 (0.1)
Folate deficiency	0	2 (0.0)
Food intolerance	3 (0.0)	2 (0.0)
Fructose intolerance	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Glucose tolerance impaired	241 (1.1)	231 (1.1)
Gluten sensitivity	22 (0.1)	29 (0.1)
Gout	278 (1.3)	284 (1.3)
Haemochromatosis	13 (0.1)	5 (0.0)
Histamine intolerance	0	1 (0.0)
Hyperamylasaemia	1 (0.0)	0
Hypercalcaemia	10 (0.0)	1 (0.0)
Hypercholesterolaemia	1627 (7.5)	1615 (7.4)
Hyperglycaemia	21 (0.1)	21 (0.1)
Hyperhomocysteinaemia	3 (0.0)	1 (0.0)
Hyperinsulinaemia	0	1 (0.0)
Hyperinsulinism	1 (0.0)	0
Hyperkalaemia	4 (0.0)	1 (0.0)
Hyperlactacidaemia	0	1 (0.0)
Hyperlipidaemia	1484 (6.8)	1440 (6.6)
Hypernatraemia	1 (0.0)	0
Hyperphagia	1 (0.0)	0
Hypertriglyceridaemia	87 (0.4)	82 (0.4)
Hyperuricaemia	21 (0.1)	33 (0.2)
Hypocalcaemia	1 (0.0)	1 (0.0)
Hypocholesterolaemia	12 (0.1)	6 (0.0)
Hypoglycaemia	12 (0.1)	8 (0.0)
Hypokalaemia	31 (0.1)	28 (0.1)
Hypolipidaemia	1 (0.0)	4 (0.0)
Hypomagnesaemia	0	5 (0.0)
Hypometabolism	0	1 (0.0)
Hyponatraemia	5 (0.0)	3 (0.0)
Hypophosphataemia	2 (0.0)	0
Hypovitaminosis	1 (0.0)	4 (0.0)
Impaired fasting glucose	29 (0.1)	18 (0.1)
Insulin resistance	15 (0.1)	15 (0.1)
Insulin resistant diabetes	0	1 (0.0)
Insulin-requiring type 2 diabetes mellitus	1 (0.0)	2 (0.0)
Iron deficiency	24 (0.1)	37 (0.2)
Iron metabolism disorder	1 (0.0)	0
Ketoacidosis	1 (0.0)	1 (0.0)
Lactose intolerance	67 (0.3)	76 (0.3)
Latent autoimmune diabetes in adults	1 (0.0)	0
Lipid metabolism disorder	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Lipoedema	2 (0.0)	1 (0.0)
Lipomatosis	0	1 (0.0)
Lipoprotein deficiency	0	1 (0.0)
Magnesium deficiency	2 (0.0)	1 (0.0)
Malnutrition	2 (0.0)	0
Metabolic acidosis	1 (0.0)	0
Metabolic disorder	1 (0.0)	0
Metabolic syndrome	20 (0.1)	6 (0.0)
Monogenic diabetes	0	1 (0.0)
Obesity	1580 (7.3)	1604 (7.4)
Overweight	364 (1.7)	370 (1.7)
Polydipsia	1 (0.0)	0
Postprandial hypoglycaemia	0	1 (0.0)
Protein intolerance	0	1 (0.0)
Refeeding syndrome	0	1 (0.0)
Type 1 diabetes mellitus	93 (0.4)	87 (0.4)
Type 2 diabetes mellitus	1569 (7.2)	1567 (7.2)
Underweight	2 (0.0)	5 (0.0)
Vitamin A deficiency	2 (0.0)	1 (0.0)
Vitamin B complex deficiency	9 (0.0)	10 (0.0)
Vitamin B12 deficiency	74 (0.3)	76 (0.3)
Vitamin B6 deficiency	0	1 (0.0)
Vitamin D deficiency	396 (1.8)	372 (1.7)
Vitamin E deficiency	1 (0.0)	0
Vitamin K deficiency	0	1 (0.0)
Musculoskeletal and connective tissue disorders	4313 (19.9)	4218 (19.4)
Ankle impingement	0	1 (0.0)
Ankylosing spondylitis	7 (0.0)	7 (0.0)
Arthralgia	415 (1.9)	431 (2.0)
Arthritis	236 (1.1)	222 (1.0)
Arthritis reactive	1 (0.0)	1 (0.0)
Arthropathy	16 (0.1)	10 (0.0)
Articular calcification	2 (0.0)	3 (0.0)
Autoimmune arthritis	1 (0.0)	0
Axillary mass	1 (0.0)	0
Back disorder	3 (0.0)	2 (0.0)
Back pain	836 (3.8)	844 (3.9)
Blount's disease	0	1 (0.0)
Bone cyst	5 (0.0)	5 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Bone deformity	0	2 (0.0)
Bone disorder	0	2 (0.0)
Bone erosion	0	1 (0.0)
Bone hypertrophy	1 (0.0)	1 (0.0)
Bone lesion	1 (0.0)	1 (0.0)
Bone loss	0	1 (0.0)
Bone pain	1 (0.0)	1 (0.0)
Bursa disorder	1 (0.0)	0
Bursitis	30 (0.1)	54 (0.2)
CREST syndrome	1 (0.0)	1 (0.0)
Cervical spinal stenosis	11 (0.1)	7 (0.0)
Chondromalacia	4 (0.0)	1 (0.0)
Chondropathy	6 (0.0)	8 (0.0)
Coccydynia	2 (0.0)	0
Compartment syndrome	5 (0.0)	5 (0.0)
Connective tissue disorder	0	1 (0.0)
Costochondritis	3 (0.0)	4 (0.0)
Degenerative bone disease	0	1 (0.0)
Diastasis recti abdominis	4 (0.0)	1 (0.0)
Diffuse idiopathic skeletal hyperostosis	2 (0.0)	0
Dupuytren's contracture	13 (0.1)	20 (0.1)
Dwarfism	1 (0.0)	0
Eagle's syndrome	1 (0.0)	0
Enthesopathy	3 (0.0)	1 (0.0)
Epiphysiolysis	1 (0.0)	0
Exostosis	54 (0.2)	55 (0.3)
Exostosis of jaw	0	1 (0.0)
Extremity contracture	2 (0.0)	0
Facet joint syndrome	4 (0.0)	2 (0.0)
Femoroacetabular impingement	2 (0.0)	2 (0.0)
Fibromyalgia	163 (0.8)	119 (0.5)
Finger deformity	1 (0.0)	1 (0.0)
Fistula	3 (0.0)	1 (0.0)
Flank pain	1 (0.0)	1 (0.0)
Floating patella	1 (0.0)	2 (0.0)
Foot deformity	105 (0.5)	113 (0.5)
Fracture nonunion	0	1 (0.0)
Gouty arthritis	1 (0.0)	3 (0.0)
Growth retardation	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Hypermobility syndrome	4 (0.0)	3 (0.0)
Inclusion body myositis	1 (0.0)	1 (0.0)
Intervertebral disc compression	7 (0.0)	11 (0.1)
Intervertebral disc degeneration	172 (0.8)	126 (0.6)
Intervertebral disc disorder	9 (0.0)	13 (0.1)
Intervertebral disc displacement	2 (0.0)	2 (0.0)
Intervertebral disc protrusion	275 (1.3)	260 (1.2)
Jaw cyst	1 (0.0)	1 (0.0)
Jaw disorder	2 (0.0)	4 (0.0)
Joint contracture	1 (0.0)	0
Joint effusion	1 (0.0)	1 (0.0)
Joint instability	3 (0.0)	2 (0.0)
Joint range of motion decreased	2 (0.0)	6 (0.0)
Joint stiffness	2 (0.0)	1 (0.0)
Joint swelling	7 (0.0)	8 (0.0)
Juvenile idiopathic arthritis	2 (0.0)	2 (0.0)
Knee deformity	0	1 (0.0)
Kyphosis	9 (0.0)	5 (0.0)
Ligament calcification	1 (0.0)	0
Ligament disorder	1 (0.0)	2 (0.0)
Ligament laxity	1 (0.0)	1 (0.0)
Limb asymmetry	3 (0.0)	2 (0.0)
Limb deformity	1 (0.0)	1 (0.0)
Limb mass	2 (0.0)	2 (0.0)
Loose body in joint	0	2 (0.0)
Lordosis	0	1 (0.0)
Lumbar spinal stenosis	20 (0.1)	22 (0.1)
Metatarsalgia	2 (0.0)	1 (0.0)
Mixed connective tissue disease	2 (0.0)	0
Mobility decreased	1 (0.0)	2 (0.0)
Morphoea	1 (0.0)	1 (0.0)
Muscle atrophy	1 (0.0)	1 (0.0)
Muscle contracture	0	1 (0.0)
Muscle disorder	0	1 (0.0)
Muscle fatigue	0	1 (0.0)
Muscle spasms	126 (0.6)	147 (0.7)
Muscle tightness	2 (0.0)	2 (0.0)
Muscle twitching	3 (0.0)	2 (0.0)
Muscular weakness	7 (0.0)	5 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Musculoskeletal chest pain	4 (0.0)	3 (0.0)
Musculoskeletal disorder	1 (0.0)	0
Musculoskeletal pain	3 (0.0)	2 (0.0)
Musculoskeletal stiffness	4 (0.0)	2 (0.0)
Myalgia	99 (0.5)	110 (0.5)
Myalgia intercostal	0	1 (0.0)
Myofascial pain syndrome	3 (0.0)	6 (0.0)
Myopathy	1 (0.0)	1 (0.0)
Myositis	1 (0.0)	0
Neck mass	2 (0.0)	2 (0.0)
Neck pain	101 (0.5)	99 (0.5)
Neuropathic arthropathy	1 (0.0)	0
Os trigonum syndrome	1 (0.0)	0
Osteitis	2 (0.0)	0
Osteitis deformans	0	2 (0.0)
Osteoarthritis	1538 (7.1)	1543 (7.1)
Osteochondritis	1 (0.0)	1 (0.0)
Osteochondrosis	10 (0.0)	10 (0.0)
Osteolysis	0	2 (0.0)
Osteomalacia	1 (0.0)	0
Osteonecrosis	9 (0.0)	11 (0.1)
Osteonecrosis of jaw	0	1 (0.0)
Osteopenia	291 (1.3)	271 (1.2)
Osteoporosis	322 (1.5)	291 (1.3)
Osteoporosis postmenopausal	1 (0.0)	0
Osteosclerosis	0	1 (0.0)
Pain in extremity	62 (0.3)	73 (0.3)
Pain in jaw	3 (0.0)	4 (0.0)
Patellofemoral pain syndrome	6 (0.0)	5 (0.0)
Periarthritis	17 (0.1)	16 (0.1)
Perthes disease	2 (0.0)	0
Plantar fascial fibromatosis	1 (0.0)	5 (0.0)
Plantar fasciitis	49 (0.2)	67 (0.3)
Plica syndrome	0	2 (0.0)
Polyarthritis	13 (0.1)	7 (0.0)
Polymyalgia rheumatica	7 (0.0)	3 (0.0)
Posterior tibial tendon dysfunction	1 (0.0)	1 (0.0)
Prognathism	1 (0.0)	1 (0.0)
Psoriatic arthropathy	5 (0.0)	5 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Retrognathia	1 (0.0)	1 (0.0)
Reynold's syndrome	1 (0.0)	0
Rhabdomyolysis	1 (0.0)	3 (0.0)
Rheumatic disorder	1 (0.0)	1 (0.0)
Rheumatic fever	5 (0.0)	6 (0.0)
Rheumatoid arthritis	42 (0.2)	34 (0.2)
Rickets	1 (0.0)	0
Rotator cuff syndrome	243 (1.1)	169 (0.8)
Sacroiliac joint dysfunction	1 (0.0)	1 (0.0)
Sacroiliitis	3 (0.0)	3 (0.0)
Scapholunate dissociation	0	1 (0.0)
Scleroderma	2 (0.0)	2 (0.0)
Scoliosis	79 (0.4)	84 (0.4)
Senile osteoporosis	0	2 (0.0)
Seronegative arthritis	1 (0.0)	1 (0.0)
Sinus tarsi syndrome	1 (0.0)	0
Sjogren's syndrome	5 (0.0)	5 (0.0)
Snapping hip syndrome	0	1 (0.0)
Soft tissue disorder	0	1 (0.0)
Somatic dysfunction	0	1 (0.0)
Spinal deformity	1 (0.0)	2 (0.0)
Spinal disorder	14 (0.1)	8 (0.0)
Spinal osteoarthritis	182 (0.8)	211 (1.0)
Spinal pain	13 (0.1)	18 (0.1)
Spinal stenosis	60 (0.3)	57 (0.3)
Spinal synovial cyst	0	2 (0.0)
Spondylitis	25 (0.1)	32 (0.1)
Spondyloarthropathy	4 (0.0)	1 (0.0)
Spondylolisthesis	18 (0.1)	13 (0.1)
Spondylolysis	5 (0.0)	0
Symphysiolysis	0	1 (0.0)
Synovial cyst	35 (0.2)	32 (0.1)
Synovitis	1 (0.0)	1 (0.0)
Systemic lupus erythematosus	5 (0.0)	3 (0.0)
Temporomandibular joint syndrome	35 (0.2)	28 (0.1)
Tendon disorder	5 (0.0)	3 (0.0)
Tendon laxity	0	2 (0.0)
Tendon pain	2 (0.0)	1 (0.0)
Tendonitis	56 (0.3)	63 (0.3)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Tenosynovitis	2 (0.0)	4 (0.0)
Tenosynovitis stenosans	9 (0.0)	9 (0.0)
Torticollis	2 (0.0)	4 (0.0)
Trigger finger	49 (0.2)	40 (0.2)
Ulnocarpal abutment syndrome	1 (0.0)	0
Undifferentiated connective tissue disease	0	1 (0.0)
Vertebral foraminal stenosis	1 (0.0)	3 (0.0)
Vertebral osteophyte	4 (0.0)	8 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1843 (8.5)	1857 (8.5)
Abdominal neoplasm	1 (0.0)	0
Abdominal wall neoplasm	0	1 (0.0)
Acanthoma	0	1 (0.0)
Acinic cell carcinoma of salivary gland	1 (0.0)	0
Acoustic neuroma	9 (0.0)	10 (0.0)
Acrochordon	0	3 (0.0)
Acute lymphocytic leukaemia	1 (0.0)	1 (0.0)
Acute myeloid leukaemia	2 (0.0)	1 (0.0)
Adenocarcinoma	0	2 (0.0)
Adenocarcinoma of appendix	1 (0.0)	0
Adenocarcinoma of colon	0	1 (0.0)
Adenocarcinoma of the cervix	0	1 (0.0)
Adenoid cystic carcinoma	1 (0.0)	1 (0.0)
Adenoma benign	8 (0.0)	7 (0.0)
Adrenal adenoma	2 (0.0)	2 (0.0)
Adrenal neoplasm	0	1 (0.0)
Anal cancer	2 (0.0)	0
Angiofibroma	1 (0.0)	0
Angiomyolipoma	0	1 (0.0)
Anogenital warts	1 (0.0)	4 (0.0)
Appendix cancer	2 (0.0)	3 (0.0)
Astrocytoma	1 (0.0)	0
B-cell lymphoma	2 (0.0)	0
Basal cell carcinoma	283 (1.3)	298 (1.4)
Basosquamous carcinoma	3 (0.0)	2 (0.0)
Basosquamous carcinoma of skin	0	2 (0.0)
Benign bone neoplasm	4 (0.0)	6 (0.0)
Benign breast neoplasm	41 (0.2)	30 (0.1)
Benign cardiac neoplasm	0	1 (0.0)
Benign gastric neoplasm	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Benign gastrointestinal neoplasm	1 (0.0)	2 (0.0)
Benign hydatidiform mole	1 (0.0)	0
Benign joint neoplasm	1 (0.0)	0
Benign laryngeal neoplasm	0	1 (0.0)
Benign lung neoplasm	4 (0.0)	12 (0.1)
Benign mediastinal neoplasm	0	1 (0.0)
Benign muscle neoplasm	2 (0.0)	0
Benign neoplasm	7 (0.0)	9 (0.0)
Benign neoplasm of adrenal gland	0	1 (0.0)
Benign neoplasm of bladder	2 (0.0)	0
Benign neoplasm of cornea	1 (0.0)	0
Benign neoplasm of eye	0	1 (0.0)
Benign neoplasm of eyelid	0	1 (0.0)
Benign neoplasm of prostate	0	1 (0.0)
Benign neoplasm of skin	2 (0.0)	5 (0.0)
Benign neoplasm of spinal cord	0	1 (0.0)
Benign neoplasm of testis	2 (0.0)	2 (0.0)
Benign neoplasm of thymus	1 (0.0)	0
Benign neoplasm of thyroid gland	28 (0.1)	37 (0.2)
Benign ovarian tumour	5 (0.0)	8 (0.0)
Benign pancreatic neoplasm	1 (0.0)	2 (0.0)
Benign renal neoplasm	0	2 (0.0)
Benign salivary gland neoplasm	4 (0.0)	0
Benign small intestinal neoplasm	0	1 (0.0)
Benign uterine neoplasm	6 (0.0)	2 (0.0)
Benign vascular neoplasm	0	2 (0.0)
Bladder cancer	23 (0.1)	12 (0.1)
Bladder cancer stage 0, with cancer in situ	1 (0.0)	0
Bladder neoplasm	1 (0.0)	1 (0.0)
Bladder transitional cell carcinoma	0	1 (0.0)
Bone cancer	1 (0.0)	0
Bone neoplasm	2 (0.0)	2 (0.0)
Bowen's disease	0	1 (0.0)
Brain neoplasm	4 (0.0)	1 (0.0)
Brain neoplasm benign	2 (0.0)	9 (0.0)
Brain neoplasm malignant	1 (0.0)	1 (0.0)
Breast cancer	202 (0.9)	201 (0.9)
Breast cancer female	1 (0.0)	0
Breast cancer in situ	3 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Breast cancer metastatic	1 (0.0)	0
Breast cancer recurrent	1 (0.0)	0
Breast cancer stage I	7 (0.0)	4 (0.0)
Breast cancer stage II	5 (0.0)	1 (0.0)
Breast cancer stage III	1 (0.0)	1 (0.0)
Breast fibroma	4 (0.0)	3 (0.0)
Breast neoplasm	3 (0.0)	3 (0.0)
Bronchial neoplasm	1 (0.0)	0
Cancer in remission	1 (0.0)	1 (0.0)
Carcinoid tumour	1 (0.0)	0
Carcinoid tumour pulmonary	1 (0.0)	0
Cervix carcinoma	33 (0.2)	25 (0.1)
Cervix carcinoma stage 0	1 (0.0)	1 (0.0)
Cervix carcinoma stage I	0	1 (0.0)
Cholesteatoma	3 (0.0)	3 (0.0)
Choroid melanoma	1 (0.0)	2 (0.0)
Chromophobe renal cell carcinoma	1 (0.0)	0
Chronic lymphocytic leukaemia	4 (0.0)	4 (0.0)
Chronic myeloid leukaemia	0	1 (0.0)
Clear cell renal cell carcinoma	3 (0.0)	0
Colon adenoma	23 (0.1)	14 (0.1)
Colon cancer	32 (0.1)	30 (0.1)
Colon cancer stage I	0	1 (0.0)
Colon cancer stage II	0	1 (0.0)
Colon cancer stage III	1 (0.0)	0
Colon cancer stage IV	1 (0.0)	0
Colorectal cancer	1 (0.0)	3 (0.0)
Colorectal cancer metastatic	1 (0.0)	0
Cutaneous T-cell lymphoma	1 (0.0)	2 (0.0)
Cutaneous lymphoma	0	1 (0.0)
Dermatofibrosarcoma protuberans	1 (0.0)	0
Desmoid tumour	2 (0.0)	1 (0.0)
Desmoplastic melanoma	0	1 (0.0)
Diffuse large B-cell lymphoma	1 (0.0)	0
Dysplastic naevus	2 (0.0)	3 (0.0)
Ear neoplasm	0	1 (0.0)
Ear neoplasm malignant	0	2 (0.0)
Elastofibroma	1 (0.0)	0
Enchondromatosis	1 (0.0)	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Endocrine neoplasm malignant	1 (0.0)	0
Endometrial cancer	14 (0.1)	14 (0.1)
Endometrial cancer stage III	1 (0.0)	0
Essential thrombocythaemia	2 (0.0)	1 (0.0)
Ewing's sarcoma	0	1 (0.0)
Extragonadal primary seminoma (pure)	0	2 (0.0)
Eye naevus	1 (0.0)	3 (0.0)
Eyelid haemangioma	1 (0.0)	0
Fallopian tube cancer	1 (0.0)	0
Fibroadenoma of breast	8 (0.0)	10 (0.0)
Fibroma	16 (0.1)	16 (0.1)
Fibrosarcoma	1 (0.0)	0
Fibrous histiocytoma	1 (0.0)	1 (0.0)
Follicle centre lymphoma, follicular grade I, II, III	0	1 (0.0)
Follicular thyroid cancer	0	1 (0.0)
Ganglioneuroblastoma	0	1 (0.0)
Gastric cancer	1 (0.0)	1 (0.0)
Gastric neoplasm	1 (0.0)	0
Gastrinoma	0	1 (0.0)
Gastrointestinal melanoma	1 (0.0)	0
Gastrointestinal stromal tumour	0	1 (0.0)
Gastrointestinal tract adenoma	2 (0.0)	1 (0.0)
Gestational trophoblastic tumour	1 (0.0)	0
Giant cell tumour of tendon sheath	0	1 (0.0)
Glomus tumour	0	1 (0.0)
Haemangioma	1 (0.0)	7 (0.0)
Haemangioma of liver	2 (0.0)	1 (0.0)
Haemangioma of skin	2 (0.0)	0
Haemangioma of spleen	1 (0.0)	0
Hair follicle tumour benign	1 (0.0)	0
Hairy cell leukaemia	0	1 (0.0)
Hepatic adenoma	1 (0.0)	1 (0.0)
Hepatic cancer	2 (0.0)	0
Hodgkin's disease	9 (0.0)	9 (0.0)
Hodgkin's disease nodular sclerosis	0	1 (0.0)
Hypergammaglobulinaemia benign monoclonal	2 (0.0)	4 (0.0)
Intraductal papilloma of breast	0	1 (0.0)
Intraductal proliferative breast lesion	7 (0.0)	7 (0.0)
Intraocular melanoma	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Invasive breast carcinoma	1 (0.0)	0
Invasive ductal breast carcinoma	2 (0.0)	6 (0.0)
Invasive lobular breast carcinoma	1 (0.0)	0
Iris melanoma	0	1 (0.0)
Juvenile melanoma benign	1 (0.0)	0
Kaposi's sarcoma	0	1 (0.0)
Langerhans' cell histiocytosis	1 (0.0)	0
Large granular lymphocytosis	1 (0.0)	0
Large intestine benign neoplasm	3 (0.0)	1 (0.0)
Laryngeal cancer	5 (0.0)	2 (0.0)
Laryngeal neoplasm	1 (0.0)	0
Laryngeal papilloma	1 (0.0)	0
Leiomyoma	4 (0.0)	4 (0.0)
Leiomyosarcoma	0	1 (0.0)
Lentigo maligna	1 (0.0)	1 (0.0)
Leukaemia	6 (0.0)	2 (0.0)
Lip and/or oral cavity cancer	4 (0.0)	2 (0.0)
Lip neoplasm malignant stage unspecified	0	1 (0.0)
Lip squamous cell carcinoma	3 (0.0)	2 (0.0)
Lipoma	40 (0.2)	43 (0.2)
Lipoma of breast	1 (0.0)	1 (0.0)
Liposarcoma	0	1 (0.0)
Lobular breast carcinoma in situ	4 (0.0)	2 (0.0)
Lung adenocarcinoma	1 (0.0)	0
Lung carcinoma cell type unspecified stage IV	1 (0.0)	0
Lung neoplasm malignant	11 (0.1)	11 (0.1)
Lymphangioma	1 (0.0)	0
Lymphoma	5 (0.0)	8 (0.0)
Malignant melanoma	107 (0.5)	93 (0.4)
Malignant melanoma in situ	4 (0.0)	2 (0.0)
Malignant melanoma of eyelid	1 (0.0)	1 (0.0)
Malignant melanoma stage I	2 (0.0)	2 (0.0)
Malignant melanoma stage II	1 (0.0)	0
Mantle cell lymphoma	1 (0.0)	1 (0.0)
Melanocytic naevus	17 (0.1)	16 (0.1)
Melanoma recurrent	1 (0.0)	0
Meningioma	8 (0.0)	13 (0.1)
Meningioma benign	8 (0.0)	3 (0.0)
Metaplastic breast carcinoma	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Metastases to bone	1 (0.0)	0
Metastatic malignant melanoma	0	1 (0.0)
Metastatic neoplasm	1 (0.0)	0
Metastatic squamous cell carcinoma	0	1 (0.0)
Monoclonal gammopathy	1 (0.0)	1 (0.0)
Nasopharyngeal cancer	1 (0.0)	0
Neoplasm	1 (0.0)	3 (0.0)
Neoplasm malignant	3 (0.0)	2 (0.0)
Neoplasm of appendix	1 (0.0)	1 (0.0)
Neoplasm skin	0	1 (0.0)
Nephroblastoma	1 (0.0)	1 (0.0)
Nervous system neoplasm benign	0	1 (0.0)
Neurilemmoma benign	0	2 (0.0)
Neuroendocrine carcinoma	1 (0.0)	0
Neuroendocrine tumour	0	1 (0.0)
Neurofibroma	1 (0.0)	0
Neuroma	11 (0.1)	9 (0.0)
Non-Hodgkin's lymphoma	6 (0.0)	12 (0.1)
Non-small cell lung cancer	0	1 (0.0)
Ocular neoplasm	0	1 (0.0)
Oesophageal adenocarcinoma	1 (0.0)	0
Oesophageal carcinoma	1 (0.0)	0
Oesophageal carcinoma stage 0	1 (0.0)	0
Oral neoplasm	1 (0.0)	0
Oral neoplasm benign	0	1 (0.0)
Oropharyngeal cancer	0	1 (0.0)
Osteochondroma	1 (0.0)	5 (0.0)
Osteoma	0	3 (0.0)
Osteosarcoma	0	2 (0.0)
Ovarian adenoma	1 (0.0)	0
Ovarian cancer	11 (0.1)	16 (0.1)
Ovarian cancer metastatic	0	1 (0.0)
Ovarian cancer stage IV	1 (0.0)	0
Ovarian dysgerminoma stage unspecified	1 (0.0)	0
Ovarian fibroma	2 (0.0)	0
Ovarian germ cell teratoma	2 (0.0)	0
Ovarian germ cell teratoma benign	1 (0.0)	5 (0.0)
Ovarian neoplasm	1 (0.0)	2 (0.0)
Paget's disease of nipple	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Pancreatic carcinoma	2 (0.0)	0
Pancreatic neoplasm	0	1 (0.0)
Papillary thyroid cancer	10 (0.0)	9 (0.0)
Papilloma	0	1 (0.0)
Paraganglion neoplasm benign	0	1 (0.0)
Paranasal sinus benign neoplasm	1 (0.0)	0
Parathyroid tumour	1 (0.0)	1 (0.0)
Parathyroid tumour benign	5 (0.0)	10 (0.0)
Phaeochromocytoma	0	1 (0.0)
Pharyngeal cancer	0	1 (0.0)
Pharyngeal neoplasm	1 (0.0)	0
Phyllodes tumour	1 (0.0)	0
Pineal germinoma	0	1 (0.0)
Pituitary tumour	1 (0.0)	2 (0.0)
Pituitary tumour benign	16 (0.1)	11 (0.1)
Plasma cell myeloma	4 (0.0)	2 (0.0)
Pleural neoplasm	0	1 (0.0)
Polycythaemia vera	1 (0.0)	1 (0.0)
Prolactin-producing pituitary tumour	1 (0.0)	2 (0.0)
Prostate cancer	174 (0.8)	180 (0.8)
Prostate cancer stage I	1 (0.0)	2 (0.0)
Prostate cancer stage III	1 (0.0)	0
Prostate cancer stage IV	1 (0.0)	0
Prostatic adenoma	1 (0.0)	5 (0.0)
Rectal cancer	2 (0.0)	4 (0.0)
Rectal cancer stage III	0	1 (0.0)
Rectal neoplasm	1 (0.0)	0
Renal adenoma	1 (0.0)	0
Renal cancer	15 (0.1)	13 (0.1)
Renal cell carcinoma	4 (0.0)	5 (0.0)
Renal hamartoma	1 (0.0)	1 (0.0)
Renal neoplasm	1 (0.0)	0
Retinoblastoma	1 (0.0)	2 (0.0)
Round cell liposarcoma	1 (0.0)	0
Salivary gland cancer	0	3 (0.0)
Salivary gland neoplasm	0	2 (0.0)
Sarcoma	0	1 (0.0)
Schwannoma	4 (0.0)	5 (0.0)
Seborrhoeic keratosis	17 (0.1)	24 (0.1)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Seminoma	1 (0.0)	1 (0.0)
Sinonasal papilloma	1 (0.0)	0
Skin cancer	24 (0.1)	22 (0.1)
Skin papilloma	14 (0.1)	4 (0.0)
Small intestine carcinoma	1 (0.0)	2 (0.0)
Soft tissue sarcoma	1 (0.0)	1 (0.0)
Spinal cord neoplasm	0	1 (0.0)
Squamous cell breast carcinoma	1 (0.0)	0
Squamous cell carcinoma	76 (0.3)	76 (0.3)
Squamous cell carcinoma of lung	1 (0.0)	0
Squamous cell carcinoma of skin	46 (0.2)	33 (0.2)
Squamous cell carcinoma of the oral cavity	0	1 (0.0)
Squamous cell carcinoma of the tongue	2 (0.0)	2 (0.0)
Squamous cell carcinoma of the vulva	1 (0.0)	0
Sweat gland tumour	0	2 (0.0)
Synovial sarcoma	0	1 (0.0)
T-cell lymphoma	2 (0.0)	1 (0.0)
Teratoma	0	1 (0.0)
Testis cancer	16 (0.1)	15 (0.1)
Throat cancer	5 (0.0)	6 (0.0)
Thymoma	1 (0.0)	0
Thyroid adenoma	2 (0.0)	1 (0.0)
Thyroid cancer	46 (0.2)	39 (0.2)
Thyroid cancer stage IV	1 (0.0)	0
Thyroid neoplasm	2 (0.0)	5 (0.0)
Tongue neoplasm	0	1 (0.0)
Tongue neoplasm malignant stage unspecified	4 (0.0)	1 (0.0)
Tonsil cancer	3 (0.0)	5 (0.0)
Tonsillar neoplasm benign	0	1 (0.0)
Triple negative breast cancer	1 (0.0)	0
Uterine cancer	21 (0.1)	20 (0.1)
Uterine carcinoma in situ	1 (0.0)	0
Uterine leiomyoma	393 (1.8)	396 (1.8)
Uterine neoplasm	1 (0.0)	0
Vulval cancer	2 (0.0)	1 (0.0)
Vulvovaginal warts	1 (0.0)	0
Xanthogranuloma	1 (0.0)	0
Nervous system disorders	2931 (13.5)	2806 (12.9)
Ageusia	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Akathisia	1 (0.0)	0
Amnesia	17 (0.1)	16 (0.1)
Angiopathic neuropathy	1 (0.0)	1 (0.0)
Anosmia	7 (0.0)	6 (0.0)
Arachnoid cyst	5 (0.0)	2 (0.0)
Arachnoiditis	0	1 (0.0)
Ataxia	3 (0.0)	0
Aura	0	1 (0.0)
Autoimmune encephalopathy	1 (0.0)	0
Autonomic nervous system imbalance	0	2 (0.0)
Autonomic neuropathy	2 (0.0)	0
Balance disorder	1 (0.0)	2 (0.0)
Blood brain barrier defect	1 (0.0)	0
Brachial plexopathy	1 (0.0)	1 (0.0)
Brain injury	3 (0.0)	1 (0.0)
Brain stem stroke	1 (0.0)	0
Carotid arterial embolus	0	1 (0.0)
Carotid arteriosclerosis	10 (0.0)	9 (0.0)
Carotid artery disease	9 (0.0)	5 (0.0)
Carotid artery dissection	3 (0.0)	2 (0.0)
Carotid artery occlusion	6 (0.0)	6 (0.0)
Carotid artery stenosis	14 (0.1)	15 (0.1)
Carotid artery thrombosis	0	1 (0.0)
Carpal tunnel syndrome	218 (1.0)	176 (0.8)
Cataplexy	0	1 (0.0)
Cauda equina syndrome	0	1 (0.0)
Central auditory processing disorder	1 (0.0)	0
Cerebellar ataxia	1 (0.0)	0
Cerebellar atrophy	1 (0.0)	0
Cerebellar infarction	2 (0.0)	0
Cerebellar stroke	2 (0.0)	0
Cerebral atrophy	1 (0.0)	0
Cerebral cyst	1 (0.0)	0
Cerebral haemorrhage	2 (0.0)	1 (0.0)
Cerebral infarction	2 (0.0)	0
Cerebral ischaemia	1 (0.0)	0
Cerebral microangiopathy	0	1 (0.0)
Cerebral thrombosis	1 (0.0)	0
Cerebral venous sinus thrombosis	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Cerebral venous thrombosis	1 (0.0)	0
Cerebrospinal fluid leakage	0	1 (0.0)
Cerebrovascular accident	92 (0.4)	85 (0.4)
Cerebrovascular disorder	2 (0.0)	1 (0.0)
Cervical cord compression	1 (0.0)	0
Cervical radiculopathy	15 (0.1)	18 (0.1)
Cervicobrachial syndrome	2 (0.0)	1 (0.0)
Cervicogenic headache	0	2 (0.0)
Cervicogenic vertigo	0	1 (0.0)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	3 (0.0)
Circadian rhythm sleep disorder	2 (0.0)	1 (0.0)
Cluster headache	14 (0.1)	8 (0.0)
Cognitive disorder	4 (0.0)	7 (0.0)
Colloid brain cyst	0	1 (0.0)
Coma	2 (0.0)	0
Complex regional pain syndrome	2 (0.0)	8 (0.0)
Convulsive threshold lowered	0	1 (0.0)
Cramp-fasciculation syndrome	0	1 (0.0)
Cranial nerve disorder	0	1 (0.0)
Cubital tunnel syndrome	1 (0.0)	5 (0.0)
Dementia	5 (0.0)	7 (0.0)
Dementia Alzheimer's type	1 (0.0)	1 (0.0)
Demyelination	1 (0.0)	0
Depressed level of consciousness	1 (0.0)	0
Diabetic neuropathy	98 (0.5)	114 (0.5)
Disturbance in attention	6 (0.0)	3 (0.0)
Dizziness	22 (0.1)	25 (0.1)
Dizziness postural	0	1 (0.0)
Drug withdrawal headache	1 (0.0)	0
Dural arteriovenous fistula	1 (0.0)	0
Dysaesthesia	0	2 (0.0)
Dysgeusia	0	2 (0.0)
Dyskinesia	1 (0.0)	0
Dyslexia	2 (0.0)	2 (0.0)
Dystonia	3 (0.0)	0
Dystonic tremor	0	1 (0.0)
Embolic stroke	1 (0.0)	0
Encephalopathy	0	3 (0.0)
Epilepsy	43 (0.2)	51 (0.2)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Essential tremor	35 (0.2)	40 (0.2)
Extrapyramidal disorder	1 (0.0)	1 (0.0)
Facial nerve disorder	0	2 (0.0)
Facial neuralgia	3 (0.0)	0
Facial paralysis	19 (0.1)	16 (0.1)
Facial paresis	1 (0.0)	0
Facial spasm	0	1 (0.0)
Febrile convulsion	3 (0.0)	2 (0.0)
Fine motor skill dysfunction	1 (0.0)	0
Focal dyscognitive seizures	0	1 (0.0)
Generalised tonic-clonic seizure	3 (0.0)	5 (0.0)
Glossopharyngeal neuralgia	1 (0.0)	0
Guillain-Barre syndrome	1 (0.0)	1 (0.0)
Haemorrhagic stroke	1 (0.0)	5 (0.0)
Hashimoto's encephalopathy	0	1 (0.0)
Head titubation	2 (0.0)	2 (0.0)
Headache	493 (2.3)	495 (2.3)
Hemiparesis	1 (0.0)	4 (0.0)
Hemiplegia	3 (0.0)	3 (0.0)
Hemiplegic migraine	1 (0.0)	2 (0.0)
Horner's syndrome	2 (0.0)	0
Hydrocephalus	2 (0.0)	7 (0.0)
Hypersomnia	9 (0.0)	11 (0.1)
Hypoaesthesia	14 (0.1)	12 (0.1)
Hypogeusia	1 (0.0)	0
Hyporeflexia	1 (0.0)	0
Hyposmia	1 (0.0)	3 (0.0)
Hypotonia	0	1 (0.0)
Hypoxic-ischaemic encephalopathy	0	1 (0.0)
IVth nerve paralysis	2 (0.0)	0
Idiopathic generalised epilepsy	0	1 (0.0)
Idiopathic intracranial hypertension	1 (0.0)	3 (0.0)
Incoherent	0	1 (0.0)
Intention tremor	2 (0.0)	2 (0.0)
Intercostal neuralgia	0	1 (0.0)
Intracranial aneurysm	10 (0.0)	11 (0.1)
Intracranial mass	0	1 (0.0)
Intracranial pressure increased	1 (0.0)	2 (0.0)
Irlen syndrome	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Ischaemic stroke	9 (0.0)	9 (0.0)
Juvenile myoclonic epilepsy	0	1 (0.0)
Lacunar infarction	1 (0.0)	0
Lacunar stroke	0	1 (0.0)
Lethargy	1 (0.0)	0
Lumbar radiculopathy	27 (0.1)	35 (0.2)
Lumbosacral radiculopathy	2 (0.0)	4 (0.0)
Medication overuse headache	1 (0.0)	0
Meige's syndrome	0	1 (0.0)
Memory impairment	3 (0.0)	3 (0.0)
Meralgia paraesthetica	1 (0.0)	1 (0.0)
Migraine	973 (4.5)	967 (4.5)
Migraine with aura	31 (0.1)	32 (0.1)
Migraine without aura	28 (0.1)	25 (0.1)
Mononeuritis	0	1 (0.0)
Monoparesis	1 (0.0)	0
Monoplegia	5 (0.0)	1 (0.0)
Morton's neuralgia	11 (0.1)	12 (0.1)
Multiple sclerosis	3 (0.0)	6 (0.0)
Muscle contractions involuntary	2 (0.0)	4 (0.0)
Muscle spasticity	1 (0.0)	0
Myasthenia gravis	3 (0.0)	5 (0.0)
Myelopathy	2 (0.0)	2 (0.0)
Myoclonic epilepsy	0	1 (0.0)
Myoclonus	3 (0.0)	3 (0.0)
Narcolepsy	10 (0.0)	18 (0.1)
Nerve compression	25 (0.1)	29 (0.1)
Nervous system disorder	2 (0.0)	1 (0.0)
Neuralgia	42 (0.2)	30 (0.1)
Neuralgic amyotrophy	1 (0.0)	0
Neuritis	1 (0.0)	2 (0.0)
Neurological symptom	1 (0.0)	0
Neuropathy peripheral	225 (1.0)	202 (0.9)
Neuropathy vitamin B6 deficiency	0	1 (0.0)
Normal pressure hydrocephalus	0	2 (0.0)
Notalgia paraesthetica	1 (0.0)	0
Nystagmus	2 (0.0)	3 (0.0)
Occipital neuralgia	2 (0.0)	2 (0.0)
Olfactory nerve disorder	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Optic neuritis	3 (0.0)	1 (0.0)
Paraesthesia	13 (0.1)	11 (0.1)
Paralysis	1 (0.0)	0
Paraparesis	1 (0.0)	1 (0.0)
Paraplegia	1 (0.0)	2 (0.0)
Parkinson's disease	18 (0.1)	15 (0.1)
Parkinsonism	0	2 (0.0)
Parosmia	0	1 (0.0)
Paroxysmal choreoathetosis	0	1 (0.0)
Partial seizures	2 (0.0)	0
Perineurial cyst	1 (0.0)	0
Periodic limb movement disorder	3 (0.0)	6 (0.0)
Peripheral nerve lesion	1 (0.0)	0
Peripheral sensory neuropathy	1 (0.0)	0
Peroneal nerve palsy	9 (0.0)	6 (0.0)
Petit mal epilepsy	2 (0.0)	4 (0.0)
Phantom limb syndrome	1 (0.0)	0
Pineal gland cyst	1 (0.0)	0
Piriformis syndrome	4 (0.0)	0
Polyneuropathy	6 (0.0)	3 (0.0)
Polyneuropathy alcoholic	1 (0.0)	0
Post herpetic neuralgia	3 (0.0)	10 (0.0)
Post polio syndrome	2 (0.0)	1 (0.0)
Post stroke seizure	1 (0.0)	0
Post-traumatic epilepsy	0	1 (0.0)
Post-traumatic headache	1 (0.0)	3 (0.0)
Post-traumatic neuralgia	1 (0.0)	0
Posterior reversible encephalopathy syndrome	0	2 (0.0)
Postural tremor	1 (0.0)	0
Presyncope	4 (0.0)	3 (0.0)
Psychogenic seizure	1 (0.0)	1 (0.0)
Psychomotor hyperactivity	1 (0.0)	2 (0.0)
Radial nerve compression	1 (0.0)	0
Radicular pain	0	1 (0.0)
Radiculitis brachial	1 (0.0)	1 (0.0)
Radiculopathy	8 (0.0)	8 (0.0)
Relapsing multiple sclerosis	1 (0.0)	0
Resting tremor	1 (0.0)	0
Restless legs syndrome	149 (0.7)	166 (0.8)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Ruptured cerebral aneurysm	0	1 (0.0)
Sacral radiculopathy	1 (0.0)	0
Sciatic nerve neuropathy	1 (0.0)	0
Sciatica	128 (0.6)	113 (0.5)
Seizure	53 (0.2)	53 (0.2)
Senile dementia	1 (0.0)	3 (0.0)
Sensory disturbance	0	1 (0.0)
Serotonin syndrome	2 (0.0)	1 (0.0)
Shift work disorder	4 (0.0)	1 (0.0)
Sinus headache	47 (0.2)	36 (0.2)
Sleep deficit	1 (0.0)	1 (0.0)
Small fibre neuropathy	1 (0.0)	2 (0.0)
Somnolence	2 (0.0)	1 (0.0)
Spasmodic dysphonia	2 (0.0)	2 (0.0)
Speech disorder	0	1 (0.0)
Spinal cord disorder	1 (0.0)	0
Spondylitic myelopathy	2 (0.0)	1 (0.0)
Stiff person syndrome	0	1 (0.0)
Subarachnoid haemorrhage	3 (0.0)	4 (0.0)
Syncope	29 (0.1)	24 (0.1)
Tardive dyskinesia	2 (0.0)	1 (0.0)
Tarsal tunnel syndrome	5 (0.0)	2 (0.0)
Temporal lobe epilepsy	2 (0.0)	1 (0.0)
Tension headache	126 (0.6)	73 (0.3)
Thoracic outlet syndrome	3 (0.0)	4 (0.0)
Thoracic radiculopathy	0	1 (0.0)
Tonic convulsion	0	1 (0.0)
Toxic neuropathy	0	1 (0.0)
Transient global amnesia	3 (0.0)	3 (0.0)
Transient ischaemic attack	67 (0.3)	54 (0.2)
Tremor	35 (0.2)	30 (0.1)
Trigeminal nerve disorder	0	2 (0.0)
Trigeminal neuralgia	15 (0.1)	13 (0.1)
VIth nerve paralysis	2 (0.0)	0
Vertebral artery dissection	1 (0.0)	0
Vertebral artery occlusion	1 (0.0)	0
Vertebral artery stenosis	1 (0.0)	0
Vestibular migraine	2 (0.0)	3 (0.0)
Visual field defect	0	3 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Vocal cord paralysis	3 (0.0)	1 (0.0)
Vocal cord paresis	1 (0.0)	0
Writer's cramp	1 (0.0)	0
Pregnancy, puerperium and perinatal conditions	141 (0.6)	147 (0.7)
Abnormal cord insertion	1 (0.0)	0
Abortion	6 (0.0)	2 (0.0)
Abortion incomplete	0	1 (0.0)
Abortion spontaneous	25 (0.1)	24 (0.1)
Breech delivery	0	1 (0.0)
Breech presentation	1 (0.0)	1 (0.0)
Cephalo-pelvic disproportion	1 (0.0)	1 (0.0)
Complication of pregnancy	2 (0.0)	0
Delivery	56 (0.3)	49 (0.2)
Eclampsia	1 (0.0)	0
Ectopic pregnancy	22 (0.1)	31 (0.1)
Foetal death	0	2 (0.0)
Foetal distress syndrome	0	1 (0.0)
Gestational diabetes	12 (0.1)	13 (0.1)
Gestational hypertension	1 (0.0)	4 (0.0)
HELLP syndrome	0	1 (0.0)
Habitual abortion	0	1 (0.0)
Morning sickness	1 (0.0)	0
Peripartum cardiomyopathy	1 (0.0)	0
Placenta accreta	1 (0.0)	4 (0.0)
Post abortion haemorrhage	0	1 (0.0)
Postpartum haemorrhage	3 (0.0)	4 (0.0)
Pre-eclampsia	8 (0.0)	5 (0.0)
Pregnancy	5 (0.0)	9 (0.0)
Premature baby	0	1 (0.0)
Premature labour	1 (0.0)	0
Premature separation of placenta	0	1 (0.0)
Retained placenta or membranes	1 (0.0)	0
Stillbirth	0	2 (0.0)
Unintended pregnancy	0	1 (0.0)
Product issues	3 (0.0)	2 (0.0)
Device breakage	0	1 (0.0)
Device leakage	1 (0.0)	0
Device malfunction	0	1 (0.0)
Embedded device	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Stent malfunction	1 (0.0)	0
Psychiatric disorders	4649 (21.4)	4726 (21.8)
Abnormal dreams	0	1 (0.0)
Adjustment disorder	4 (0.0)	8 (0.0)
Adjustment disorder with depressed mood	14 (0.1)	6 (0.0)
Adjustment disorder with mixed anxiety and depressed mood	2 (0.0)	3 (0.0)
Aerophobia	0	1 (0.0)
Affect lability	2 (0.0)	1 (0.0)
Affective disorder	16 (0.1)	9 (0.0)
Aggression	0	1 (0.0)
Agitated depression	0	1 (0.0)
Agitation	1 (0.0)	0
Agoraphobia	0	1 (0.0)
Alcohol abuse	20 (0.1)	15 (0.1)
Alcohol problem	0	1 (0.0)
Alcohol use disorder	2 (0.0)	5 (0.0)
Alcohol withdrawal syndrome	0	1 (0.0)
Alcoholism	26 (0.1)	16 (0.1)
Anger	2 (0.0)	3 (0.0)
Anorexia nervosa	2 (0.0)	2 (0.0)
Anxiety	1824 (8.4)	1917 (8.8)
Anxiety disorder	131 (0.6)	132 (0.6)
Attention deficit hyperactivity disorder	545 (2.5)	500 (2.3)
Autism spectrum disorder	16 (0.1)	18 (0.1)
Behaviour disorder	1 (0.0)	1 (0.0)
Binge eating	3 (0.0)	9 (0.0)
Bipolar I disorder	6 (0.0)	11 (0.1)
Bipolar II disorder	16 (0.1)	13 (0.1)
Bipolar disorder	171 (0.8)	176 (0.8)
Borderline personality disorder	4 (0.0)	1 (0.0)
Breathing-related sleep disorder	1 (0.0)	0
Bruxism	1 (0.0)	4 (0.0)
Bulimia nervosa	2 (0.0)	4 (0.0)
Cardiovascular somatic symptom disorder	0	1 (0.0)
Chronic tic disorder	1 (0.0)	0
Conversion disorder	0	1 (0.0)
Cyclothymic disorder	2 (0.0)	3 (0.0)
Delirium tremens	0	1 (0.0)
Dependence	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Depressed mood	3 (0.0)	0
Depression	1992 (9.2)	2039 (9.4)
Depression suicidal	0	1 (0.0)
Depressive symptom	1 (0.0)	0
Dissociative disorder	0	1 (0.0)
Drug abuse	20 (0.1)	17 (0.1)
Drug dependence	13 (0.1)	14 (0.1)
Drug use disorder	1 (0.0)	1 (0.0)
Dysphemia	0	2 (0.0)
Eating disorder	4 (0.0)	3 (0.0)
Enuresis	0	1 (0.0)
Gambling disorder	0	2 (0.0)
Gastrointestinal somatic symptom disorder	1 (0.0)	0
Gender dysphoria	4 (0.0)	2 (0.0)
Generalised anxiety disorder	93 (0.4)	97 (0.4)
Grief reaction	0	3 (0.0)
Hallucination	1 (0.0)	2 (0.0)
Initial insomnia	0	3 (0.0)
Insomnia	1171 (5.4)	1156 (5.3)
Intentional self-injury	1 (0.0)	0
Intermittent explosive disorder	1 (0.0)	1 (0.0)
Irritability	1 (0.0)	4 (0.0)
Libido decreased	28 (0.1)	24 (0.1)
Major depression	145 (0.7)	150 (0.7)
Mania	1 (0.0)	3 (0.0)
Menopausal depression	1 (0.0)	0
Mental disorder	3 (0.0)	4 (0.0)
Middle insomnia	1 (0.0)	0
Mood swings	3 (0.0)	2 (0.0)
Nicotine dependence	38 (0.2)	21 (0.1)
Nightmare	1 (0.0)	2 (0.0)
Obsessive-compulsive disorder	43 (0.2)	46 (0.2)
Obsessive-compulsive personality disorder	0	1 (0.0)
Obsessive-compulsive symptom	1 (0.0)	0
Oppositional defiant disorder	0	4 (0.0)
Panic attack	30 (0.1)	36 (0.2)
Panic disorder	15 (0.1)	14 (0.1)
Panic reaction	2 (0.0)	2 (0.0)
Parasomnia	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Performance fear	1 (0.0)	0
Perinatal depression	13 (0.1)	15 (0.1)
Persistent depressive disorder	3 (0.0)	14 (0.1)
Personality disorder	0	1 (0.0)
Post-traumatic amnestic disorder	0	1 (0.0)
Post-traumatic stress disorder	121 (0.6)	110 (0.5)
Postpartum anxiety	2 (0.0)	0
Premature ejaculation	1 (0.0)	6 (0.0)
Psychogenic erectile dysfunction	1 (0.0)	0
Psychosexual disorder	0	1 (0.0)
Psychotic disorder	3 (0.0)	3 (0.0)
Rapid eye movements sleep abnormal	1 (0.0)	1 (0.0)
Restlessness	1 (0.0)	3 (0.0)
Schizoaffective disorder	8 (0.0)	4 (0.0)
Schizophrenia	24 (0.1)	29 (0.1)
Seasonal affective disorder	14 (0.1)	7 (0.0)
Selective eating disorder	1 (0.0)	1 (0.0)
Sexual inhibition	0	1 (0.0)
Sleep disorder	22 (0.1)	44 (0.2)
Sleep disorder due to general medical condition, insomnia type	2 (0.0)	0
Sleep terror	2 (0.0)	1 (0.0)
Social anxiety disorder	10 (0.0)	0
Somatic symptom disorder	1 (0.0)	1 (0.0)
Somnambulism	0	2 (0.0)
Stress	6 (0.0)	4 (0.0)
Substance abuse	3 (0.0)	2 (0.0)
Substance dependence	1 (0.0)	1 (0.0)
Substance use disorder	1 (0.0)	0
Suicidal behaviour	1 (0.0)	0
Suicidal ideation	4 (0.0)	3 (0.0)
Suicide attempt	4 (0.0)	2 (0.0)
Tachyphrenia	0	1 (0.0)
Terminal insomnia	1 (0.0)	0
Tic	1 (0.0)	2 (0.0)
Tobacco abuse	10 (0.0)	8 (0.0)
Trichotillomania	2 (0.0)	1 (0.0)
Renal and urinary disorders	1039 (4.8)	1037 (4.8)
Acute kidney injury	6 (0.0)	1 (0.0)
Albuminuria	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Atonic urinary bladder	0	1 (0.0)
Bladder disorder	1 (0.0)	1 (0.0)
Bladder diverticulum	1 (0.0)	0
Bladder dysfunction	0	1 (0.0)
Bladder irritation	0	2 (0.0)
Bladder malposition acquired	1 (0.0)	0
Bladder neck obstruction	1 (0.0)	0
Bladder obstruction	1 (0.0)	1 (0.0)
Bladder outlet obstruction	1 (0.0)	2 (0.0)
Bladder perforation	0	2 (0.0)
Bladder prolapse	22 (0.1)	30 (0.1)
Bladder spasm	9 (0.0)	6 (0.0)
Bladder stenosis	1 (0.0)	0
Calculus bladder	3 (0.0)	2 (0.0)
Calculus urinary	1 (0.0)	4 (0.0)
Chronic kidney disease	100 (0.5)	99 (0.5)
Cystitis glandularis	0	1 (0.0)
Cystitis haemorrhagic	1 (0.0)	0
Cystitis interstitial	14 (0.1)	10 (0.0)
Diabetic nephropathy	4 (0.0)	2 (0.0)
Dysuria	11 (0.1)	7 (0.0)
End stage renal disease	1 (0.0)	1 (0.0)
Focal segmental glomerulosclerosis	2 (0.0)	0
Glomerulonephritis	0	1 (0.0)
Glomerulonephritis membranous	1 (0.0)	2 (0.0)
Haematuria	7 (0.0)	21 (0.1)
Hydronephrosis	9 (0.0)	4 (0.0)
Hypercalciuria	3 (0.0)	4 (0.0)
Hypertensive nephropathy	2 (0.0)	0
Hypertonic bladder	168 (0.8)	174 (0.8)
IgA nephropathy	1 (0.0)	1 (0.0)
Incontinence	14 (0.1)	12 (0.1)
Kidney small	0	1 (0.0)
Lower urinary tract symptoms	2 (0.0)	2 (0.0)
Lupus nephritis	0	1 (0.0)
Microalbuminuria	10 (0.0)	5 (0.0)
Micturition disorder	3 (0.0)	6 (0.0)
Micturition urgency	6 (0.0)	14 (0.1)
Mixed incontinence	3 (0.0)	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Nephritis	1 (0.0)	3 (0.0)
Nephrogenic diabetes insipidus	1 (0.0)	0
Nephrolithiasis	410 (1.9)	383 (1.8)
Nephropathy	14 (0.1)	15 (0.1)
Nephrotic syndrome	0	3 (0.0)
Neurogenic bladder	2 (0.0)	6 (0.0)
Nocturia	29 (0.1)	31 (0.1)
Pelvi-ureteric obstruction	1 (0.0)	1 (0.0)
Pollakiuria	26 (0.1)	28 (0.1)
Polyuria	4 (0.0)	4 (0.0)
Post streptococcal glomerulonephritis	1 (0.0)	0
Proteinuria	4 (0.0)	8 (0.0)
Reflux nephropathy	1 (0.0)	0
Renal artery stenosis	0	3 (0.0)
Renal atrophy	0	1 (0.0)
Renal colic	0	1 (0.0)
Renal cyst	12 (0.1)	20 (0.1)
Renal disorder	5 (0.0)	2 (0.0)
Renal failure	11 (0.1)	16 (0.1)
Renal impairment	5 (0.0)	3 (0.0)
Renal infarct	1 (0.0)	0
Renal injury	1 (0.0)	0
Renal mass	4 (0.0)	3 (0.0)
Renal necrosis	0	1 (0.0)
Single functional kidney	2 (0.0)	5 (0.0)
Stress urinary incontinence	41 (0.2)	35 (0.2)
Trigonitis	1 (0.0)	1 (0.0)
Ureteral disorder	2 (0.0)	0
Ureteric obstruction	0	1 (0.0)
Ureteric stenosis	1 (0.0)	5 (0.0)
Ureterolithiasis	0	1 (0.0)
Urethral cyst	1 (0.0)	0
Urethral dilatation	0	3 (0.0)
Urethral disorder	1 (0.0)	2 (0.0)
Urethral polyp	0	1 (0.0)
Urethral prolapse	0	1 (0.0)
Urethral stenosis	3 (0.0)	5 (0.0)
Urge incontinence	20 (0.1)	14 (0.1)
Urinary bladder polyp	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Urinary hesitation	6 (0.0)	2 (0.0)
Urinary incontinence	88 (0.4)	95 (0.4)
Urinary retention	21 (0.1)	24 (0.1)
Urinary tract obstruction	1 (0.0)	0
Urinary tract pain	0	1 (0.0)
Urine flow decreased	0	3 (0.0)
Urogenital fistula	0	2 (0.0)
Urogenital haemorrhage	0	1 (0.0)
Vesicoureteric reflux	1 (0.0)	2 (0.0)
Reproductive system and breast disorders	2129 (9.8)	2055 (9.5)
Adenomyosis	10 (0.0)	15 (0.1)
Adnexa uteri cyst	2 (0.0)	0
Adnexa uteri pain	1 (0.0)	0
Adnexal torsion	2 (0.0)	1 (0.0)
Amenorrhoea	19 (0.1)	13 (0.1)
Anisomastia	1 (0.0)	1 (0.0)
Artificial menopause	2 (0.0)	2 (0.0)
Atrophic vulvovaginitis	19 (0.1)	23 (0.1)
Azoospermia	2 (0.0)	1 (0.0)
Balanoposthitis	1 (0.0)	1 (0.0)
Bartholin's cyst	3 (0.0)	1 (0.0)
Benign prostatic hyperplasia	561 (2.6)	546 (2.5)
Breast calcifications	5 (0.0)	2 (0.0)
Breast cyst	19 (0.1)	23 (0.1)
Breast disorder	0	1 (0.0)
Breast dysplasia	0	1 (0.0)
Breast enlargement	6 (0.0)	7 (0.0)
Breast fibrosis	2 (0.0)	0
Breast hyperplasia	2 (0.0)	3 (0.0)
Breast mass	18 (0.1)	20 (0.1)
Breast pain	4 (0.0)	1 (0.0)
Breast swelling	1 (0.0)	0
Calculus prostatic	0	2 (0.0)
Cervical cyst	2 (0.0)	0
Cervical discharge	1 (0.0)	0
Cervical dysplasia	20 (0.1)	15 (0.1)
Cervical polyp	3 (0.0)	3 (0.0)
Cervix disorder	0	1 (0.0)
Colpocele	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Cystocele	5 (0.0)	8 (0.0)
Dysfunctional uterine bleeding	15 (0.1)	9 (0.0)
Dysmenorrhoea	56 (0.3)	76 (0.3)
Dyspareunia	7 (0.0)	4 (0.0)
Ectropion of cervix	1 (0.0)	0
Ejaculation disorder	0	1 (0.0)
Endometrial disorder	0	3 (0.0)
Endometrial hyperplasia	10 (0.0)	4 (0.0)
Endometrial hypertrophy	0	1 (0.0)
Endometrial hypoplasia	1 (0.0)	0
Endometrial thickening	1 (0.0)	1 (0.0)
Endometriosis	202 (0.9)	178 (0.8)
Epididymal cyst	1 (0.0)	2 (0.0)
Epididymal enlargement	0	1 (0.0)
Erectile dysfunction	335 (1.5)	376 (1.7)
Fallopian tube cyst	0	3 (0.0)
Fallopian tube disorder	1 (0.0)	2 (0.0)
Fallopian tube obstruction	3 (0.0)	5 (0.0)
Female genital tract fistula	1 (0.0)	1 (0.0)
Fibrocystic breast disease	29 (0.1)	26 (0.1)
Genital cyst	0	1 (0.0)
Genital lesion	0	1 (0.0)
Genital rash	1 (0.0)	0
Genitourinary syndrome of menopause	0	1 (0.0)
Gynaecomastia	5 (0.0)	9 (0.0)
Haematospermia	1 (0.0)	1 (0.0)
Infertility	20 (0.1)	15 (0.1)
Infertility female	4 (0.0)	7 (0.0)
Infertility male	2 (0.0)	1 (0.0)
Mammary duct ectasia	1 (0.0)	0
Mastoptosis	1 (0.0)	0
Menometrorrhagia	3 (0.0)	1 (0.0)
Menopausal disorder	0	1 (0.0)
Menopausal symptoms	47 (0.2)	51 (0.2)
Menorrhagia	189 (0.9)	168 (0.8)
Menstrual discomfort	1 (0.0)	0
Menstrual disorder	28 (0.1)	26 (0.1)
Menstruation irregular	36 (0.2)	23 (0.1)
Metrorrhagia	5 (0.0)	6 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Nipple exudate bloody	0	1 (0.0)
Oligomenorrhoea	3 (0.0)	2 (0.0)
Oligospermia	1 (0.0)	0
Organic erectile dysfunction	2 (0.0)	2 (0.0)
Ovarian adhesion	0	1 (0.0)
Ovarian cyst	120 (0.6)	117 (0.5)
Ovarian cyst ruptured	7 (0.0)	1 (0.0)
Ovarian disorder	1 (0.0)	0
Ovarian enlargement	0	1 (0.0)
Ovarian failure	1 (0.0)	3 (0.0)
Ovarian fibrosis	1 (0.0)	2 (0.0)
Ovarian haemorrhage	1 (0.0)	1 (0.0)
Ovarian mass	1 (0.0)	2 (0.0)
Ovarian rupture	2 (0.0)	1 (0.0)
Ovulation pain	0	1 (0.0)
Pelvic cyst	1 (0.0)	0
Pelvic floor muscle weakness	1 (0.0)	0
Pelvic pain	8 (0.0)	3 (0.0)
Pelvic prolapse	2 (0.0)	1 (0.0)
Perineal cyst	0	1 (0.0)
Peyronie's disease	2 (0.0)	6 (0.0)
Polycystic ovaries	110 (0.5)	95 (0.4)
Postmenopausal haemorrhage	4 (0.0)	3 (0.0)
Premature menopause	11 (0.1)	5 (0.0)
Premenstrual dysphoric disorder	8 (0.0)	8 (0.0)
Premenstrual headache	0	1 (0.0)
Premenstrual syndrome	4 (0.0)	5 (0.0)
Prostatic calcification	0	1 (0.0)
Prostatic disorder	15 (0.1)	8 (0.0)
Prostatic dysplasia	1 (0.0)	0
Prostatic hypoplasia	0	2 (0.0)
Prostatic mass	0	1 (0.0)
Prostatism	10 (0.0)	7 (0.0)
Prostatitis	11 (0.1)	11 (0.1)
Prostatomegaly	115 (0.5)	117 (0.5)
Pruritus genital	0	1 (0.0)
Rectocele	5 (0.0)	5 (0.0)
Scrotal cyst	1 (0.0)	1 (0.0)
Sexual dysfunction	4 (0.0)	4 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Spermatocele	1 (0.0)	0
Testicular atrophy	0	1 (0.0)
Testicular cyst	1 (0.0)	0
Testicular mass	0	1 (0.0)
Testicular pain	2 (0.0)	1 (0.0)
Testicular swelling	0	1 (0.0)
Testicular torsion	2 (0.0)	4 (0.0)
Uterine adhesions	0	1 (0.0)
Uterine cervix stenosis	0	1 (0.0)
Uterine cyst	4 (0.0)	7 (0.0)
Uterine disorder	3 (0.0)	1 (0.0)
Uterine enlargement	1 (0.0)	1 (0.0)
Uterine haemorrhage	20 (0.1)	16 (0.1)
Uterine inflammation	1 (0.0)	0
Uterine malposition	2 (0.0)	2 (0.0)
Uterine mass	0	1 (0.0)
Uterine polyp	17 (0.1)	12 (0.1)
Uterine prolapse	43 (0.2)	38 (0.2)
Uterine scar	1 (0.0)	2 (0.0)
Vaginal cyst	2 (0.0)	1 (0.0)
Vaginal discharge	0	1 (0.0)
Vaginal disorder	0	1 (0.0)
Vaginal fistula	0	1 (0.0)
Vaginal haemorrhage	13 (0.1)	9 (0.0)
Vaginal polyp	0	1 (0.0)
Vaginal prolapse	2 (0.0)	4 (0.0)
Vaginal stricture	1 (0.0)	0
Varicocele	15 (0.1)	12 (0.1)
Varicose veins pelvic	1 (0.0)	0
Vulval disorder	2 (0.0)	0
Vulvar dysplasia	0	1 (0.0)
Vulvovaginal burning sensation	0	1 (0.0)
Vulvovaginal dryness	30 (0.1)	29 (0.1)
Vulvovaginal pain	1 (0.0)	1 (0.0)
Respiratory, thoracic and mediastinal disorders	3301 (15.2)	3360 (15.5)
Acute pulmonary oedema	0	1 (0.0)
Acute respiratory failure	1 (0.0)	0
Adenoidal hypertrophy	14 (0.1)	14 (0.1)
Allergic bronchitis	3 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Allergic cough	3 (0.0)	4 (0.0)
Allergic pharyngitis	1 (0.0)	0
Allergic respiratory symptom	1 (0.0)	0
Allergic sinusitis	29 (0.1)	30 (0.1)
Apnoea	2 (0.0)	3 (0.0)
Aspiration	0	1 (0.0)
Asthma	1370 (6.3)	1360 (6.3)
Asthma exercise induced	68 (0.3)	50 (0.2)
Asthma late onset	0	1 (0.0)
Asthma-chronic obstructive pulmonary disease overlap syndrome	0	1 (0.0)
Asthmatic crisis	1 (0.0)	0
Atelectasis	0	1 (0.0)
Bronchial hyperreactivity	20 (0.1)	21 (0.1)
Bronchiectasis	7 (0.0)	10 (0.0)
Bronchitis chronic	35 (0.2)	27 (0.1)
Bronchospasm	11 (0.1)	7 (0.0)
Childhood asthma	10 (0.0)	19 (0.1)
Chronic obstructive pulmonary disease	236 (1.1)	243 (1.1)
Chronic respiratory disease	0	1 (0.0)
Chronic respiratory failure	0	2 (0.0)
Cough	35 (0.2)	55 (0.3)
Cough variant asthma	1 (0.0)	3 (0.0)
Cystic lung disease	1 (0.0)	2 (0.0)
Diaphragmatic disorder	1 (0.0)	0
Diaphragmatic paralysis	1 (0.0)	1 (0.0)
Dysphonia	2 (0.0)	5 (0.0)
Dyspnoea	22 (0.1)	22 (0.1)
Dyspnoea exertional	4 (0.0)	6 (0.0)
Emphysema	27 (0.1)	38 (0.2)
Epiglottic oedema	1 (0.0)	0
Epistaxis	9 (0.0)	11 (0.1)
Haemothorax	0	1 (0.0)
Hypoxia	4 (0.0)	1 (0.0)
Idiopathic pulmonary fibrosis	0	2 (0.0)
Interstitial lung disease	2 (0.0)	1 (0.0)
Laryngeal disorder	1 (0.0)	0
Laryngeal oedema	0	1 (0.0)
Laryngeal polyp	0	1 (0.0)
Laryngospasm	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Lung cyst	0	1 (0.0)
Lung disorder	1 (0.0)	2 (0.0)
Nasal congestion	16 (0.1)	30 (0.1)
Nasal cyst	2 (0.0)	0
Nasal discomfort	1 (0.0)	0
Nasal disorder	0	1 (0.0)
Nasal obstruction	1 (0.0)	2 (0.0)
Nasal polyps	29 (0.1)	29 (0.1)
Nasal septum deviation	157 (0.7)	153 (0.7)
Nasal turbinate hypertrophy	4 (0.0)	5 (0.0)
Obliterative bronchiolitis	0	1 (0.0)
Obstructive airways disorder	0	1 (0.0)
Organising pneumonia	1 (0.0)	0
Oropharyngeal pain	9 (0.0)	9 (0.0)
Paranasal cyst	1 (0.0)	1 (0.0)
Paranasal sinus discomfort	0	1 (0.0)
Paranasal sinus haemorrhage	1 (0.0)	0
Pharyngeal cyst	0	1 (0.0)
Pharyngeal disorder	1 (0.0)	1 (0.0)
Pharyngeal mass	0	1 (0.0)
Pharyngeal polyp	1 (0.0)	1 (0.0)
Pleural calcification	0	1 (0.0)
Pleural effusion	1 (0.0)	2 (0.0)
Pleurisy	2 (0.0)	3 (0.0)
Pneumonia aspiration	0	1 (0.0)
Pneumonitis	0	2 (0.0)
Pneumothorax	16 (0.1)	15 (0.1)
Pneumothorax spontaneous	9 (0.0)	5 (0.0)
Productive cough	1 (0.0)	0
Pulmonary calcification	1 (0.0)	0
Pulmonary embolism	38 (0.2)	36 (0.2)
Pulmonary fibrosis	5 (0.0)	7 (0.0)
Pulmonary granuloma	3 (0.0)	4 (0.0)
Pulmonary hypertension	5 (0.0)	2 (0.0)
Pulmonary mass	12 (0.1)	15 (0.1)
Pulmonary oedema	1 (0.0)	2 (0.0)
Pulmonary sarcoidosis	0	1 (0.0)
Pulmonary thrombosis	1 (0.0)	2 (0.0)
Rales	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Reflux laryngitis	3 (0.0)	10 (0.0)
Respiratory disorder	0	2 (0.0)
Respiratory distress	0	2 (0.0)
Respiratory failure	0	2 (0.0)
Respiratory tract congestion	0	1 (0.0)
Restrictive pulmonary disease	1 (0.0)	1 (0.0)
Rhinitis allergic	873 (4.0)	835 (3.8)
Rhinitis perennial	44 (0.2)	51 (0.2)
Rhinitis ulcerative	0	1 (0.0)
Rhinorrhoea	6 (0.0)	2 (0.0)
Rhonchi	0	1 (0.0)
Sinus congestion	23 (0.1)	21 (0.1)
Sinus disorder	6 (0.0)	5 (0.0)
Sinus pain	0	1 (0.0)
Sinus polyp	6 (0.0)	10 (0.0)
Sleep apnoea syndrome	607 (2.8)	636 (2.9)
Sneezing	0	1 (0.0)
Snoring	3 (0.0)	6 (0.0)
Throat clearing	0	1 (0.0)
Throat irritation	0	1 (0.0)
Throat tightness	0	1 (0.0)
Tonsillar disorder	1 (0.0)	0
Tonsillar hypertrophy	13 (0.1)	12 (0.1)
Tonsillar inflammation	2 (0.0)	3 (0.0)
Tonsillolith	3 (0.0)	1 (0.0)
Upper airway resistance syndrome	1 (0.0)	0
Upper-airway cough syndrome	13 (0.1)	14 (0.1)
Vasomotor rhinitis	2 (0.0)	0
Vocal cord cyst	0	1 (0.0)
Vocal cord disorder	0	1 (0.0)
Vocal cord leukoplakia	0	1 (0.0)
Vocal cord polyp	7 (0.0)	4 (0.0)
Vocal cord thickening	1 (0.0)	1 (0.0)
Wheezing	3 (0.0)	10 (0.0)
Skin and subcutaneous tissue disorders	1554 (7.2)	1566 (7.2)
Acanthosis	1 (0.0)	0
Acanthosis nigricans	3 (0.0)	2 (0.0)
Acne	279 (1.3)	264 (1.2)
Acne cystic	6 (0.0)	8 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Actinic cheilitis	0	1 (0.0)
Actinic keratosis	82 (0.4)	71 (0.3)
Alopecia	96 (0.4)	101 (0.5)
Alopecia areata	3 (0.0)	4 (0.0)
Androgenetic alopecia	10 (0.0)	25 (0.1)
Angioedema	1 (0.0)	2 (0.0)
Angiokeratoma	0	1 (0.0)
Blister	0	1 (0.0)
Brow ptosis	1 (0.0)	0
Cafe au lait spots	1 (0.0)	0
Chloasma	1 (0.0)	4 (0.0)
Chronic pigmented purpura	1 (0.0)	0
Chronic spontaneous urticaria	2 (0.0)	7 (0.0)
Cold urticaria	3 (0.0)	1 (0.0)
Cutaneous amyloidosis	0	1 (0.0)
Cutaneous lupus erythematosus	1 (0.0)	4 (0.0)
Dandruff	4 (0.0)	4 (0.0)
Decubitus ulcer	0	1 (0.0)
Dermal cyst	29 (0.1)	18 (0.1)
Dermatitis	41 (0.2)	28 (0.1)
Dermatitis acneiform	0	1 (0.0)
Dermatitis allergic	5 (0.0)	12 (0.1)
Dermatitis atopic	49 (0.2)	39 (0.2)
Dermatitis contact	83 (0.4)	95 (0.4)
Dermatomyositis	1 (0.0)	2 (0.0)
Diabetic dermopathy	0	1 (0.0)
Diabetic foot	2 (0.0)	1 (0.0)
Diabetic ulcer	1 (0.0)	0
Diffuse alopecia	0	1 (0.0)
Drug eruption	37 (0.2)	50 (0.2)
Dry skin	16 (0.1)	12 (0.1)
Dyshidrotic eczema	1 (0.0)	6 (0.0)
Eczema	281 (1.3)	274 (1.3)
Eczema asteatotic	0	1 (0.0)
Eczema nummular	0	1 (0.0)
Eosinophilic cellulitis	0	1 (0.0)
Erythema	0	2 (0.0)
Erythema multiforme	0	1 (0.0)
Excessive skin	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Granuloma annulare	5 (0.0)	4 (0.0)
Granuloma skin	1 (0.0)	0
Guttate psoriasis	0	1 (0.0)
Hair growth abnormal	1 (0.0)	0
Hand dermatitis	14 (0.1)	28 (0.1)
Henoch-Schonlein purpura	1 (0.0)	0
Hidradenitis	7 (0.0)	8 (0.0)
Hirsutism	7 (0.0)	3 (0.0)
Hyperhidrosis	16 (0.1)	10 (0.0)
Hyperkeratosis	8 (0.0)	4 (0.0)
Hypertrichosis	0	1 (0.0)
Hypertrophic scar	1 (0.0)	0
Hypohidrosis	0	1 (0.0)
Hypotrichosis	0	1 (0.0)
Idiopathic guttate hypomelanosis	1 (0.0)	0
Idiopathic urticaria	6 (0.0)	1 (0.0)
Ingrowing nail	4 (0.0)	0
Ingrown hair	1 (0.0)	1 (0.0)
Intertrigo	2 (0.0)	1 (0.0)
Keloid scar	2 (0.0)	7 (0.0)
Keratosis pilaris	8 (0.0)	9 (0.0)
Lentigo	2 (0.0)	1 (0.0)
Leukoplakia	0	1 (0.0)
Lichen planopilaris	0	1 (0.0)
Lichen planus	6 (0.0)	7 (0.0)
Lichen sclerosus	8 (0.0)	9 (0.0)
Lichenification	0	2 (0.0)
Lichenoid keratosis	0	1 (0.0)
Lipodystrophy acquired	1 (0.0)	0
Madarosis	0	1 (0.0)
Mechanical urticaria	2 (0.0)	7 (0.0)
Melanocytic hyperplasia	0	1 (0.0)
Miliaria	2 (0.0)	2 (0.0)
Myxoid cyst	1 (0.0)	1 (0.0)
Nail bed disorder	0	1 (0.0)
Nail discolouration	1 (0.0)	0
Nail dystrophy	0	2 (0.0)
Nail growth abnormal	0	1 (0.0)
Necrobiosis lipoidica diabeticorum	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Neurodermatitis	7 (0.0)	4 (0.0)
Night sweats	2 (0.0)	4 (0.0)
Palmoplantar keratoderma	1 (0.0)	0
Panniculitis	1 (0.0)	0
Papulopustular rosacea	1 (0.0)	0
Parapsoriasis	1 (0.0)	0
Peau d'orange	0	1 (0.0)
Perioral dermatitis	1 (0.0)	1 (0.0)
Photodermatosis	1 (0.0)	3 (0.0)
Photosensitivity reaction	1 (0.0)	0
Pigmentation disorder	1 (0.0)	0
Pityriasis	1 (0.0)	0
Pityriasis lichenoides et varioliformis acuta	0	1 (0.0)
Pityriasis rosea	2 (0.0)	0
Polymorphic light eruption	2 (0.0)	0
Precancerous skin lesion	4 (0.0)	3 (0.0)
Pruritus	10 (0.0)	13 (0.1)
Pruritus allergic	10 (0.0)	6 (0.0)
Pseudofolliculitis	1 (0.0)	1 (0.0)
Psoriasis	151 (0.7)	152 (0.7)
Purpura	2 (0.0)	1 (0.0)
Purpura senile	5 (0.0)	2 (0.0)
Rash	29 (0.1)	38 (0.2)
Rash macular	1 (0.0)	0
Rash pruritic	0	2 (0.0)
Rhinophyma	0	1 (0.0)
Rosacea	172 (0.8)	152 (0.7)
Scab	0	1 (0.0)
Seborrhoea	3 (0.0)	1 (0.0)
Seborrhoeic dermatitis	37 (0.2)	27 (0.1)
Sensitive skin	1 (0.0)	3 (0.0)
Skin atrophy	4 (0.0)	0
Skin burning sensation	1 (0.0)	0
Skin discolouration	3 (0.0)	3 (0.0)
Skin disorder	1 (0.0)	1 (0.0)
Skin exfoliation	1 (0.0)	1 (0.0)
Skin fissures	0	1 (0.0)
Skin hyperpigmentation	1 (0.0)	1 (0.0)
Skin hypertrophy	2 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Skin hypopigmentation	1 (0.0)	1 (0.0)
Skin irritation	1 (0.0)	1 (0.0)
Skin lesion	4 (0.0)	9 (0.0)
Skin mass	1 (0.0)	3 (0.0)
Skin ulcer	3 (0.0)	1 (0.0)
Solar lentigo	2 (0.0)	0
Stasis dermatitis	0	1 (0.0)
Stevens-Johnson syndrome	1 (0.0)	1 (0.0)
Telangiectasia	1 (0.0)	0
Transient acantholytic dermatosis	5 (0.0)	2 (0.0)
Urticaria	63 (0.3)	80 (0.4)
Urticaria cholinergic	0	1 (0.0)
Urticaria chronic	1 (0.0)	3 (0.0)
Urticaria papular	1 (0.0)	0
Urticaria thermal	1 (0.0)	0
Vitiligo	27 (0.1)	21 (0.1)
Social circumstances	2944 (13.6)	2896 (13.3)
Aborted pregnancy	0	1 (0.0)
Alcohol use	24 (0.1)	21 (0.1)
Alcoholic	0	2 (0.0)
Andropause	1 (0.0)	1 (0.0)
Bereavement	2 (0.0)	0
Blood donor	29 (0.1)	34 (0.2)
Cardiac assistance device user	1 (0.0)	0
Celibacy	8 (0.0)	6 (0.0)
Corrective lens user	268 (1.2)	271 (1.2)
Denture wearer	8 (0.0)	10 (0.0)
Dependence on oxygen therapy	1 (0.0)	0
Drug abuser	1 (0.0)	1 (0.0)
Electronic cigarette user	4 (0.0)	1 (0.0)
Ex-tobacco user	82 (0.4)	76 (0.3)
Eye prosthesis user	0	2 (0.0)
Familial risk factor	4 (0.0)	2 (0.0)
Hearing aid user	31 (0.1)	22 (0.1)
High risk sexual behaviour	0	2 (0.0)
Inadequate diet	0	1 (0.0)
Limb prosthesis user	1 (0.0)	0
Menarche	0	2 (0.0)
Menopause	475 (2.2)	465 (2.1)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Multigravida	0	1 (0.0)
Multiparous	0	1 (0.0)
Organ donor	8 (0.0)	15 (0.1)
Orthodontic appliance user	1 (0.0)	0
Orthosis user	1 (0.0)	1 (0.0)
Personal relationship issue	1 (0.0)	0
Physical assault	1 (0.0)	1 (0.0)
Postmenopause	1939 (8.9)	1952 (9.0)
Social alcohol drinker	7 (0.0)	3 (0.0)
Substance use	30 (0.1)	20 (0.1)
Tattoo	1 (0.0)	0
Testicular prosthesis user	1 (0.0)	0
Tobacco user	195 (0.9)	152 (0.7)
Trans-sexualism	5 (0.0)	1 (0.0)
Woman of childbearing potential	1 (0.0)	1 (0.0)
Surgical and medical procedures	8306 (38.2)	8328 (38.3)
Abdominal cavity drainage	0	1 (0.0)
Abdominal exploration	3 (0.0)	1 (0.0)
Abdominal hernia repair	44 (0.2)	41 (0.2)
Abdominal operation	12 (0.1)	8 (0.0)
Abdominal panniculectomy	3 (0.0)	3 (0.0)
Abdominal wall operation	2 (0.0)	2 (0.0)
Abdominoplasty	72 (0.3)	60 (0.3)
Abortion induced	2 (0.0)	3 (0.0)
Abscess drainage	14 (0.1)	14 (0.1)
Acoustic neuroma removal	4 (0.0)	4 (0.0)
Acupuncture	0	1 (0.0)
Adenoidectomy	105 (0.5)	87 (0.4)
Adenotonsillectomy	24 (0.1)	27 (0.1)
Adhesiolysis	1 (0.0)	3 (0.0)
Adrenalectomy	4 (0.0)	2 (0.0)
Alcohol rehabilitation	0	1 (0.0)
Amblyopia therapy	1 (0.0)	1 (0.0)
Amputation	0	2 (0.0)
Anal fissure excision	1 (0.0)	1 (0.0)
Anal fistula repair	5 (0.0)	6 (0.0)
Anal sphincterotomy	0	1 (0.0)
Aneurysm repair	3 (0.0)	5 (0.0)
Angioplasty	21 (0.1)	19 (0.1)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Ankle arthroplasty	12 (0.1)	14 (0.1)
Ankle operation	62 (0.3)	66 (0.3)
Anorectal operation	7 (0.0)	12 (0.1)
Antibiotic prophylaxis	1 (0.0)	0
Antibiotic therapy	1 (0.0)	0
Anticoagulant therapy	2 (0.0)	3 (0.0)
Antidepressant therapy	1 (0.0)	0
Antiviral prophylaxis	2 (0.0)	0
Antiviral treatment	1 (0.0)	1 (0.0)
Anxiolytic therapy	1 (0.0)	0
Aortic aneurysm repair	7 (0.0)	3 (0.0)
Aortic stent insertion	1 (0.0)	3 (0.0)
Aortic surgery	2 (0.0)	0
Aortic valve repair	3 (0.0)	2 (0.0)
Aortic valve replacement	21 (0.1)	25 (0.1)
Apicectomy	0	1 (0.0)
Appendicectomy	697 (3.2)	693 (3.2)
Arm amputation	1 (0.0)	0
Arterial aneurysm repair	0	1 (0.0)
Arterial bypass operation	1 (0.0)	0
Arterial graft	0	1 (0.0)
Arterial repair	2 (0.0)	2 (0.0)
Arterial stent insertion	2 (0.0)	4 (0.0)
Arterial therapeutic procedure	2 (0.0)	3 (0.0)
Arteriovenous fistula operation	2 (0.0)	1 (0.0)
Arthrodesis	18 (0.1)	23 (0.1)
Arthroscopic surgery	4 (0.0)	3 (0.0)
Arthrotomy	0	2 (0.0)
Artificial crown procedure	1 (0.0)	2 (0.0)
Artificial insemination	1 (0.0)	0
Artificial urinary sphincter implant	1 (0.0)	2 (0.0)
Astrocytoma surgery	1 (0.0)	0
Atrial appendage closure	1 (0.0)	3 (0.0)
Atrial septal defect repair	9 (0.0)	11 (0.1)
Axillary lymphadenectomy	3 (0.0)	3 (0.0)
Baker's cyst excision	1 (0.0)	0
Bartholin's cyst removal	4 (0.0)	1 (0.0)
Benign breast lump removal	19 (0.1)	19 (0.1)
Benign tumour excision	6 (0.0)	5 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Bilateral orchidectomy	1 (0.0)	2 (0.0)
Bile duct stent insertion	1 (0.0)	0
Bile duct stent removal	1 (0.0)	0
Biliary stent placement	1 (0.0)	0
Birth defect correction	1 (0.0)	0
Bladder calculus removal	3 (0.0)	2 (0.0)
Bladder lesion excision	0	1 (0.0)
Bladder neoplasm surgery	6 (0.0)	4 (0.0)
Bladder operation	4 (0.0)	9 (0.0)
Bladder polypectomy	2 (0.0)	1 (0.0)
Bladder repair	7 (0.0)	14 (0.1)
Blepharoplasty	25 (0.1)	23 (0.1)
Blood donation	0	1 (0.0)
Blood pressure management	1 (0.0)	0
Bone anchored hearing aid implantation	0	2 (0.0)
Bone cyst excision	8 (0.0)	9 (0.0)
Bone debridement	2 (0.0)	1 (0.0)
Bone graft	7 (0.0)	3 (0.0)
Bone lesion excision	35 (0.2)	36 (0.2)
Bone marrow donation	2 (0.0)	2 (0.0)
Bone operation	60 (0.3)	45 (0.2)
Bone prosthesis insertion	1 (0.0)	0
Botulinum toxin injection	0	2 (0.0)
Brachytherapy	4 (0.0)	1 (0.0)
Brachytherapy to prostate	3 (0.0)	1 (0.0)
Brain lobectomy	2 (0.0)	0
Brain operation	5 (0.0)	7 (0.0)
Brain stent insertion	1 (0.0)	0
Brain tumour operation	5 (0.0)	6 (0.0)
Breast conserving surgery	140 (0.6)	134 (0.6)
Breast cyst excision	12 (0.1)	14 (0.1)
Breast operation	8 (0.0)	7 (0.0)
Breast prosthesis removal	8 (0.0)	0
Breast reconstruction	17 (0.1)	17 (0.1)
Breast tumour excision	3 (0.0)	3 (0.0)
Bunion operation	104 (0.5)	121 (0.6)
Burn operation	2 (0.0)	0
Bursa removal	2 (0.0)	3 (0.0)
Bursal operation	0	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Caecectomy	1 (0.0)	0
Caecopexy	0	1 (0.0)
Caesarean section	604 (2.8)	634 (2.9)
Calcific deposits removal	2 (0.0)	1 (0.0)
Canalith repositioning procedure	0	1 (0.0)
Cancer surgery	63 (0.3)	53 (0.2)
Capsulorrhaphy	1 (0.0)	0
Cardiac ablation	80 (0.4)	79 (0.4)
Cardiac operation	13 (0.1)	15 (0.1)
Cardiac pacemaker insertion	56 (0.3)	62 (0.3)
Cardiac pacemaker removal	0	3 (0.0)
Cardiac pacemaker replacement	1 (0.0)	2 (0.0)
Cardiovascular event prophylaxis	0	1 (0.0)
Cardioversion	8 (0.0)	9 (0.0)
Carotid artery bypass	1 (0.0)	0
Carotid artery stent insertion	4 (0.0)	5 (0.0)
Carotid endarterectomy	7 (0.0)	6 (0.0)
Carotid revascularisation	0	1 (0.0)
Carpal tunnel decompression	142 (0.7)	123 (0.6)
Carpectomy	1 (0.0)	2 (0.0)
Cartilage graft	2 (0.0)	0
Cartilage operation	3 (0.0)	1 (0.0)
Cataract operation	360 (1.7)	365 (1.7)
Catheter placement	0	2 (0.0)
Central venous catheter removal	0	1 (0.0)
Central venous catheterisation	4 (0.0)	1 (0.0)
Cerebral cyst excision	0	1 (0.0)
Cerebral endovascular aneurysm repair	0	1 (0.0)
Cerebrovascular accident prophylaxis	1 (0.0)	0
Cerebrovascular operation	0	1 (0.0)
Cervical conisation	2 (0.0)	2 (0.0)
Cervical laser therapy	2 (0.0)	0
Cervical polypectomy	2 (0.0)	2 (0.0)
Cervicectomy	0	4 (0.0)
Cervix cautery	1 (0.0)	0
Cervix cryotherapy	3 (0.0)	0
Cervix operation	1 (0.0)	0
Cheilectomy	2 (0.0)	3 (0.0)
Chemical contraception	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Chemotherapy	13 (0.1)	10 (0.0)
Chest tube insertion	4 (0.0)	3 (0.0)
Chest wall operation	0	1 (0.0)
Cholecystectomy	801 (3.7)	795 (3.7)
Cholecystostomy	2 (0.0)	1 (0.0)
Choledocholithotomy	0	1 (0.0)
Cholelithotomy	7 (0.0)	5 (0.0)
Cholesteatoma removal	0	3 (0.0)
Chondrectomy	1 (0.0)	4 (0.0)
Chondroplasty	35 (0.2)	38 (0.2)
Circumcision	8 (0.0)	9 (0.0)
Cleft lip repair	1 (0.0)	1 (0.0)
Cleft palate repair	4 (0.0)	2 (0.0)
Closed fracture manipulation	1 (0.0)	2 (0.0)
Coccygectomy	2 (0.0)	1 (0.0)
Cochlea implant	9 (0.0)	6 (0.0)
Colectomy	63 (0.3)	56 (0.3)
Colectomy total	3 (0.0)	2 (0.0)
Colon operation	10 (0.0)	4 (0.0)
Colostomy	6 (0.0)	7 (0.0)
Colostomy closure	3 (0.0)	3 (0.0)
Colpocleisis	0	1 (0.0)
Colporrhaphy	2 (0.0)	2 (0.0)
Commissurotomy of pulmonary valve	1 (0.0)	0
Contact lens therapy	1 (0.0)	1 (0.0)
Continuous positive airway pressure	19 (0.1)	13 (0.1)
Contraception	14 (0.1)	19 (0.1)
Contraceptive implant	4 (0.0)	7 (0.0)
Corneal implant	0	1 (0.0)
Corneal operation	3 (0.0)	4 (0.0)
Corneal transplant	15 (0.1)	12 (0.1)
Coronary angioplasty	16 (0.1)	20 (0.1)
Coronary arterial stent insertion	169 (0.8)	170 (0.8)
Coronary artery bypass	106 (0.5)	123 (0.6)
Coronary artery stent removal	1 (0.0)	0
Coronary artery surgery	3 (0.0)	4 (0.0)
Coronary revascularisation	3 (0.0)	4 (0.0)
Cranial nerve decompression	2 (0.0)	0
Cranial operation	7 (0.0)	5 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Craniectomy	0	1 (0.0)
Cranioplasty	1 (0.0)	1 (0.0)
Craniotomy	5 (0.0)	10 (0.0)
Cryotherapy	4 (0.0)	6 (0.0)
Cyst drainage	2 (0.0)	0
Cyst removal	17 (0.1)	13 (0.1)
Cystocele repair	3 (0.0)	2 (0.0)
Cystoprostatectomy	1 (0.0)	0
Cytoreductive surgery	1 (0.0)	1 (0.0)
Dacryocystorhinostomy	3 (0.0)	2 (0.0)
Debridement	8 (0.0)	10 (0.0)
Decompressive craniectomy	0	1 (0.0)
Deep brain stimulation	1 (0.0)	3 (0.0)
Dental care	0	1 (0.0)
Dental cosmetic procedure	1 (0.0)	1 (0.0)
Dental implantation	15 (0.1)	14 (0.1)
Dental operation	5 (0.0)	2 (0.0)
Dental prosthesis placement	3 (0.0)	2 (0.0)
Dermabrasion	1 (0.0)	0
Detoxification	0	1 (0.0)
Dialysis	0	1 (0.0)
Diaphragmatic operation	1 (0.0)	1 (0.0)
Diplopia correction	1 (0.0)	0
Diverticulectomy	2 (0.0)	3 (0.0)
Drug delivery device placement	1 (0.0)	2 (0.0)
Drug rehabilitation	1 (0.0)	1 (0.0)
Duodenal operation	1 (0.0)	0
Duodenal switch	0	3 (0.0)
Duodenal ulcer repair	0	1 (0.0)
Duodenectomy	1 (0.0)	0
Dupuytren's contracture operation	4 (0.0)	5 (0.0)
Ear operation	12 (0.1)	8 (0.0)
Ear tube insertion	24 (0.1)	26 (0.1)
Ear tube removal	1 (0.0)	3 (0.0)
Ectopic pregnancy termination	2 (0.0)	1 (0.0)
Elbow operation	23 (0.1)	27 (0.1)
Electrodesiccation	1 (0.0)	0
Endarterectomy	1 (0.0)	0
Endocervical curettage	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Endocrine gland operation	1 (0.0)	0
Endodontic procedure	1 (0.0)	5 (0.0)
Endometrial ablation	118 (0.5)	107 (0.5)
Endometriosis ablation	6 (0.0)	11 (0.1)
Endoscopic sleeve gastroplasty	0	1 (0.0)
Enterorrhaphy	0	1 (0.0)
Enterostomy	1 (0.0)	0
Epidermoid cyst excision	1 (0.0)	1 (0.0)
Epididymal cyst removal	3 (0.0)	0
Epididymal operation	1 (0.0)	0
Epidural injection	1 (0.0)	0
Epiphysiodesis	1 (0.0)	0
Ethmoid sinus surgery	1 (0.0)	1 (0.0)
Eustachian tube operation	1 (0.0)	2 (0.0)
Exeresis	9 (0.0)	11 (0.1)
Explorative laparotomy	6 (0.0)	7 (0.0)
External fixation of fracture	2 (0.0)	1 (0.0)
External nose lesion excision	1 (0.0)	0
Eye excision	3 (0.0)	3 (0.0)
Eye irrigation	0	1 (0.0)
Eye laser surgery	42 (0.2)	27 (0.1)
Eye muscle operation	4 (0.0)	10 (0.0)
Eye operation	30 (0.1)	28 (0.1)
Eye prosthesis insertion	1 (0.0)	0
Eyeglasses therapy	1 (0.0)	1 (0.0)
Eyelid cyst removal	2 (0.0)	2 (0.0)
Eyelid operation	7 (0.0)	9 (0.0)
Face lift	13 (0.1)	11 (0.1)
Facet joint block	0	1 (0.0)
Facial lesion excision	0	2 (0.0)
Facial operation	5 (0.0)	2 (0.0)
Fallopian tube operation	4 (0.0)	3 (0.0)
Fascia release	4 (0.0)	4 (0.0)
Fascial operation	2 (0.0)	4 (0.0)
Fasciotomy	9 (0.0)	8 (0.0)
Female genital operation	1 (0.0)	0
Female sterilisation	705 (3.2)	733 (3.4)
Femoral derotation osteotomy	0	1 (0.0)
Femoral hernia repair	1 (0.0)	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Finger amputation	10 (0.0)	15 (0.1)
Finger repair operation	7 (0.0)	7 (0.0)
Fistula repair	3 (0.0)	2 (0.0)
Fistulotomy	1 (0.0)	0
Foetal surgery	0	1 (0.0)
Foot amputation	3 (0.0)	1 (0.0)
Foot operation	49 (0.2)	47 (0.2)
Foraminotomy	3 (0.0)	2 (0.0)
Fracture reduction	1 (0.0)	3 (0.0)
Fracture treatment	146 (0.7)	144 (0.7)
Frontal sinus operation	1 (0.0)	0
Fulguration	0	1 (0.0)
Functional endoscopic sinus surgery	3 (0.0)	4 (0.0)
Gallbladder operation	9 (0.0)	7 (0.0)
Gastrectomy	80 (0.4)	100 (0.5)
Gastric banding	28 (0.1)	30 (0.1)
Gastric banding reversal	3 (0.0)	4 (0.0)
Gastric bypass	143 (0.7)	136 (0.6)
Gastric bypass reversal	0	1 (0.0)
Gastric operation	2 (0.0)	8 (0.0)
Gastric stapling	0	4 (0.0)
Gastric ulcer surgery	0	3 (0.0)
Gastroenterostomy	1 (0.0)	2 (0.0)
Gastrointestinal dilation procedure	0	1 (0.0)
Gastrointestinal surgery	3 (0.0)	1 (0.0)
Gastrointestinal ulcer management	3 (0.0)	1 (0.0)
Gastroplasty	1 (0.0)	4 (0.0)
Gastrostomy	1 (0.0)	0
Gastrostomy tube removal	1 (0.0)	0
Genitourinary operation	1 (0.0)	1 (0.0)
Gingival graft	2 (0.0)	7 (0.0)
Gingival operation	0	2 (0.0)
Gingivectomy	0	1 (0.0)
Glaucoma drainage device placement	1 (0.0)	1 (0.0)
Glaucoma surgery	6 (0.0)	10 (0.0)
Glossectomy	1 (0.0)	1 (0.0)
Haemangioma removal	2 (0.0)	3 (0.0)
Haematoma evacuation	0	2 (0.0)
Haemorrhoid operation	50 (0.2)	55 (0.3)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Haemostasis	2 (0.0)	1 (0.0)
Hair transplant	2 (0.0)	4 (0.0)
Hand amputation	1 (0.0)	1 (0.0)
Hand repair operation	3 (0.0)	6 (0.0)
Hearing aid therapy	0	1 (0.0)
Heart valve replacement	7 (0.0)	9 (0.0)
Hepatectomy	2 (0.0)	2 (0.0)
Hepatitis B immunisation	0	1 (0.0)
Hernia diaphragmatic repair	1 (0.0)	0
Hernia hiatus repair	18 (0.1)	38 (0.2)
Hernia repair	146 (0.7)	134 (0.6)
Herpes zoster immunisation	0	1 (0.0)
High frequency ablation	2 (0.0)	2 (0.0)
Hip arthroplasty	217 (1.0)	205 (0.9)
Hip surgery	27 (0.1)	21 (0.1)
Hormone replacement therapy	12 (0.1)	10 (0.0)
Hormone therapy	1 (0.0)	0
Hospitalisation	1 (0.0)	1 (0.0)
Hydrocele operation	6 (0.0)	7 (0.0)
Hyperbaric oxygen therapy	1 (0.0)	0
Hyperthermic chemotherapy	0	1 (0.0)
Hypophysectomy	1 (0.0)	0
Hysterectomy	1533 (7.1)	1480 (6.8)
Hysteropexy	0	2 (0.0)
Hysterosalpingectomy	0	1 (0.0)
Hysterosalpingo-oophorectomy	17 (0.1)	19 (0.1)
Hysterotomy	0	1 (0.0)
Ileectomy	1 (0.0)	1 (0.0)
Ileostomy	4 (0.0)	2 (0.0)
Ileostomy closure	1 (0.0)	2 (0.0)
Immune tolerance induction	2 (0.0)	0
Immunoglobulin therapy	1 (0.0)	0
Implantable cardiac monitor insertion	4 (0.0)	7 (0.0)
Implantable defibrillator insertion	15 (0.1)	11 (0.1)
Implantable defibrillator removal	1 (0.0)	1 (0.0)
Implantable defibrillator replacement	2 (0.0)	5 (0.0)
In vitro fertilisation	1 (0.0)	3 (0.0)
Incisional drainage	3 (0.0)	6 (0.0)
Incisional hernia repair	2 (0.0)	9 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Infection prophylaxis	0	1 (0.0)
Influenza immunisation	1 (0.0)	4 (0.0)
Infusion	0	1 (0.0)
Inguinal hernia repair	263 (1.2)	275 (1.3)
Injection	1 (0.0)	2 (0.0)
Inner ear operation	2 (0.0)	2 (0.0)
Internal fixation of fracture	11 (0.1)	12 (0.1)
Internal fixation of spine	0	1 (0.0)
Intervertebral disc operation	112 (0.5)	125 (0.6)
Intestinal adhesion lysis	1 (0.0)	0
Intestinal anastomosis	1 (0.0)	1 (0.0)
Intestinal fistula repair	0	1 (0.0)
Intestinal malrotation repair	0	1 (0.0)
Intestinal operation	15 (0.1)	7 (0.0)
Intestinal polypectomy	0	2 (0.0)
Intestinal resection	19 (0.1)	18 (0.1)
Intra-cerebral aneurysm operation	6 (0.0)	2 (0.0)
Intra-thoracic aortic aneurysm repair	0	1 (0.0)
Intra-uterine contraceptive device insertion	30 (0.1)	31 (0.1)
Intracerebral haematoma evacuation	1 (0.0)	0
Intramedullary rod insertion	3 (0.0)	2 (0.0)
Intraocular lens implant	23 (0.1)	38 (0.2)
Intrauterine contraception	26 (0.1)	34 (0.2)
Iridotomy	2 (0.0)	2 (0.0)
Jaw lesion excision	1 (0.0)	0
Jaw operation	25 (0.1)	29 (0.1)
Jejunal operation	0	1 (0.0)
Jejunostomy	0	1 (0.0)
Joint arthroplasty	19 (0.1)	18 (0.1)
Joint debridement	5 (0.0)	5 (0.0)
Joint dislocation reduction	16 (0.1)	13 (0.1)
Joint fluid drainage	1 (0.0)	0
Joint irrigation	0	1 (0.0)
Joint manipulation	0	4 (0.0)
Joint resurfacing surgery	2 (0.0)	0
Joint stabilisation	1 (0.0)	1 (0.0)
Joint surgery	4 (0.0)	9 (0.0)
Keratectomy	1 (0.0)	1 (0.0)
Keratomileusis	121 (0.6)	115 (0.5)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Keratoplasty	2 (0.0)	1 (0.0)
Keratotomy	3 (0.0)	6 (0.0)
Kidney ablation	1 (0.0)	0
Knee arthroplasty	338 (1.6)	333 (1.5)
Knee operation	188 (0.9)	182 (0.8)
Lacrimal duct procedure	3 (0.0)	5 (0.0)
Lacrimal gland operation	0	1 (0.0)
Laminaplasty	0	1 (0.0)
Laparoscopic surgery	5 (0.0)	5 (0.0)
Laparotomy	6 (0.0)	5 (0.0)
Large intestinal polypectomy	60 (0.3)	54 (0.2)
Large intestine anastomosis	1 (0.0)	0
Large intestine operation	1 (0.0)	2 (0.0)
Laryngeal cyst removal	0	1 (0.0)
Laryngeal operation	2 (0.0)	1 (0.0)
Laryngeal polypectomy	0	2 (0.0)
Laryngectomy	2 (0.0)	0
Laryngoplasty	0	1 (0.0)
Laser therapy	1 (0.0)	2 (0.0)
Leg amputation	7 (0.0)	8 (0.0)
Lens capsulotomy	5 (0.0)	0
Lens extraction	1 (0.0)	0
Lenticular operation	1 (0.0)	0
Lesion excision	2 (0.0)	1 (0.0)
Ligament operation	168 (0.8)	168 (0.8)
Limb operation	96 (0.4)	101 (0.5)
Limb reattachment surgery	4 (0.0)	1 (0.0)
Limb reconstructive surgery	1 (0.0)	3 (0.0)
Lip operation	1 (0.0)	1 (0.0)
Lipectomy	2 (0.0)	2 (0.0)
Lipoma excision	34 (0.2)	32 (0.1)
Liposuction	12 (0.1)	19 (0.1)
Lithotomy position	0	1 (0.0)
Lithotripsy	44 (0.2)	38 (0.2)
Liver ablation	1 (0.0)	0
Liver operation	0	1 (0.0)
Liver transplant	0	1 (0.0)
Loop electrosurgical excision procedure	15 (0.1)	13 (0.1)
Lower oesophageal sphincter magnetic augmentation	3 (0.0)	3 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Lung cyst removal	1 (0.0)	0
Lung lobectomy	7 (0.0)	9 (0.0)
Lung neoplasm surgery	1 (0.0)	0
Lung operation	2 (0.0)	5 (0.0)
Lymphadenectomy	13 (0.1)	22 (0.1)
Lymphoid tissue operation	3 (0.0)	0
Lymphoma operation	2 (0.0)	2 (0.0)
Mammary ductectomy	1 (0.0)	2 (0.0)
Mammoplasty	237 (1.1)	217 (1.0)
Manipulation	1 (0.0)	0
Mass excision	2 (0.0)	1 (0.0)
Mastectomy	93 (0.4)	96 (0.4)
Mastoidectomy	3 (0.0)	5 (0.0)
Maxillofacial operation	4 (0.0)	2 (0.0)
Mediastinal operation	0	1 (0.0)
Medical cannabis therapy	0	1 (0.0)
Medical device battery replacement	1 (0.0)	2 (0.0)
Medical device implantation	2 (0.0)	3 (0.0)
Medical device removal	5 (0.0)	5 (0.0)
Meningioma surgery	6 (0.0)	4 (0.0)
Meniscus operation	147 (0.7)	148 (0.7)
Meniscus removal	20 (0.1)	29 (0.1)
Metabolic disorder prophylaxis	0	1 (0.0)
Metabolic surgery	49 (0.2)	50 (0.2)
Metacarpal excision	0	1 (0.0)
Metatarsal excision	1 (0.0)	0
Micrographic skin surgery	39 (0.2)	44 (0.2)
Microsurgery to hand	0	1 (0.0)
Middle ear lesion excision	1 (0.0)	0
Middle ear operation	1 (0.0)	0
Middle ear prosthesis insertion	0	1 (0.0)
Mitral valve repair	13 (0.1)	8 (0.0)
Mitral valve replacement	6 (0.0)	8 (0.0)
Modified radical mastectomy	1 (0.0)	0
Mole excision	15 (0.1)	12 (0.1)
Muscle flap operation	1 (0.0)	0
Muscle graft	0	1 (0.0)
Muscle operation	17 (0.1)	22 (0.1)
Muscle reattachment	2 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Myectomy	0	3 (0.0)
Myomectomy	26 (0.1)	35 (0.2)
Myopia correction	2 (0.0)	5 (0.0)
Myringotomy	6 (0.0)	13 (0.1)
Nail operation	5 (0.0)	1 (0.0)
Nasal operation	13 (0.1)	14 (0.1)
Nasal polypectomy	16 (0.1)	10 (0.0)
Nasal septal operation	133 (0.6)	135 (0.6)
Nasal sinus irrigation	1 (0.0)	1 (0.0)
Nasopharyngeal surgery	0	1 (0.0)
Neck dissection	5 (0.0)	2 (0.0)
Neck lift	0	2 (0.0)
Neck surgery	20 (0.1)	14 (0.1)
Neoplasm prophylaxis	0	1 (0.0)
Nephrectomy	36 (0.2)	36 (0.2)
Nephrostomy	0	2 (0.0)
Nerve block	5 (0.0)	3 (0.0)
Nerve graft	0	1 (0.0)
Nervous system neoplasm surgery	5 (0.0)	2 (0.0)
Neurectomy	16 (0.1)	13 (0.1)
Neuroprosthesis implantation	2 (0.0)	1 (0.0)
Neurosurgery	1 (0.0)	3 (0.0)
Oesophageal dilation procedure	4 (0.0)	7 (0.0)
Oesophageal lesion excision	0	1 (0.0)
Oesophageal operation	4 (0.0)	3 (0.0)
Oesophagectomy	1 (0.0)	1 (0.0)
Oesophagocardiomyotomy	0	2 (0.0)
Oesophagogastrectomy	1 (0.0)	0
Oesophagogastric fundoplasty	21 (0.1)	14 (0.1)
Oestrogen replacement therapy	1 (0.0)	0
Oestrogen therapy	0	1 (0.0)
Oocyte harvest	2 (0.0)	1 (0.0)
Oophorectomy	76 (0.3)	75 (0.3)
Oophorectomy bilateral	60 (0.3)	43 (0.2)
Open reduction of fracture	55 (0.3)	54 (0.2)
Oral cavity neoplasm surgery	1 (0.0)	2 (0.0)
Oral contraception	1 (0.0)	0
Oral surgery	2 (0.0)	3 (0.0)
Orbit plastic repair	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Orbital decompression	0	1 (0.0)
Orchidectomy	18 (0.1)	15 (0.1)
Orchidopexy	5 (0.0)	3 (0.0)
Orthognathic surgery	11 (0.1)	10 (0.0)
Orthopaedic procedure	6 (0.0)	6 (0.0)
Ossicular operation	0	2 (0.0)
Ossiculoplasty	1 (0.0)	1 (0.0)
Ostectomy	9 (0.0)	10 (0.0)
Osteotomy	14 (0.1)	8 (0.0)
Otoplasty	6 (0.0)	6 (0.0)
Ovarian cystectomy	27 (0.1)	40 (0.2)
Ovarian lesion excision	2 (0.0)	2 (0.0)
Ovarian neoplasm surgery	4 (0.0)	1 (0.0)
Ovarian operation	1 (0.0)	3 (0.0)
Ovariocentesis	0	1 (0.0)
Oxygen therapy	0	1 (0.0)
Pain management	0	1 (0.0)
Palatal operation	3 (0.0)	0
Palatoplasty	0	1 (0.0)
Pancreatectomy	2 (0.0)	1 (0.0)
Pancreatic operation	0	1 (0.0)
Pancreatic stent placement	0	1 (0.0)
Pancreatic stent removal	0	1 (0.0)
Pancreaticoduodenectomy	3 (0.0)	4 (0.0)
Papilloma excision	6 (0.0)	2 (0.0)
Paranasal sinus polypectomy	4 (0.0)	9 (0.0)
Paraovarian cystectomy	0	1 (0.0)
Parathyroid gland operation	3 (0.0)	4 (0.0)
Parathyroidectomy	29 (0.1)	14 (0.1)
Parotidectomy	8 (0.0)	2 (0.0)
Patellectomy	0	2 (0.0)
Patent ductus arteriosus repair	2 (0.0)	1 (0.0)
Pelvic floor repair	3 (0.0)	2 (0.0)
Pelvic operation	2 (0.0)	0
Penile prosthesis insertion	8 (0.0)	8 (0.0)
Percutaneous coronary intervention	2 (0.0)	5 (0.0)
Pericardial excision	0	1 (0.0)
Peripheral artery bypass	1 (0.0)	3 (0.0)
Peripheral artery stent insertion	1 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Peripheral artery surgery	1 (0.0)	0
Peripheral nerve decompression	11 (0.1)	14 (0.1)
Peripheral nerve destruction	0	2 (0.0)
Peripheral nerve neurostimulation	0	3 (0.0)
Peripheral nerve operation	6 (0.0)	18 (0.1)
Peripheral nerve transposition	6 (0.0)	5 (0.0)
Permanent contraceptive tubal implant	1 (0.0)	2 (0.0)
Pharyngeal operation	6 (0.0)	6 (0.0)
Pharyngeal polypectomy	1 (0.0)	0
Phlebectomy	5 (0.0)	12 (0.1)
Photorefractive keratectomy	8 (0.0)	10 (0.0)
Physiotherapy	1 (0.0)	2 (0.0)
Pilonidal sinus repair	19 (0.1)	21 (0.1)
Pituitary tumour removal	5 (0.0)	4 (0.0)
Plastic surgery	6 (0.0)	2 (0.0)
Plastic surgery to the face	7 (0.0)	11 (0.1)
Platelet rich plasma therapy	1 (0.0)	0
Pleural operation	0	4 (0.0)
Pleurectomy	0	1 (0.0)
Pleurodesis	1 (0.0)	0
Pneumocentesis	0	1 (0.0)
Pneumonectomy	2 (0.0)	4 (0.0)
Polypectomy	23 (0.1)	16 (0.1)
Portal shunt procedure	0	1 (0.0)
Postoperative care	0	1 (0.0)
Precancerous lesion excision	3 (0.0)	2 (0.0)
Preventive surgery	1 (0.0)	0
Proctectomy	0	2 (0.0)
Proctocolectomy	1 (0.0)	0
Proctoplasty	1 (0.0)	0
Prophylaxis	2 (0.0)	3 (0.0)
Prophylaxis against HIV infection	6 (0.0)	2 (0.0)
Prostate ablation	2 (0.0)	4 (0.0)
Prostate cryoablation	1 (0.0)	1 (0.0)
Prostatectomy	87 (0.4)	101 (0.5)
Prostatic operation	13 (0.1)	19 (0.1)
Prostatic urethral lift procedure	2 (0.0)	7 (0.0)
Prosthesis implantation	1 (0.0)	1 (0.0)
Psychotherapy	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Pterygium operation	3 (0.0)	3 (0.0)
Ptosis repair	4 (0.0)	2 (0.0)
Pulmonary bullectomy	1 (0.0)	1 (0.0)
Pulmonary resection	3 (0.0)	3 (0.0)
Pulmonary valve repair	1 (0.0)	0
Pulmonary valve replacement	0	1 (0.0)
Punctal plug insertion	1 (0.0)	0
Pyeloplasty	1 (0.0)	1 (0.0)
Pyloromyotomy	2 (0.0)	2 (0.0)
Pyloroplasty	2 (0.0)	7 (0.0)
Pylorus dilation procedure	0	1 (0.0)
Rabies immunisation	0	1 (0.0)
Rachiotomy	1 (0.0)	0
Radiation therapy to ear, nose, or throat	1 (0.0)	0
Radical cystectomy	1 (0.0)	0
Radical hysterectomy	3 (0.0)	6 (0.0)
Radical mastectomy	1 (0.0)	0
Radical prostatectomy	13 (0.1)	10 (0.0)
Radiculotomy	1 (0.0)	1 (0.0)
Radioactive iodine therapy	6 (0.0)	3 (0.0)
Radiotherapy	13 (0.1)	7 (0.0)
Radiotherapy to breast	4 (0.0)	5 (0.0)
Radiotherapy to eye	0	1 (0.0)
Radiotherapy to prostate	5 (0.0)	5 (0.0)
Radiotherapy to skin	1 (0.0)	0
Radiotherapy to thyroid	0	3 (0.0)
Rectal fistula repair	2 (0.0)	2 (0.0)
Rectal lesion excision	2 (0.0)	0
Rectal polypectomy	1 (0.0)	0
Rectal prolapse repair	3 (0.0)	2 (0.0)
Rectocele repair	7 (0.0)	4 (0.0)
Reduction of increased intracranial pressure	1 (0.0)	0
Rehabilitation therapy	1 (0.0)	1 (0.0)
Removal of foreign body	7 (0.0)	11 (0.1)
Removal of foreign body from eye	0	2 (0.0)
Removal of foreign body from gastrointestinal tract	1 (0.0)	1 (0.0)
Removal of foreign body from joint	1 (0.0)	1 (0.0)
Removal of foreign body from rectum	1 (0.0)	0
Removal of foreign body from throat	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Renal artery stent placement	0	2 (0.0)
Renal cyst excision	2 (0.0)	2 (0.0)
Renal stone removal	57 (0.3)	60 (0.3)
Renal surgery	2 (0.0)	15 (0.1)
Renal tumour excision	2 (0.0)	1 (0.0)
Retinal operation	18 (0.1)	24 (0.1)
Retinopexy	25 (0.1)	16 (0.1)
Rhinoplasty	72 (0.3)	90 (0.4)
Rib excision	4 (0.0)	1 (0.0)
Rotator cuff repair	194 (0.9)	177 (0.8)
Salivary gland operation	3 (0.0)	5 (0.0)
Salivary gland resection	5 (0.0)	1 (0.0)
Salpingectomy	96 (0.4)	97 (0.4)
Salpingo-oophorectomy	2 (0.0)	2 (0.0)
Salpingo-oophorectomy bilateral	13 (0.1)	7 (0.0)
Salpingo-oophorectomy unilateral	4 (0.0)	2 (0.0)
Salpingoplasty	2 (0.0)	2 (0.0)
Salpingostomy	4 (0.0)	2 (0.0)
Sarcoma excision	1 (0.0)	2 (0.0)
Scar excision	3 (0.0)	9 (0.0)
Scleral buckling surgery	3 (0.0)	0
Sclerotherapy	2 (0.0)	1 (0.0)
Scoliosis surgery	5 (0.0)	3 (0.0)
Scrotal cystectomy	0	1 (0.0)
Scrotal operation	2 (0.0)	0
Sebaceous cyst excision	5 (0.0)	7 (0.0)
Seizure prophylaxis	1 (0.0)	0
Septal myectomy	0	1 (0.0)
Sesamoidectomy	1 (0.0)	2 (0.0)
Shoulder arthroplasty	46 (0.2)	41 (0.2)
Shoulder operation	143 (0.7)	98 (0.5)
Sigmoidectomy	6 (0.0)	7 (0.0)
Simple mastectomy	2 (0.0)	2 (0.0)
Sinuplasty	16 (0.1)	12 (0.1)
Sinus antrostomy	3 (0.0)	0
Sinus operation	80 (0.4)	65 (0.3)
Skin cosmetic procedure	5 (0.0)	7 (0.0)
Skin cryotherapy	1 (0.0)	1 (0.0)
Skin cyst excision	6 (0.0)	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Skin graft	13 (0.1)	16 (0.1)
Skin lesion removal	18 (0.1)	16 (0.1)
Skin neoplasm excision	171 (0.8)	205 (0.9)
Skin operation	7 (0.0)	5 (0.0)
Skin ulcer excision	0	1 (0.0)
Skull fracture treatment	1 (0.0)	2 (0.0)
Small intestinal resection	7 (0.0)	4 (0.0)
Small intestine operation	4 (0.0)	2 (0.0)
Soft tissue flap operation	0	1 (0.0)
Spermatic cord operation	1 (0.0)	0
Sphenoid sinus operation	1 (0.0)	1 (0.0)
Spinal cord operation	2 (0.0)	1 (0.0)
Spinal corpectomy	3 (0.0)	1 (0.0)
Spinal decompression	13 (0.1)	13 (0.1)
Spinal deformity correction	0	1 (0.0)
Spinal fracture treatment	6 (0.0)	3 (0.0)
Spinal fusion surgery	187 (0.9)	187 (0.9)
Spinal laminectomy	82 (0.4)	95 (0.4)
Spinal nerve stimulator implantation	14 (0.1)	14 (0.1)
Spinal nerve stimulator removal	0	1 (0.0)
Spinal operation	120 (0.6)	105 (0.5)
Spinal rod insertion	2 (0.0)	1 (0.0)
Spleen operation	0	1 (0.0)
Splenectomy	21 (0.1)	25 (0.1)
Splenic artery embolisation	1 (0.0)	1 (0.0)
Stapedectomy	5 (0.0)	4 (0.0)
Stem cell therapy	2 (0.0)	1 (0.0)
Stem cell transplant	2 (0.0)	2 (0.0)
Stent placement	21 (0.1)	30 (0.1)
Sterilisation	20 (0.1)	8 (0.0)
Sterilisation reversal	3 (0.0)	4 (0.0)
Sternotomy	0	1 (0.0)
Steroid therapy	1 (0.0)	0
Stomach lesion excision	2 (0.0)	0
Strabismus correction	23 (0.1)	29 (0.1)
Stricturoplasty	1 (0.0)	0
Subdural haematoma evacuation	1 (0.0)	0
Surgery	9 (0.0)	14 (0.1)
Surgical fixation of rib fracture	1 (0.0)	0

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Suture insertion	2 (0.0)	2 (0.0)
Suture removal	0	1 (0.0)
Sympathectomy	0	3 (0.0)
Synovectomy	1 (0.0)	1 (0.0)
Synovial cyst removal	34 (0.2)	24 (0.1)
Talipes correction	1 (0.0)	5 (0.0)
Tarsal tunnel decompression	0	2 (0.0)
Temporomandibular joint surgery	8 (0.0)	2 (0.0)
Tendon graft	3 (0.0)	0
Tendon operation	7 (0.0)	9 (0.0)
Tendon sheath incision	38 (0.2)	25 (0.1)
Tendon transfer	4 (0.0)	3 (0.0)
Tenodesis	1 (0.0)	1 (0.0)
Tenolysis	2 (0.0)	3 (0.0)
Tenonectomy	1 (0.0)	0
Tenoplasty	90 (0.4)	98 (0.5)
Tenotomy	7 (0.0)	20 (0.1)
Testes exploration	1 (0.0)	3 (0.0)
Testicular operation	0	3 (0.0)
Tetralogy of Fallot repair	1 (0.0)	1 (0.0)
Therapeutic aspiration	0	1 (0.0)
Therapeutic embolisation	5 (0.0)	1 (0.0)
Therapeutic nerve ablation	5 (0.0)	1 (0.0)
Therapeutic procedure	4 (0.0)	0
Thermal ablation	1 (0.0)	0
Thoracic operation	4 (0.0)	1 (0.0)
Thoracic outlet surgery	1 (0.0)	0
Thoracoplasty	2 (0.0)	2 (0.0)
Thoracotomy	5 (0.0)	4 (0.0)
Thrombectomy	4 (0.0)	2 (0.0)
Thromboembolectomy	0	1 (0.0)
Thymectomy	2 (0.0)	2 (0.0)
Thyroglossal cyst excision	1 (0.0)	3 (0.0)
Thyroid cystectomy	0	2 (0.0)
Thyroid nodule removal	4 (0.0)	7 (0.0)
Thyroid operation	5 (0.0)	6 (0.0)
Thyroidectomy	161 (0.7)	172 (0.8)
Toe amputation	15 (0.1)	15 (0.1)
Toe operation	28 (0.1)	26 (0.1)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Tongue operation	0	2 (0.0)
Tongue tie operation	1 (0.0)	3 (0.0)
Tonsillectomy	835 (3.8)	780 (3.6)
Tooth extraction	15 (0.1)	16 (0.1)
Tooth repair	0	1 (0.0)
Trabeculectomy	4 (0.0)	5 (0.0)
Trabeculoplasty	0	2 (0.0)
Tracheal fistula repair	1 (0.0)	0
Tracheostomy	4 (0.0)	6 (0.0)
Tracheostomy tube removal	1 (0.0)	1 (0.0)
Transcatheter aortic valve implantation	1 (0.0)	0
Transfusion	10 (0.0)	12 (0.1)
Transgender hormonal therapy	2 (0.0)	2 (0.0)
Transgender operation	3 (0.0)	1 (0.0)
Transplant	3 (0.0)	1 (0.0)
Transurethral bladder resection	5 (0.0)	0
Transurethral incision of prostate	1 (0.0)	0
Transurethral prostatectomy	18 (0.1)	32 (0.1)
Trapeziectomy	0	2 (0.0)
Tumour excision	6 (0.0)	3 (0.0)
Tumour vaccine therapy	1 (0.0)	0
Turbinectomy	11 (0.1)	13 (0.1)
Turbinoplasty	1 (0.0)	2 (0.0)
Tympanomastoidectomy	1 (0.0)	0
Tympanoplasty	14 (0.1)	16 (0.1)
Umbilical hernia repair	104 (0.5)	121 (0.6)
Umbilicoplasty	0	1 (0.0)
Ureteral stent insertion	8 (0.0)	9 (0.0)
Ureteral stent removal	1 (0.0)	1 (0.0)
Ureterectomy	0	1 (0.0)
Ureteric calculus removal	1 (0.0)	0
Ureteric operation	2 (0.0)	2 (0.0)
Ureteric repair	1 (0.0)	3 (0.0)
Ureterolithotomy	0	1 (0.0)
Urethral bulking agent injection	1 (0.0)	0
Urethral dilation procedure	1 (0.0)	1 (0.0)
Urethral operation	6 (0.0)	6 (0.0)
Urethral repair	2 (0.0)	5 (0.0)
Urethral stent insertion	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Urethrectomy	0	1 (0.0)
Urethrotomy	0	1 (0.0)
Urinary bladder suspension	57 (0.3)	53 (0.2)
Urinary calculus removal	1 (0.0)	0
Urinary control neurostimulator implantation	2 (0.0)	3 (0.0)
Urinary incontinence surgery	2 (0.0)	1 (0.0)
Urinary tract operation	2 (0.0)	3 (0.0)
Urogenital fistula repair	0	1 (0.0)
Urostomy	1 (0.0)	0
Uterine cystectomy	1 (0.0)	3 (0.0)
Uterine dilation and curettage	52 (0.2)	64 (0.3)
Uterine irrigation	1 (0.0)	0
Uterine leiomyoma embolisation	2 (0.0)	3 (0.0)
Uterine operation	6 (0.0)	3 (0.0)
Uterine polypectomy	10 (0.0)	5 (0.0)
Uterine prolapse repair	2 (0.0)	1 (0.0)
Uterine repair	1 (0.0)	0
Uterine tumour excision	1 (0.0)	2 (0.0)
Uvulectomy	4 (0.0)	8 (0.0)
Uvulopalatopharyngoplasty	6 (0.0)	10 (0.0)
Uvuloplasty	1 (0.0)	0
Vagal nerve stimulator implantation	1 (0.0)	0
Vaginal fistula repair	0	1 (0.0)
Vaginal operation	5 (0.0)	1 (0.0)
Vaginal pessary insertion	0	1 (0.0)
Vaginal prolapse repair	4 (0.0)	0
Vaginal ring	1 (0.0)	0
Valvuloplasty cardiac	1 (0.0)	1 (0.0)
Varicocele repair	13 (0.1)	14 (0.1)
Varicose vein operation	23 (0.1)	20 (0.1)
Vascular graft	4 (0.0)	7 (0.0)
Vascular operation	2 (0.0)	3 (0.0)
Vascular stent insertion	10 (0.0)	17 (0.1)
Vasectomy	801 (3.7)	751 (3.5)
Vasectomy reversal	4 (0.0)	3 (0.0)
Vena cava filter insertion	5 (0.0)	0
Venous ligation	1 (0.0)	1 (0.0)
Venous operation	2 (0.0)	3 (0.0)
Venous reconstruction	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Venous stent insertion	2 (0.0)	0
Ventricular drainage	1 (0.0)	0
Ventricular septal defect repair	1 (0.0)	1 (0.0)
Ventriculo-peritoneal shunt	1 (0.0)	5 (0.0)
Vertebroplasty	4 (0.0)	5 (0.0)
Vesicoureteral reflux surgery	0	1 (0.0)
Vessel harvesting	1 (0.0)	0
Vestibular apparatus operation	0	1 (0.0)
Vision correction operation	5 (0.0)	3 (0.0)
Vitamin supplementation	2 (0.0)	0
Vitrectomy	10 (0.0)	10 (0.0)
Vocal cord nodule removal	1 (0.0)	1 (0.0)
Vocal cord operation	0	3 (0.0)
Vocal cord polypectomy	3 (0.0)	3 (0.0)
Vulval operation	1 (0.0)	1 (0.0)
Vulvectomy	2 (0.0)	2 (0.0)
Weight control	2 (0.0)	0
Wisdom teeth removal	151 (0.7)	160 (0.7)
Wound closure	7 (0.0)	8 (0.0)
Wound treatment	2 (0.0)	2 (0.0)
Wrist surgery	40 (0.2)	55 (0.3)
Vascular disorders	5696 (26.2)	5723 (26.3)
Aneurysm	6 (0.0)	2 (0.0)
Aneurysm ruptured	0	1 (0.0)
Angiopathy	3 (0.0)	2 (0.0)
Aortic aneurysm	31 (0.1)	27 (0.1)
Aortic arteriosclerosis	46 (0.2)	36 (0.2)
Aortic dilatation	7 (0.0)	8 (0.0)
Aortic disorder	2 (0.0)	3 (0.0)
Aortic stenosis	8 (0.0)	9 (0.0)
Arterial occlusive disease	5 (0.0)	5 (0.0)
Arterial stenosis	1 (0.0)	0
Arterial thrombosis	1 (0.0)	1 (0.0)
Arteriosclerosis	21 (0.1)	21 (0.1)
Arteriovenous fistula	1 (0.0)	0
Capillary fragility	0	1 (0.0)
Collateral circulation	0	1 (0.0)
Deep vein thrombosis	72 (0.3)	81 (0.4)
Diabetic vascular disorder	1 (0.0)	2 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Embolism	1 (0.0)	1 (0.0)
Embolism arterial	1 (0.0)	0
Embolism venous	2 (0.0)	1 (0.0)
Endocrine hypertension	0	1 (0.0)
Erythromelalgia	1 (0.0)	0
Essential hypertension	97 (0.4)	83 (0.4)
Fibromuscular dysplasia	0	2 (0.0)
Flushing	0	1 (0.0)
Giant cell arteritis	0	1 (0.0)
Haematoma	1 (0.0)	3 (0.0)
Haemorrhage	2 (0.0)	1 (0.0)
Hot flush	133 (0.6)	144 (0.7)
Hypertension	5271 (24.3)	5287 (24.3)
Hypotension	22 (0.1)	11 (0.1)
Infarction	1 (0.0)	2 (0.0)
Intermittent claudication	7 (0.0)	3 (0.0)
Ischaemia	1 (0.0)	0
Kawasaki's disease	1 (0.0)	0
Lymphoedema	11 (0.1)	8 (0.0)
May-Thurner syndrome	2 (0.0)	2 (0.0)
Microangiopathy	1 (0.0)	0
Neovascularisation	1 (0.0)	0
Orthostatic hypertension	1 (0.0)	0
Orthostatic hypotension	2 (0.0)	5 (0.0)
Peripheral arterial occlusive disease	16 (0.1)	13 (0.1)
Peripheral artery aneurysm	2 (0.0)	5 (0.0)
Peripheral artery thrombosis	1 (0.0)	0
Peripheral vascular disorder	18 (0.1)	24 (0.1)
Peripheral venous disease	15 (0.1)	25 (0.1)
Phlebitis	4 (0.0)	0
Phlebosclerosis	1 (0.0)	0
Poor peripheral circulation	1 (0.0)	4 (0.0)
Post thrombotic syndrome	0	1 (0.0)
Prehypertension	2 (0.0)	5 (0.0)
Raynaud's phenomenon	27 (0.1)	40 (0.2)
Spider vein	1 (0.0)	0
Subclavian artery aneurysm	1 (0.0)	0
Subclavian artery occlusion	1 (0.0)	0
Subclavian artery thrombosis	0	1 (0.0)

14.294. Medical History – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21728) n[b] (%)
Subclavian vein thrombosis	1 (0.0)	1 (0.0)
Thrombophlebitis	1 (0.0)	4 (0.0)
Thrombosis	25 (0.1)	20 (0.1)
Varicose vein	72 (0.3)	85 (0.4)
Varicose vein ruptured	1 (0.0)	0
Vasculitis	1 (0.0)	0
Vena cava thrombosis	2 (0.0)	0
Venous haemorrhage	0	1 (0.0)
Venous thrombosis	4 (0.0)	1 (0.0)
Venous thrombosis limb	1 (0.0)	2 (0.0)
White coat hypertension	9 (0.0)	5 (0.0)

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:04) Source Data: admh Table Generation: 24NOV2020 (11:18)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 EUA FAEF RR/admh s002 all p3 saf

14.295. Baseline Charlson Comorbidities – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=21720)	Placebo (N[a]=21728)	Total (N[a]=43448)
Charlson Comorbidity Index Category	n[b] (%)	n[b] (%)	n[b] (%)
Subjects with any Charlson comorbidity	4559 (21.0)	4419 (20.3)	8978 (20.7)
AIDS/HIV	99 (0.5)	98 (0.5)	197 (0.5)
Any Malignancy	808 (3.7)	753 (3.5)	1561 (3.6)
Cerebrovascular Disease	227 (1.0)	194 (0.9)	421 (1.0)
Chronic Pulmonary Disease	1730 (8.0)	1713 (7.9)	3443 (7.9)
Congestive Heart Failure	108 (0.5)	97 (0.4)	205 (0.5)
Dementia	7 (0.0)	11 (0.1)	18 (0.0)
Diabetes With Chronic Complication	112 (0.5)	125 (0.6)	237 (0.5)
Diabetes Without Chronic Complication	1692 (7.8)	1676 (7.7)	3368 (7.8)
Hemiplegia or Paraplegia	15 (0.1)	22 (0.1)	37 (0.1)
Leukemia	14 (0.1)	10 (0.0)	24 (0.1)
Lymphoma	25 (0.1)	36 (0.2)	61 (0.1)
Metastatic Solid Tumor	4 (0.0)	3 (0.0)	7 (0.0)
Mild Liver Disease	145 (0.7)	112 (0.5)	257 (0.6)
Moderate or Severe Liver Disease	1 (0.0)	2 (0.0)	3 (0.0)
Myocardial Infarction	220 (1.0)	216 (1.0)	436 (1.0)
Peptic Ulcer Disease	62 (0.3)	81 (0.4)	143 (0.3)
Peripheral Vascular Disease	144 (0.7)	132 (0.6)	276 (0.6)
Renal Disease	139 (0.6)	145 (0.7)	284 (0.7)
Rheumatic Disease	75 (0.3)	65 (0.3)	140 (0.3)

Note: MedDRA (v23.1) coding dictionary applied.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (10:04) Source Data: admh Table Generation: 17NOV2020 (16:25)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/admh_s002_risk_all_p3_saf

14.296. Baseline Charlson Comorbidities, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=12780)	Placebo (N[a]=12822)	Total (N[a]=25602)
Charlson Comorbidity Index Category	n[b] (%)	n[b] (%)	n[b] (%)
Subjects with any Charlson comorbidity	1717 (13.4)	1662 (13.0)	3379 (13.2)
AIDS/HIV	74 (0.6)	67 (0.5)	141 (0.6)
Any Malignancy	139 (1.1)	127 (1.0)	266 (1.0)
Cerebrovascular Disease	48 (0.4)	40 (0.3)	88 (0.3)
Chronic Pulmonary Disease	939 (7.3)	909 (7.1)	1848 (7.2)
Congestive Heart Failure	23 (0.2)	22 (0.2)	45 (0.2)
Diabetes With Chronic Complication	19 (0.1)	17 (0.1)	36 (0.1)
Diabetes Without Chronic Complication	479 (3.7)	470 (3.7)	949 (3.7)
Hemiplegia or Paraplegia	3 (0.0)	13 (0.1)	16 (0.1)
Leukemia	5 (0.0)	3 (0.0)	8 (0.0)
Lymphoma	6 (0.0)	12 (0.1)	18 (0.1)
Metastatic Solid Tumor	1 (0.0)	0	1 (0.0)
Mild Liver Disease	58 (0.5)	54 (0.4)	112 (0.4)
Myocardial Infarction	33 (0.3)	28 (0.2)	61 (0.2)
Peptic Ulcer Disease	22 (0.2)	27 (0.2)	49 (0.2)
Peripheral Vascular Disease	8 (0.1)	11 (0.1)	19 (0.1)
Renal Disease	20 (0.2)	21 (0.2)	41 (0.2)
Rheumatic Disease	25 (0.2)	23 (0.2)	48 (0.2)

Note: MedDRA (v23.1) coding dictionary applied.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (10:04) Source Data: admh Table Generation: 17NOV2020 (16:25)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/admh_s002_risk_all_age_p3_saf

14.297. Baseline Charlson Comorbidities, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
Charlson Comorbidity Index Category	BNT162b2 (30 µg) (N[a]=8940) n[b] (%)	Placebo (N[a]=8906) n[b] (%)	Total (N[a]=17846) n[b] (%)
Subjects with any Charlson comorbidity	2842 (31.8)	2757 (31.0)	5599 (31.4)
AIDS/HIV	25 (0.3)	31 (0.3)	56 (0.3)
Any Malignancy	669 (7.5)	626 (7.0)	1295 (7.3)
Cerebrovascular Disease	179 (2.0)	154 (1.7)	333 (1.9)
Chronic Pulmonary Disease	791 (8.8)	804 (9.0)	1595 (8.9)
Congestive Heart Failure	85 (1.0)	75 (0.8)	160 (0.9)
Dementia	7 (0.1)	11 (0.1)	18 (0.1)
Diabetes With Chronic Complication	93 (1.0)	108 (1.2)	201 (1.1)
Diabetes Without Chronic Complication	1213 (13.6)	1206 (13.5)	2419 (13.6)
Hemiplegia or Paraplegia	12 (0.1)	9 (0.1)	21 (0.1)
Leukemia	9 (0.1)	7 (0.1)	16 (0.1)
Lymphoma	19 (0.2)	24 (0.3)	43 (0.2)
Metastatic Solid Tumor	3 (0.0)	3 (0.0)	6 (0.0)
Mild Liver Disease	87 (1.0)	58 (0.7)	145 (0.8)
Moderate or Severe Liver Disease	1 (0.0)	2 (0.0)	3 (0.0)
Myocardial Infarction	187 (2.1)	188 (2.1)	375 (2.1)
Peptic Ulcer Disease	40 (0.4)	54 (0.6)	94 (0.5)
Peripheral Vascular Disease	136 (1.5)	121 (1.4)	257 (1.4)
Renal Disease	119 (1.3)	124 (1.4)	243 (1.4)
Rheumatic Disease	50 (0.6)	42 (0.5)	92 (0.5)

Note: MedDRA (v23.1) coding dictionary applied.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (10:04) Source Data: admh Table Generation: 17NOV2020 (16:25)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/admh_s002_risk_all_age_p3_saf

14.298. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16463) n[b] (%)	Placebo (N[a]=16426) n[b] (%)	Total (N[a]=32889) n[b] (%)
Sex			
Male	8404 (51.0)	8256 (50.3)	16660 (50.7)
Female	8059 (49.0)	8170 (49.7)	16229 (49.3)
Race			
White	13877 (84.3)	13875 (84.5)	27752 (84.4)
Black or African American	1316 (8.0)	1311 (8.0)	2627 (8.0)
American Indian or Alaska native	88 (0.5)	83 (0.5)	171 (0.5)
Asian	719 (4.4)	726 (4.4)	1445 (4.4)
Native Hawaiian or other Pacific Islander	41 (0.2)	27 (0.2)	68 (0.2)
Multiracial	342 (2.1)	302 (1.8)	644 (2.0)
Not reported	80 (0.5)	102 (0.6)	182 (0.6)
Ethnicity			
Hispanic/Latino	4525 (27.5)	4479 (27.3)	9004 (27.4)
Non-Hispanic/non-Latino	11840 (71.9)	11848 (72.1)	23688 (72.0)
Not reported	98 (0.6)	99 (0.6)	197 (0.6)
Country			
Argentina	2525 (15.3)	2491 (15.2)	5016 (15.3)
Brazil	889 (5.4)	891 (5.4)	1780 (5.4)
South Africa	216 (1.3)	218 (1.3)	434 (1.3)
USA	12833 (78.0)	12826 (78.1)	25659 (78.0)
Age group			
16-55 Years	9318 (56.6)	9290 (56.6)	18608 (56.6)
>55 Years	7145 (43.4)	7136 (43.4)	14281 (43.4)
Age at vaccination (years)			
Mean (SD)	50.9 (15.59)	50.7 (15.68)	50.8 (15.64)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 91)	(16, 91)

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 06NOV2020 (01:29) Source Data: adsl Table Generation: 06NOV2020 (16:35)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File:
./nda2 unblinded ia/C4591001 IA 62/adsl demo 7d d2 aai

14.299. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18701) n[b] (%)	Placebo (N[a]=18627) n[b] (%)	Total (N[a]=37328) n[b] (%)
Sex			
Male	9557 (51.1)	9359 (50.2)	18916 (50.7)
Female	9144 (48.9)	9268 (49.8)	18412 (49.3)
Race			
White	15531 (83.0)	15521 (83.3)	31052 (83.2)
Black or African American	1645 (8.8)	1627 (8.7)	3272 (8.8)
American Indian or Alaska native	118 (0.6)	108 (0.6)	226 (0.6)
Asian	823 (4.4)	820 (4.4)	1643 (4.4)
Native Hawaiian or other Pacific Islander	49 (0.3)	30 (0.2)	79 (0.2)
Multiracial	449 (2.4)	407 (2.2)	856 (2.3)
Not reported	86 (0.5)	114 (0.6)	200 (0.5)
Ethnicity			
Hispanic/Latino	5005 (26.8)	4963 (26.6)	9968 (26.7)
Non-Hispanic/non-Latino	13588 (72.7)	13554 (72.8)	27142 (72.7)
Not reported	108 (0.6)	110 (0.6)	218 (0.6)
Country			
Argentina	2644 (14.1)	2618 (14.1)	5262 (14.1)
Brazil	1234 (6.6)	1226 (6.6)	2460 (6.6)
Germany	127 (0.7)	131 (0.7)	258 (0.7)
South Africa	288 (1.5)	279 (1.5)	567 (1.5)
USA	14408 (77.0)	14373 (77.2)	28781 (77.1)
Age group			
12-15 Years	46 (0.2)	42 (0.2)	88 (0.2)
16-55 Years	10689 (57.2)	10647 (57.2)	21336 (57.2)
>55 Years	7966 (42.6)	7938 (42.6)	15904 (42.6)
≥65 Years	4101 (21.9)	4096 (22.0)	8197 (22.0)
Age at vaccination (years)			
Mean (SD)	50.6 (15.72)	50.4 (15.81)	50.5 (15.76)
Median	52.0	52.0	52.0
Min, max	(12, 89)	(12, 91)	(12, 91)

14.299. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=18701) n^b (%)	Placebo (N^a=18627) n^b (%)	Total (N^a=37328) n^b (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo 7d d2 aai

14.300. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18219) n[b] (%)	Placebo (N[a]=18315) n[b] (%)	Total (N[a]=36534) n[b] (%)
Sex			
Male	9306 (51.1)	9194 (50.2)	18500 (50.6)
Female	8913 (48.9)	9121 (49.8)	18034 (49.4)
Race			
White	15092 (82.8)	15245 (83.2)	30337 (83.0)
Black or African American	1614 (8.9)	1613 (8.8)	3227 (8.8)
American Indian or Alaska native	118 (0.6)	105 (0.6)	223 (0.6)
Asian	813 (4.5)	809 (4.4)	1622 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)	77 (0.2)
Multiracial	448 (2.5)	402 (2.2)	850 (2.3)
Not reported	86 (0.5)	112 (0.6)	198 (0.5)
Ethnicity			
Hispanic/Latino	4883 (26.8)	4838 (26.4)	9721 (26.6)
Non-Hispanic/non-Latino	13234 (72.6)	13367 (73.0)	26601 (72.8)
Not reported	102 (0.6)	110 (0.6)	212 (0.6)
Country			
Argentina	2560 (14.1)	2526 (13.8)	5086 (13.9)
Brazil	1231 (6.8)	1219 (6.7)	2450 (6.7)
Germany	121 (0.7)	125 (0.7)	246 (0.7)
South Africa	287 (1.6)	279 (1.5)	566 (1.5)
USA	14020 (77.0)	14166 (77.3)	28186 (77.2)
Age group			
12-15 Years	46 (0.3)	42 (0.2)	88 (0.2)
16-55 Years	10416 (57.2)	10464 (57.1)	20880 (57.2)
>55 Years	7757 (42.6)	7809 (42.6)	15566 (42.6)
≥65 Years	3971 (21.8)	4027 (22.0)	7998 (21.9)
Age at vaccination (years)			
Mean (SD)	50.6 (15.70)	50.4 (15.81)	50.5 (15.76)
Median	52.0	52.0	52.0
Min, max	(12, 89)	(12, 91)	(12, 91)

14.300. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=18219) n^b (%)	Placebo (N^a=18315) n^b (%)	Total (N^a=36534) n^b (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo 14d eval eff

14.301. Demographic Characteristics – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21768) n[b] (%)	Placebo (N[a]=21783) n[b] (%)	Total (N[a]=43551) n[b] (%)
Sex			
Male	11215 (51.5)	10969 (50.4)	22184 (50.9)
Female	10553 (48.5)	10814 (49.6)	21367 (49.1)
Race			
White	17876 (82.1)	17898 (82.2)	35774 (82.1)
Black or African American	2100 (9.6)	2116 (9.7)	4216 (9.7)
American Indian or Alaska native	160 (0.7)	159 (0.7)	319 (0.7)
Asian	935 (4.3)	933 (4.3)	1868 (4.3)
Native Hawaiian or other Pacific Islander	56 (0.3)	32 (0.1)	88 (0.2)
Multiracial	538 (2.5)	514 (2.4)	1052 (2.4)
Not reported	103 (0.5)	131 (0.6)	234 (0.5)
Ethnicity			
Hispanic/Latino	5680 (26.1)	5673 (26.0)	11353 (26.1)
Non-Hispanic/non-Latino	15967 (73.4)	15990 (73.4)	31957 (73.4)
Not reported	121 (0.6)	120 (0.6)	241 (0.6)
Country			
Argentina	2882 (13.2)	2882 (13.2)	5764 (13.2)
Brazil	1452 (6.7)	1448 (6.6)	2900 (6.7)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	16535 (76.0)	16555 (76.0)	33090 (76.0)
Age group			
12-15 Years	49 (0.2)	51 (0.2)	100 (0.2)
16-55 Years	12781 (58.7)	12822 (58.9)	25603 (58.8)
>55 Years	8938 (41.1)	8910 (40.9)	17848 (41.0)
≥65 Years	4545 (20.9)	4539 (20.8)	9084 (20.9)
Age at vaccination (years)			
Mean (SD)	50.0 (15.76)	49.8 (15.86)	49.9 (15.81)
Median	51.0	51.0	51.0
Min, max	(12, 89)	(12, 91)	(12, 91)

14.301. Demographic Characteristics – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21768) n[b] (%)	Placebo (N[a]=21783) n[b] (%)	Total (N[a]=43551) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo d1 aai

14.302. Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20033) n[b] (%)	Placebo (N[a]=20244) n[b] (%)	Total (N[a]=40277) n[b] (%)
Sex			
Male	10239 (51.1)	10137 (50.1)	20376 (50.6)
Female	9794 (48.9)	10107 (49.9)	19901 (49.4)
Race			
White	16387 (81.8)	16619 (82.1)	33006 (81.9)
Black or African American	1957 (9.8)	1972 (9.7)	3929 (9.8)
American Indian or Alaska native	131 (0.7)	122 (0.6)	253 (0.6)
Asian	880 (4.4)	883 (4.4)	1763 (4.4)
Native Hawaiian or other Pacific Islander	54 (0.3)	29 (0.1)	83 (0.2)
Multiracial	523 (2.6)	493 (2.4)	1016 (2.5)
Not reported	101 (0.5)	126 (0.6)	227 (0.6)
Ethnicity			
Hispanic/Latino	5272 (26.3)	5281 (26.1)	10553 (26.2)
Non-Hispanic/non-Latino	14652 (73.1)	14847 (73.3)	29499 (73.2)
Not reported	109 (0.5)	116 (0.6)	225 (0.6)
Country			
Argentina	2686 (13.4)	2711 (13.4)	5397 (13.4)
Brazil	1430 (7.1)	1425 (7.0)	2855 (7.1)
Germany	198 (1.0)	201 (1.0)	399 (1.0)
South Africa	390 (1.9)	393 (1.9)	783 (1.9)
Turkey	31 (0.2)	26 (0.1)	57 (0.1)
USA	15298 (76.4)	15488 (76.5)	30786 (76.4)
Age group			
12-15 Years	48 (0.2)	47 (0.2)	95 (0.2)
16-55 Years	11589 (57.8)	11743 (58.0)	23332 (57.9)
>55 Years	8396 (41.9)	8454 (41.8)	16850 (41.8)
≥65 Years	4294 (21.4)	4319 (21.3)	8613 (21.4)
Age at vaccination (years)			
Mean (SD)	50.3 (15.73)	50.1 (15.78)	50.2 (15.76)
Median	51.0	51.0	51.0
Min, max	(12, 89)	(12, 91)	(12, 91)

14.302. Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20033) n[b] (%)	Placebo (N[a]=20244) n[b] (%)	Total (N[a]=40277) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo 7d wwo eval eff

14.303. Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20566) n[b] (%)	Placebo (N[a]=20536) n[b] (%)	Total (N[a]=41102) n[b] (%)
Sex			
Male	10527 (51.2)	10293 (50.1)	20820 (50.7)
Female	10039 (48.8)	10243 (49.9)	20282 (49.3)
Race			
White	16874 (82.0)	16880 (82.2)	33754 (82.1)
Black or African American	1987 (9.7)	1985 (9.7)	3972 (9.7)
American Indian or Alaska native	131 (0.6)	124 (0.6)	255 (0.6)
Asian	894 (4.3)	893 (4.3)	1787 (4.3)
Native Hawaiian or other Pacific Islander	55 (0.3)	30 (0.1)	85 (0.2)
Multiracial	524 (2.5)	498 (2.4)	1022 (2.5)
Not reported	101 (0.5)	126 (0.6)	227 (0.6)
Ethnicity			
Hispanic/Latino	5420 (26.4)	5411 (26.3)	10831 (26.4)
Non-Hispanic/non-Latino	15032 (73.1)	15009 (73.1)	30041 (73.1)
Not reported	114 (0.6)	116 (0.6)	230 (0.6)
Country			
Argentina	2793 (13.6)	2806 (13.7)	5599 (13.6)
Brazil	1434 (7.0)	1428 (7.0)	2862 (7.0)
Germany	204 (1.0)	206 (1.0)	410 (1.0)
South Africa	392 (1.9)	394 (1.9)	786 (1.9)
Turkey	33 (0.2)	26 (0.1)	59 (0.1)
USA	15710 (76.4)	15676 (76.3)	31386 (76.4)
Age group			
12-15 Years	48 (0.2)	47 (0.2)	95 (0.2)
16-55 Years	11899 (57.9)	11914 (58.0)	23813 (57.9)
>55 Years	8619 (41.9)	8575 (41.8)	17194 (41.8)
≥65 Years	4425 (21.5)	4383 (21.3)	8808 (21.4)
Age at vaccination (years)			
Mean (SD)	50.3 (15.74)	50.1 (15.77)	50.2 (15.76)
Median	51.0	51.0	51.0
Min, max	(12, 89)	(12, 91)	(12, 91)

14.303. Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20566) n[b] (%)	Placebo (N[a]=20536) n[b] (%)	Total (N[a]=41102) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo 7d wwo d2 aai

14.304. Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20033) n[b] (%)	Placebo (N[a]=20243) n[b] (%)	Total (N[a]=40276) n[b] (%)
Sex			
Male	10239 (51.1)	10136 (50.1)	20375 (50.6)
Female	9794 (48.9)	10107 (49.9)	19901 (49.4)
Race			
White	16387 (81.8)	16618 (82.1)	33005 (81.9)
Black or African American	1957 (9.8)	1972 (9.7)	3929 (9.8)
American Indian or Alaska native	131 (0.7)	122 (0.6)	253 (0.6)
Asian	880 (4.4)	883 (4.4)	1763 (4.4)
Native Hawaiian or other Pacific Islander	54 (0.3)	29 (0.1)	83 (0.2)
Multiracial	523 (2.6)	493 (2.4)	1016 (2.5)
Not reported	101 (0.5)	126 (0.6)	227 (0.6)
Ethnicity			
Hispanic/Latino	5272 (26.3)	5281 (26.1)	10553 (26.2)
Non-Hispanic/non-Latino	14652 (73.1)	14846 (73.3)	29498 (73.2)
Not reported	109 (0.5)	116 (0.6)	225 (0.6)
Country			
Argentina	2686 (13.4)	2711 (13.4)	5397 (13.4)
Brazil	1430 (7.1)	1425 (7.0)	2855 (7.1)
Germany	198 (1.0)	201 (1.0)	399 (1.0)
South Africa	390 (1.9)	393 (1.9)	783 (1.9)
Turkey	31 (0.2)	26 (0.1)	57 (0.1)
USA	15298 (76.4)	15487 (76.5)	30785 (76.4)
Age group			
12-15 Years	48 (0.2)	47 (0.2)	95 (0.2)
16-55 Years	11589 (57.8)	11742 (58.0)	23331 (57.9)
>55 Years	8396 (41.9)	8454 (41.8)	16850 (41.8)
≥65 Years	4294 (21.4)	4319 (21.3)	8613 (21.4)
Age at vaccination (years)			
Mean (SD)	50.3 (15.73)	50.1 (15.78)	50.2 (15.76)
Median	51.0	51.0	51.0
Min, max	(12, 89)	(12, 91)	(12, 91)

14.304. Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20033) n[b] (%)	Placebo (N[a]=20243) n[b] (%)	Total (N[a]=40276) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo 14d wwo eval eff

14.305. E-Diary Transmission – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)
Vaccinated at Dose 1[b]	4176	4184
E-diary		
Not transmitted[c]	50 (1.2)	61 (1.5)
Transmitted[d]		
Day 1	3909 (93.6)	3869 (92.5)
Day 2	3924 (94.0)	3886 (92.9)
Day 3	3833 (91.8)	3878 (92.7)
Day 4	3810 (91.2)	3821 (91.3)
Day 5	3762 (90.1)	3817 (91.2)
Day 6	3792 (90.8)	3758 (89.8)
Day 7	3779 (90.5)	3794 (90.7)
All 7 days[e]	2868 (68.7)	2872 (68.6)
Vaccinated at Dose 2[b]	4105	4098
E-diary		
Not transmitted[c]	321 (7.8)	315 (7.7)
Transmitted[d]		
Day 1	3119 (76.0)	2995 (73.1)
Day 2	3492 (85.1)	3284 (80.1)
Day 3	3467 (84.5)	3345 (81.6)
Day 4	3418 (83.3)	3378 (82.4)
Day 5	3449 (84.0)	3412 (83.3)
Day 6	3440 (83.8)	3405 (83.1)
Day 7	3424 (83.4)	3428 (83.7)
All 7 days[e]	2245 (54.7)	2058 (50.2)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 to Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 to Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 18NOV2020 (09:12)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s200 trns p3 saf

14.306. Concomitant Vaccines Received After Dose 1 – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=18801) n[c] (%)	Placebo (N[a]=18785) n[c] (%)
Any concomitant vaccine	1852 (9.9)	2017 (10.7)
ANTHRAX VACCINE	0	1 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	2 (0.0)	1 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID	2 (0.0)	3 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	10 (0.1)	13 (0.1)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	3 (0.0)	0
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	1 (0.0)	1 (0.0)
DIPHTHERIA VACCINE;TETANUS VACCINE	1 (0.0)	0
HEPATITIS A VACCINE	5 (0.0)	1 (0.0)
HEPATITIS B VACCINE	6 (0.0)	6 (0.0)
HEPATITIS B VACCINE RHBSAG (YEAST)	1 (0.0)	0
HEPATITIS VACCINES	1 (0.0)	0
HPV VACCINE	2 (0.0)	0
HPV VACCINE VLP RL1 2V (BACULOVIRUS)	0	1 (0.0)
HPV VACCINE VLP RL1 4V (YEAST)	0	1 (0.0)
INFLUENZA VACCINE	1508 (8.0)	1675 (8.9)
INFLUENZA VACCINE INACT SAG 3V	19 (0.1)	17 (0.1)
INFLUENZA VACCINE INACT SAG 4V	31 (0.2)	32 (0.2)
INFLUENZA VACCINE INACT SPLIT 3V	70 (0.4)	67 (0.4)
INFLUENZA VACCINE INACT SPLIT 4V	176 (0.9)	175 (0.9)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	3 (0.0)	2 (0.0)
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	17 (0.1)	10 (0.1)
INFLUENZA VACCINES	0	1 (0.0)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	3 (0.0)	2 (0.0)
PNEUMOCOCCAL VACCINE	8 (0.0)	24 (0.1)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	2 (0.0)	4 (0.0)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	0	1 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH	2 (0.0)	2 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	3 (0.0)	0
PNEUMOCOCCAL VACCINE POLYV	1 (0.0)	0
RABIES VACCINE	0	1 (0.0)
RUBELLA VACCINE	0	1 (0.0)
TETANUS VACCINE	14 (0.1)	12 (0.1)

14.306. Concomitant Vaccines Received After Dose 1 – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=18801) n[c] (%)	Placebo (N[a]=18785) n[c] (%)
TETANUS VACCINE TOXOID	2 (0.0)	2 (0.0)
VARICELLA ZOSTER VACCINE	23 (0.1)	21 (0.1)
VARICELLA ZOSTER VACCINE RGE (CHO)	15 (0.1)	30 (0.2)

Note: WHO DDE v202003 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:50) Source Data: adcm Table Generation: 25NOV2020 (04:25)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adcm_s001_vax_p3_saf

14.307. Concomitant Vaccines Received After Dose 1 – Phase 2/3 (All Subjects) – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=21621) n[c] (%)	Placebo (N[a]=21631) n[c] (%)
Any concomitant vaccine	1855 (8.6)	2022 (9.3)
ANTHRAX VACCINE	0	1 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	2 (0.0)	1 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID	2 (0.0)	3 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	10 (0.0)	13 (0.1)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	3 (0.0)	0
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	1 (0.0)	1 (0.0)
DIPHTHERIA VACCINE;TETANUS VACCINE	1 (0.0)	0
HEPATITIS A VACCINE	5 (0.0)	1 (0.0)
HEPATITIS B VACCINE	6 (0.0)	6 (0.0)
HEPATITIS B VACCINE RHBSAG (YEAST)	1 (0.0)	0
HEPATITIS VACCINES	1 (0.0)	0
HPV VACCINE	2 (0.0)	0
HPV VACCINE VLP RL1 2V (BACULOVIRUS)	0	1 (0.0)
HPV VACCINE VLP RL1 4V (YEAST)	0	1 (0.0)
INFLUENZA VACCINE	1510 (7.0)	1679 (7.8)
INFLUENZA VACCINE INACT SAG 3V	19 (0.1)	17 (0.1)
INFLUENZA VACCINE INACT SAG 4V	31 (0.1)	32 (0.1)
INFLUENZA VACCINE INACT SPLIT 3V	70 (0.3)	67 (0.3)
INFLUENZA VACCINE INACT SPLIT 4V	176 (0.8)	175 (0.8)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	3 (0.0)	2 (0.0)
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	17 (0.1)	10 (0.0)
INFLUENZA VACCINES	0	1 (0.0)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	3 (0.0)	2 (0.0)
PNEUMOCOCCAL VACCINE	8 (0.0)	25 (0.1)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	2 (0.0)	4 (0.0)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	0	1 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH	2 (0.0)	2 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	3 (0.0)	0
PNEUMOCOCCAL VACCINE POLYV	1 (0.0)	0
RABIES VACCINE	0	1 (0.0)
RUBELLA VACCINE	0	1 (0.0)
TETANUS VACCINE	14 (0.1)	12 (0.1)

14.307. Concomitant Vaccines Received After Dose 1 – Phase 2/3 (All Subjects) – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=21621) n[c] (%)	Placebo (N[a]=21631) n[c] (%)
TETANUS VACCINE TOXOID	2 (0.0)	2 (0.0)
VARICELLA ZOSTER VACCINE	24 (0.1)	21 (0.1)
VARICELLA ZOSTER VACCINE RGE (CHO)	15 (0.1)	30 (0.1)

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
Note: WHO DDE v202003 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:50) Source Data: adcm Table Generation: 25NOV2020 (04:23)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 EUA FAEF RR/adcm s001 vax all p3 saf

Efficacy

14.308. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=16463)		Placebo (N[a]=16426)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	4	1.761 (16298)	93	1.748 (16213)	95.7	(89.3, 98.5)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
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. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details. This probability must be at least 99.5% at the interim analysis in order to conclude that the vaccine is efficacious.
PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:48) Source Data: adc19ef Table Generation: 09NOV2020 (16:43)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File:
./nda2 unblinded ia/C4591001 IA 62/adc19ef ve cov 7pd2 wo aai

14.309. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16463)		Placebo (N[a]=16426)			
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	4	1.761 (16298)	93	1.748 (16213)	95.7	(88.7, 98.9)
Age group (years)						
16 to 55	2	0.975 (9217)	70	0.968 (9156)	97.2	(89.4, 99.7)
>55	2	0.785 (7081)	23	0.780 (7057)	91.4	(65.0, 99.0)
Sex						
Male	2	0.893 (8320)	41	0.874 (8138)	95.2	(81.6, 99.4)
Female	2	0.867 (7978)	52	0.874 (8075)	96.1	(85.3, 99.5)
Race						
White	4	1.513 (13771)	88	1.505 (13708)	95.5	(88.0, 98.8)
Black or African American	0	0.125 (1281)	4	0.125 (1285)	100.0	(-50.8, 100.0)
All others[f]	0	0.122 (1246)	1	0.119 (1220)	100.0	(-3708.9, 100.0)
Ethnicity						
Hispanic/Latino	1	0.471 (4499)	35	0.464 (4437)	97.2	(83.3, 99.9)
Non-Hispanic/non-Latino	3	1.279 (11702)	58	1.274 (11678)	94.8	(84.2, 99.0)
Country						
Argentina	0	0.275 (2516)	29	0.269 (2477)	100.0	(86.7, 100.0)
Brazil	0	0.087 (878)	2	0.087 (881)	100.0	(-433.0, 100.0)
USA	4	1.395 (12702)	62	1.389 (12656)	93.6	(82.7, 98.3)

14.309. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16463)		Placebo (N[a]=16426)			
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 at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
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 to the surveillance time.
f. American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, not reported race categories are presented as “All others”.
PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:53) Source Data: adc19ef Table Generation: 09NOV2020 (16:43)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File:
./nda2 unblinded ia/C4591001 IA 62/adc19ef ve cov 7pd2 wo sg aai

14.310. Summary of Signs and Symptoms for Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=3)	Total (N[a]=4)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	3 (100.0)	4 (100.0)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	1 (33.3)	1 (25.0)
Admission to an ICU	0 (0.0)	1 (33.3)	1 (25.0)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	2 (66.7)	3 (75.0)
3	0 (0.0)	1 (33.3)	1 (25.0)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate; ICU = intensive care unit; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.
a. N = number of subjects with severe COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:49)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_sev_cov_7d2_eval

14.311. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Evaluable Efficacy (7 Days) Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5)	Placebo (N[a]=114)	Total (N[a]=119)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	52 (45.6)	52 (43.7)
New or increased cough	3 (60.0)	76 (66.7)	79 (66.4)
New or increased shortness of breath	0 (0.0)	19 (16.7)	19 (16.0)
Chills	1 (20.0)	37 (32.5)	38 (31.9)
New or increased muscle pain	0 (0.0)	61 (53.5)	61 (51.3)
New loss of taste or smell	4 (80.0)	36 (31.6)	40 (33.6)
Sore throat	3 (60.0)	53 (46.5)	56 (47.1)
Diarrhea	0 (0.0)	15 (13.2)	15 (12.6)
Vomiting	0 (0.0)	6 (5.3)	6 (5.0)
Subjects with specific number of signs and symptoms			
1	1 (20.0)	13 (11.4)	14 (11.8)
2	2 (40.0)	33 (28.9)	35 (29.4)
3	2 (40.0)	27 (23.7)	29 (24.4)
4	0 (0.0)	22 (19.3)	22 (18.5)
5	0 (0.0)	11 (9.6)	11 (9.2)
>5	0 (0.0)	8 (7.0)	8 (6.7)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_7d2_wo_age_eval

14.312. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Evaluable Efficacy (7 Days) Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=48)	Total (N[a]=51)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	24 (50.0)	26 (51.0)
New or increased cough	0 (0.0)	38 (79.2)	38 (74.5)
New or increased shortness of breath	0 (0.0)	6 (12.5)	6 (11.8)
Chills	1 (33.3)	20 (41.7)	21 (41.2)
New or increased muscle pain	1 (33.3)	20 (41.7)	21 (41.2)
New loss of taste or smell	1 (33.3)	7 (14.6)	8 (15.7)
Sore throat	0 (0.0)	15 (31.3)	15 (29.4)
Diarrhea	1 (33.3)	3 (6.3)	4 (7.8)
Vomiting	2 (66.7)	0 (0.0)	2 (3.9)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	11 (22.9)	11 (21.6)
2	1 (33.3)	13 (27.1)	14 (27.5)
3	2 (66.7)	7 (14.6)	9 (17.6)
4	0 (0.0)	11 (22.9)	11 (21.6)
5	0 (0.0)	5 (10.4)	5 (9.8)
>5	0 (0.0)	1 (2.1)	1 (2.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 wo age eval

14.313. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Evaluable Efficacy (7 Days) Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=19)	Total (N[a]=20)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	6 (31.6)	7 (35.0)
New or increased cough	0 (0.0)	15 (78.9)	15 (75.0)
New or increased shortness of breath	0 (0.0)	1 (5.3)	1 (5.0)
Chills	1 (100.0)	6 (31.6)	7 (35.0)
New or increased muscle pain	0 (0.0)	4 (21.1)	4 (20.0)
Sore throat	0 (0.0)	6 (31.6)	6 (30.0)
Vomiting	1 (100.0)	0 (0.0)	1 (5.0)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	7 (36.8)	7 (35.0)
2	0 (0.0)	7 (36.8)	7 (35.0)
3	1 (100.0)	3 (15.8)	4 (20.0)
4	0 (0.0)	2 (10.5)	2 (10.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_7d2_wo_age_eval

14.314. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=165)	Total (N[a]=173)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	78 (47.3)	80 (46.2)
New or increased cough	3 (37.5)	114 (69.1)	117 (67.6)
New or increased shortness of breath	0 (0.0)	25 (15.2)	25 (14.5)
Chills	2 (25.0)	58 (35.2)	60 (34.7)
New or increased muscle pain	1 (12.5)	82 (49.7)	83 (48.0)
New loss of taste or smell	5 (62.5)	44 (26.7)	49 (28.3)
Sore throat	3 (37.5)	70 (42.4)	73 (42.2)
Diarrhea	1 (12.5)	19 (11.5)	20 (11.6)
Vomiting	2 (25.0)	6 (3.6)	8 (4.6)
Subjects with specific number of signs and symptoms			
1	1 (12.5)	24 (14.5)	25 (14.5)
2	3 (37.5)	47 (28.5)	50 (28.9)
3	4 (50.0)	36 (21.8)	40 (23.1)
4	0 (0.0)	33 (20.0)	33 (19.1)
5	0 (0.0)	16 (9.7)	16 (9.2)
>5	0 (0.0)	9 (5.5)	9 (5.2)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_7d2_wo_aai

14.315. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5)	Placebo (N[a]=117)	Total (N[a]=122)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	54 (46.2)	54 (44.3)
New or increased cough	3 (60.0)	76 (65.0)	79 (64.8)
New or increased shortness of breath	0 (0.0)	19 (16.2)	19 (15.6)
Chills	1 (20.0)	38 (32.5)	39 (32.0)
New or increased muscle pain	0 (0.0)	62 (53.0)	62 (50.8)
New loss of taste or smell	4 (80.0)	37 (31.6)	41 (33.6)
Sore throat	3 (60.0)	55 (47.0)	58 (47.5)
Diarrhea	0 (0.0)	16 (13.7)	16 (13.1)
Vomiting	0 (0.0)	6 (5.1)	6 (4.9)
Subjects with specific number of signs and symptoms			
1	1 (20.0)	13 (11.1)	14 (11.5)
2	2 (40.0)	34 (29.1)	36 (29.5)
3	2 (40.0)	29 (24.8)	31 (25.4)
4	0 (0.0)	22 (18.8)	22 (18.0)
5	0 (0.0)	11 (9.4)	11 (9.0)
>5	0 (0.0)	8 (6.8)	8 (6.6)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_7d2_wo_age_aai

14.316. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=48)	Total (N[a]=51)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	24 (50.0)	26 (51.0)
New or increased cough	0 (0.0)	38 (79.2)	38 (74.5)
New or increased shortness of breath	0 (0.0)	6 (12.5)	6 (11.8)
Chills	1 (33.3)	20 (41.7)	21 (41.2)
New or increased muscle pain	1 (33.3)	20 (41.7)	21 (41.2)
New loss of taste or smell	1 (33.3)	7 (14.6)	8 (15.7)
Sore throat	0 (0.0)	15 (31.3)	15 (29.4)
Diarrhea	1 (33.3)	3 (6.3)	4 (7.8)
Vomiting	2 (66.7)	0 (0.0)	2 (3.9)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	11 (22.9)	11 (21.6)
2	1 (33.3)	13 (27.1)	14 (27.5)
3	2 (66.7)	7 (14.6)	9 (17.6)
4	0 (0.0)	11 (22.9)	11 (21.6)
5	0 (0.0)	5 (10.4)	5 (9.8)
>5	0 (0.0)	1 (2.1)	1 (2.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 wo age aai

14.317. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=19)	Total (N[a]=20)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	6 (31.6)	7 (35.0)
New or increased cough	0 (0.0)	15 (78.9)	15 (75.0)
New or increased shortness of breath	0 (0.0)	1 (5.3)	1 (5.0)
Chills	1 (100.0)	6 (31.6)	7 (35.0)
New or increased muscle pain	0 (0.0)	4 (21.1)	4 (20.0)
Sore throat	0 (0.0)	6 (31.6)	6 (30.0)
Vomiting	1 (100.0)	0 (0.0)	1 (5.0)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	7 (36.8)	7 (35.0)
2	0 (0.0)	7 (36.8)	7 (35.0)
3	1 (100.0)	3 (15.8)	4 (20.0)
4	0 (0.0)	2 (10.5)	2 (10.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_7d2_wo_age_aai

14.318. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Evaluable Efficacy (7 Days) Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=6)	Placebo (N[a]=120)	Total (N[a]=126)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	53 (44.2)	53 (42.1)
New or increased cough	3 (50.0)	81 (67.5)	84 (66.7)
New or increased shortness of breath	0 (0.0)	20 (16.7)	20 (15.9)
Chills	1 (16.7)	38 (31.7)	39 (31.0)
New or increased muscle pain	0 (0.0)	62 (51.7)	62 (49.2)
New loss of taste or smell	4 (66.7)	39 (32.5)	43 (34.1)
Sore throat	4 (66.7)	55 (45.8)	59 (46.8)
Diarrhea	0 (0.0)	16 (13.3)	16 (12.7)
Vomiting	0 (0.0)	6 (5.0)	6 (4.8)
Subjects with specific number of signs and symptoms			
1	2 (33.3)	13 (10.8)	15 (11.9)
2	2 (33.3)	36 (30.0)	38 (30.2)
3	2 (33.3)	30 (25.0)	32 (25.4)
4	0 (0.0)	22 (18.3)	22 (17.5)
5	0 (0.0)	11 (9.2)	11 (8.7)
>5	0 (0.0)	8 (6.7)	8 (6.3)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 age eval

14.319. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Evaluable Efficacy (7 Days) Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=49)	Total (N[a]=52)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	24 (49.0)	26 (50.0)
New or increased cough	0 (0.0)	39 (79.6)	39 (75.0)
New or increased shortness of breath	0 (0.0)	6 (12.2)	6 (11.5)
Chills	1 (33.3)	20 (40.8)	21 (40.4)
New or increased muscle pain	1 (33.3)	20 (40.8)	21 (40.4)
New loss of taste or smell	1 (33.3)	7 (14.3)	8 (15.4)
Sore throat	0 (0.0)	16 (32.7)	16 (30.8)
Diarrhea	1 (33.3)	3 (6.1)	4 (7.7)
Vomiting	2 (66.7)	0 (0.0)	2 (3.8)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	11 (22.4)	11 (21.2)
2	1 (33.3)	14 (28.6)	15 (28.8)
3	2 (66.7)	7 (14.3)	9 (17.3)
4	0 (0.0)	11 (22.4)	11 (21.2)
5	0 (0.0)	5 (10.2)	5 (9.6)
>5	0 (0.0)	1 (2.0)	1 (1.9)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 age eval

14.320. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Evaluable Efficacy (7 Days) Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=19)	Total (N[a]=20)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	6 (31.6)	7 (35.0)
New or increased cough	0 (0.0)	15 (78.9)	15 (75.0)
New or increased shortness of breath	0 (0.0)	1 (5.3)	1 (5.0)
Chills	1 (100.0)	6 (31.6)	7 (35.0)
New or increased muscle pain	0 (0.0)	4 (21.1)	4 (20.0)
Sore throat	0 (0.0)	6 (31.6)	6 (30.0)
Vomiting	1 (100.0)	0 (0.0)	1 (5.0)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	7 (36.8)	7 (35.0)
2	0 (0.0)	7 (36.8)	7 (35.0)
3	1 (100.0)	3 (15.8)	4 (20.0)
4	0 (0.0)	2 (10.5)	2 (10.0)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 age eval

14.321. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=9)	Placebo (N[a]=172)	Total (N[a]=181)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (22.2)	79 (45.9)	81 (44.8)
New or increased cough	3 (33.3)	120 (69.8)	123 (68.0)
New or increased shortness of breath	0 (0.0)	26 (15.1)	26 (14.4)
Chills	2 (22.2)	59 (34.3)	61 (33.7)
New or increased muscle pain	1 (11.1)	83 (48.3)	84 (46.4)
New loss of taste or smell	5 (55.6)	47 (27.3)	52 (28.7)
Sore throat	4 (44.4)	73 (42.4)	77 (42.5)
Diarrhea	1 (11.1)	20 (11.6)	21 (11.6)
Vomiting	2 (22.2)	6 (3.5)	8 (4.4)
Subjects with specific number of signs and symptoms			
1	2 (22.2)	24 (14.0)	26 (14.4)
2	3 (33.3)	51 (29.7)	54 (29.8)
3	4 (44.4)	39 (22.7)	43 (23.8)
4	0 (0.0)	33 (19.2)	33 (18.2)
5	0 (0.0)	16 (9.3)	16 (8.8)
>5	0 (0.0)	9 (5.2)	9 (5.0)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 aai

14.322. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=6)	Placebo (N[a]=123)	Total (N[a]=129)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	55 (44.7)	55 (42.6)
New or increased cough	3 (50.0)	81 (65.9)	84 (65.1)
New or increased shortness of breath	0 (0.0)	20 (16.3)	20 (15.5)
Chills	1 (16.7)	39 (31.7)	40 (31.0)
New or increased muscle pain	0 (0.0)	63 (51.2)	63 (48.8)
New loss of taste or smell	4 (66.7)	40 (32.5)	44 (34.1)
Sore throat	4 (66.7)	57 (46.3)	61 (47.3)
Diarrhea	0 (0.0)	17 (13.8)	17 (13.2)
Vomiting	0 (0.0)	6 (4.9)	6 (4.7)
Subjects with specific number of signs and symptoms			
1	2 (33.3)	13 (10.6)	15 (11.6)
2	2 (33.3)	37 (30.1)	39 (30.2)
3	2 (33.3)	32 (26.0)	34 (26.4)
4	0 (0.0)	22 (17.9)	22 (17.1)
5	0 (0.0)	11 (8.9)	11 (8.5)
>5	0 (0.0)	8 (6.5)	8 (6.2)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 age aai

14.323. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=49)	Total (N[a]=52)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	24 (49.0)	26 (50.0)
New or increased cough	0 (0.0)	39 (79.6)	39 (75.0)
New or increased shortness of breath	0 (0.0)	6 (12.2)	6 (11.5)
Chills	1 (33.3)	20 (40.8)	21 (40.4)
New or increased muscle pain	1 (33.3)	20 (40.8)	21 (40.4)
New loss of taste or smell	1 (33.3)	7 (14.3)	8 (15.4)
Sore throat	0 (0.0)	16 (32.7)	16 (30.8)
Diarrhea	1 (33.3)	3 (6.1)	4 (7.7)
Vomiting	2 (66.7)	0 (0.0)	2 (3.8)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	11 (22.4)	11 (21.2)
2	1 (33.3)	14 (28.6)	15 (28.8)
3	2 (66.7)	7 (14.3)	9 (17.3)
4	0 (0.0)	11 (22.4)	11 (21.2)
5	0 (0.0)	5 (10.2)	5 (9.6)
>5	0 (0.0)	1 (2.0)	1 (1.9)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 age aai

14.324. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=19)	Total (N[a]=20)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	6 (31.6)	7 (35.0)
New or increased cough	0 (0.0)	15 (78.9)	15 (75.0)
New or increased shortness of breath	0 (0.0)	1 (5.3)	1 (5.0)
Chills	1 (100.0)	6 (31.6)	7 (35.0)
New or increased muscle pain	0 (0.0)	4 (21.1)	4 (20.0)
Sore throat	0 (0.0)	6 (31.6)	6 (30.0)
Vomiting	1 (100.0)	0 (0.0)	1 (5.0)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	7 (36.8)	7 (35.0)
2	0 (0.0)	7 (36.8)	7 (35.0)
3	1 (100.0)	3 (15.8)	4 (20.0)
4	0 (0.0)	2 (10.5)	2 (10.0)

a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 7d2 age aai

14.325. Summary of Signs and Symptoms for COVID-19 Occurrence After Dose 1 – by Age Group – Dose 1 All-Available Efficacy Population Age Group: 12-15 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=2)	Total (N[a]=3)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	1 (50.0)	2 (66.7)
New or increased cough	0 (0.0)	2 (100.0)	2 (66.7)
Chills	0 (0.0)	2 (100.0)	2 (66.7)
New or increased muscle pain	0 (0.0)	1 (50.0)	1 (33.3)
New loss of taste or smell	0 (0.0)	2 (100.0)	2 (66.7)
Sore throat	0 (0.0)	2 (100.0)	2 (66.7)
Diarrhea	0 (0.0)	1 (50.0)	1 (33.3)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	0 (0.0)	1 (33.3)
5	0 (0.0)	1 (50.0)	1 (33.3)
>5	0 (0.0)	1 (50.0)	1 (33.3)

a. N = number of subjects with COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov d1 age aai

14.326. Summary of Signs and Symptoms for COVID-19 Occurrence After Dose 1 – by Age Group – Dose 1 All-Available Efficacy Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=38)	Placebo (N[a]=200)	Total (N[a]=238)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	14 (36.8)	82 (41.0)	96 (40.3)
New or increased cough	16 (42.1)	125 (62.5)	141 (59.2)
New or increased shortness of breath	2 (5.3)	30 (15.0)	32 (13.4)
Chills	9 (23.7)	56 (28.0)	65 (27.3)
New or increased muscle pain	8 (21.1)	90 (45.0)	98 (41.2)
New loss of taste or smell	20 (52.6)	79 (39.5)	99 (41.6)
Sore throat	16 (42.1)	88 (44.0)	104 (43.7)
Diarrhea	3 (7.9)	25 (12.5)	28 (11.8)
Vomiting	3 (7.9)	10 (5.0)	13 (5.5)
Subjects with specific number of signs and symptoms			
1	14 (36.8)	31 (15.5)	45 (18.9)
2	8 (21.1)	58 (29.0)	66 (27.7)
3	8 (21.1)	52 (26.0)	60 (25.2)
4	5 (13.2)	28 (14.0)	33 (13.9)
5	1 (2.6)	20 (10.0)	21 (8.8)
>5	2 (5.3)	11 (5.5)	13 (5.5)

a. N = number of subjects with COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov d1 age aai

14.327. Summary of Signs and Symptoms for COVID-19 Occurrence After Dose 1 – by Age Group – Dose 1 All-Available Efficacy Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=11)	Placebo (N[a]=73)	Total (N[a]=84)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	5 (45.5)	39 (53.4)	44 (52.4)
New or increased cough	6 (54.5)	59 (80.8)	65 (77.4)
New or increased shortness of breath	2 (18.2)	14 (19.2)	16 (19.0)
Chills	1 (9.1)	28 (38.4)	29 (34.5)
New or increased muscle pain	4 (36.4)	30 (41.1)	34 (40.5)
New loss of taste or smell	4 (36.4)	10 (13.7)	14 (16.7)
Sore throat	2 (18.2)	21 (28.8)	23 (27.4)
Diarrhea	1 (9.1)	9 (12.3)	10 (11.9)
Vomiting	2 (18.2)	1 (1.4)	3 (3.6)
Subjects with specific number of signs and symptoms			
1	1 (9.1)	13 (17.8)	14 (16.7)
2	6 (54.5)	24 (32.9)	30 (35.7)
3	3 (27.3)	11 (15.1)	14 (16.7)
4	0 (0.0)	12 (16.4)	12 (14.3)
5	1 (9.1)	10 (13.7)	11 (13.1)
>5	0 (0.0)	3 (4.1)	3 (3.6)

a. N = number of subjects with COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov d1 age aai

14.328. Summary of Signs and Symptoms for COVID-19 Occurrence After Dose 1 – by Age Group – Dose 1 All-Available Efficacy Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=6)	Placebo (N[a]=24)	Total (N[a]=30)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	3 (50.0)	10 (41.7)	13 (43.3)
New or increased cough	5 (83.3)	18 (75.0)	23 (76.7)
New or increased shortness of breath	1 (16.7)	3 (12.5)	4 (13.3)
Chills	1 (16.7)	9 (37.5)	10 (33.3)
New or increased muscle pain	1 (16.7)	8 (33.3)	9 (30.0)
New loss of taste or smell	2 (33.3)	1 (4.2)	3 (10.0)
Sore throat	2 (33.3)	6 (25.0)	8 (26.7)
Diarrhea	0 (0.0)	3 (12.5)	3 (10.0)
Vomiting	1 (16.7)	0 (0.0)	1 (3.3)
Subjects with specific number of signs and symptoms			
1	1 (16.7)	7 (29.2)	8 (26.7)
2	2 (33.3)	8 (33.3)	10 (33.3)
3	2 (33.3)	4 (16.7)	6 (20.0)
4	0 (0.0)	2 (8.3)	2 (6.7)
5	1 (16.7)	3 (12.5)	4 (13.3)

a. N = number of subjects with COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_d1_age_aai

14.329. Summary of Signs and Symptoms for Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=3)	Total (N[a]=4)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	3 (100.0)	4 (100.0)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	1 (33.3)	1 (25.0)
Admission to an ICU	0 (0.0)	1 (33.3)	1 (25.0)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	2 (66.7)	3 (75.0)
3	0 (0.0)	1 (33.3)	1 (25.0)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate; ICU = intensive care unit; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with severe COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:49)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp sev cov 14d2 wo eva

14.330. Summary of Signs and Symptoms for Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=3)	Total (N[a]=4)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	3 (100.0)	4 (100.0)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	1 (33.3)	1 (25.0)
Admission to an ICU	0 (0.0)	1 (33.3)	1 (25.0)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	2 (66.7)	3 (75.0)
3	0 (0.0)	1 (33.3)	1 (25.0)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate; ICU = intensive care unit; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.
a. N = number of subjects with severe COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:49)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_sev_cov_14d2_eval

14.331. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=139)	Total (N[a]=147)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	65 (46.8)	67 (45.6)
New or increased cough	3 (37.5)	101 (72.7)	104 (70.7)
New or increased shortness of breath	0 (0.0)	20 (14.4)	20 (13.6)
Chills	2 (25.0)	48 (34.5)	50 (34.0)
New or increased muscle pain	1 (12.5)	67 (48.2)	68 (46.3)
New loss of taste or smell	5 (62.5)	36 (25.9)	41 (27.9)
Sore throat	3 (37.5)	57 (41.0)	60 (40.8)
Diarrhea	1 (12.5)	17 (12.2)	18 (12.2)
Vomiting	2 (25.0)	5 (3.6)	7 (4.8)
Subjects with specific number of signs and symptoms			
1	1 (12.5)	21 (15.1)	22 (15.0)
2	3 (37.5)	39 (28.1)	42 (28.6)
3	4 (50.0)	31 (22.3)	35 (23.8)
4	0 (0.0)	29 (20.9)	29 (19.7)
5	0 (0.0)	10 (7.2)	10 (6.8)
>5	0 (0.0)	9 (6.5)	9 (6.1)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_14d2_wo_eval

14.332. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Evaluable Efficacy (14 Days) Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5)	Placebo (N[a]=96)	Total (N[a]=101)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	45 (46.9)	45 (44.6)
New or increased cough	3 (60.0)	67 (69.8)	70 (69.3)
New or increased shortness of breath	0 (0.0)	14 (14.6)	14 (13.9)
Chills	1 (20.0)	31 (32.3)	32 (31.7)
New or increased muscle pain	0 (0.0)	51 (53.1)	51 (50.5)
New loss of taste or smell	4 (80.0)	29 (30.2)	33 (32.7)
Sore throat	3 (60.0)	44 (45.8)	47 (46.5)
Diarrhea	0 (0.0)	14 (14.6)	14 (13.9)
Vomiting	0 (0.0)	5 (5.2)	5 (5.0)
Subjects with specific number of signs and symptoms			
1	1 (20.0)	11 (11.5)	12 (11.9)
2	2 (40.0)	27 (28.1)	29 (28.7)
3	2 (40.0)	24 (25.0)	26 (25.7)
4	0 (0.0)	19 (19.8)	19 (18.8)
5	0 (0.0)	7 (7.3)	7 (6.9)
>5	0 (0.0)	8 (8.3)	8 (7.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_14d2_wo_age_eva

14.333. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Evaluable Efficacy (14 Days) Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=43)	Total (N[a]=46)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	20 (46.5)	22 (47.8)
New or increased cough	0 (0.0)	34 (79.1)	34 (73.9)
New or increased shortness of breath	0 (0.0)	6 (14.0)	6 (13.0)
Chills	1 (33.3)	17 (39.5)	18 (39.1)
New or increased muscle pain	1 (33.3)	16 (37.2)	17 (37.0)
New loss of taste or smell	1 (33.3)	7 (16.3)	8 (17.4)
Sore throat	0 (0.0)	13 (30.2)	13 (28.3)
Diarrhea	1 (33.3)	3 (7.0)	4 (8.7)
Vomiting	2 (66.7)	0 (0.0)	2 (4.3)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	10 (23.3)	10 (21.7)
2	1 (33.3)	12 (27.9)	13 (28.3)
3	2 (66.7)	7 (16.3)	9 (19.6)
4	0 (0.0)	10 (23.3)	10 (21.7)
5	0 (0.0)	3 (7.0)	3 (6.5)
>5	0 (0.0)	1 (2.3)	1 (2.2)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 wo age eva

14.334. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Evaluable Efficacy (14 Days) Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=17)	Total (N[a]=18)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	5 (29.4)	6 (33.3)
New or increased cough	0 (0.0)	13 (76.5)	13 (72.2)
New or increased shortness of breath	0 (0.0)	1 (5.9)	1 (5.6)
Chills	1 (100.0)	5 (29.4)	6 (33.3)
New or increased muscle pain	0 (0.0)	3 (17.6)	3 (16.7)
Sore throat	0 (0.0)	6 (35.3)	6 (33.3)
Vomiting	1 (100.0)	0 (0.0)	1 (5.6)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	6 (35.3)	6 (33.3)
2	0 (0.0)	7 (41.2)	7 (38.9)
3	1 (100.0)	3 (17.6)	4 (22.2)
4	0 (0.0)	1 (5.9)	1 (5.6)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_14d2_wo_age_eva

14.335. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=141)	Total (N[a]=149)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	67 (47.5)	69 (46.3)
New or increased cough	3 (37.5)	101 (71.6)	104 (69.8)
New or increased shortness of breath	0 (0.0)	20 (14.2)	20 (13.4)
Chills	2 (25.0)	49 (34.8)	51 (34.2)
New or increased muscle pain	1 (12.5)	67 (47.5)	68 (45.6)
New loss of taste or smell	5 (62.5)	36 (25.5)	41 (27.5)
Sore throat	3 (37.5)	58 (41.1)	61 (40.9)
Diarrhea	1 (12.5)	18 (12.8)	19 (12.8)
Vomiting	2 (25.0)	5 (3.5)	7 (4.7)
Subjects with specific number of signs and symptoms			
1	1 (12.5)	21 (14.9)	22 (14.8)
2	3 (37.5)	40 (28.4)	43 (28.9)
3	4 (50.0)	32 (22.7)	36 (24.2)
4	0 (0.0)	29 (20.6)	29 (19.5)
5	0 (0.0)	10 (7.1)	10 (6.7)
>5	0 (0.0)	9 (6.4)	9 (6.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_14d2_wo_aai

14.336. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5)	Placebo (N[a]=98)	Total (N[a]=103)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	47 (48.0)	47 (45.6)
New or increased cough	3 (60.0)	67 (68.4)	70 (68.0)
New or increased shortness of breath	0 (0.0)	14 (14.3)	14 (13.6)
Chills	1 (20.0)	32 (32.7)	33 (32.0)
New or increased muscle pain	0 (0.0)	51 (52.0)	51 (49.5)
New loss of taste or smell	4 (80.0)	29 (29.6)	33 (32.0)
Sore throat	3 (60.0)	45 (45.9)	48 (46.6)
Diarrhea	0 (0.0)	15 (15.3)	15 (14.6)
Vomiting	0 (0.0)	5 (5.1)	5 (4.9)
Subjects with specific number of signs and symptoms			
1	1 (20.0)	11 (11.2)	12 (11.7)
2	2 (40.0)	28 (28.6)	30 (29.1)
3	2 (40.0)	25 (25.5)	27 (26.2)
4	0 (0.0)	19 (19.4)	19 (18.4)
5	0 (0.0)	7 (7.1)	7 (6.8)
>5	0 (0.0)	8 (8.2)	8 (7.8)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_14d2_wo_age_aai

14.337. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=43)	Total (N[a]=46)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	20 (46.5)	22 (47.8)
New or increased cough	0 (0.0)	34 (79.1)	34 (73.9)
New or increased shortness of breath	0 (0.0)	6 (14.0)	6 (13.0)
Chills	1 (33.3)	17 (39.5)	18 (39.1)
New or increased muscle pain	1 (33.3)	16 (37.2)	17 (37.0)
New loss of taste or smell	1 (33.3)	7 (16.3)	8 (17.4)
Sore throat	0 (0.0)	13 (30.2)	13 (28.3)
Diarrhea	1 (33.3)	3 (7.0)	4 (8.7)
Vomiting	2 (66.7)	0 (0.0)	2 (4.3)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	10 (23.3)	10 (21.7)
2	1 (33.3)	12 (27.9)	13 (28.3)
3	2 (66.7)	7 (16.3)	9 (19.6)
4	0 (0.0)	10 (23.3)	10 (21.7)
5	0 (0.0)	3 (7.0)	3 (6.5)
>5	0 (0.0)	1 (2.3)	1 (2.2)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 wo age aai

14.338. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=17)	Total (N[a]=18)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	5 (29.4)	6 (33.3)
New or increased cough	0 (0.0)	13 (76.5)	13 (72.2)
New or increased shortness of breath	0 (0.0)	1 (5.9)	1 (5.6)
Chills	1 (100.0)	5 (29.4)	6 (33.3)
New or increased muscle pain	0 (0.0)	3 (17.6)	3 (16.7)
Sore throat	0 (0.0)	6 (35.3)	6 (33.3)
Vomiting	1 (100.0)	0 (0.0)	1 (5.6)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	6 (35.3)	6 (33.3)
2	0 (0.0)	7 (41.2)	7 (38.9)
3	1 (100.0)	3 (17.6)	4 (22.2)
4	0 (0.0)	1 (5.9)	1 (5.6)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_14d2_wo_age_aai

14.339. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=144)	Total (N[a]=152)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	66 (45.8)	68 (44.7)
New or increased cough	3 (37.5)	105 (72.9)	108 (71.1)
New or increased shortness of breath	0 (0.0)	21 (14.6)	21 (13.8)
Chills	2 (25.0)	48 (33.3)	50 (32.9)
New or increased muscle pain	1 (12.5)	68 (47.2)	69 (45.4)
New loss of taste or smell	5 (62.5)	38 (26.4)	43 (28.3)
Sore throat	3 (37.5)	60 (41.7)	63 (41.4)
Diarrhea	1 (12.5)	17 (11.8)	18 (11.8)
Vomiting	2 (25.0)	5 (3.5)	7 (4.6)
Subjects with specific number of signs and symptoms			
1	1 (12.5)	21 (14.6)	22 (14.5)
2	3 (37.5)	42 (29.2)	45 (29.6)
3	4 (50.0)	33 (22.9)	37 (24.3)
4	0 (0.0)	29 (20.1)	29 (19.1)
5	0 (0.0)	10 (6.9)	10 (6.6)
>5	0 (0.0)	9 (6.3)	9 (5.9)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 eval

14.340. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Evaluable Efficacy (14 Days) Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5)	Placebo (N[a]=100)	Total (N[a]=105)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	46 (46.0)	46 (43.8)
New or increased cough	3 (60.0)	70 (70.0)	73 (69.5)
New or increased shortness of breath	0 (0.0)	15 (15.0)	15 (14.3)
Chills	1 (20.0)	31 (31.0)	32 (30.5)
New or increased muscle pain	0 (0.0)	52 (52.0)	52 (49.5)
New loss of taste or smell	4 (80.0)	31 (31.0)	35 (33.3)
Sore throat	3 (60.0)	46 (46.0)	49 (46.7)
Diarrhea	0 (0.0)	14 (14.0)	14 (13.3)
Vomiting	0 (0.0)	5 (5.0)	5 (4.8)
Subjects with specific number of signs and symptoms			
1	1 (20.0)	11 (11.0)	12 (11.4)
2	2 (40.0)	29 (29.0)	31 (29.5)
3	2 (40.0)	26 (26.0)	28 (26.7)
4	0 (0.0)	19 (19.0)	19 (18.1)
5	0 (0.0)	7 (7.0)	7 (6.7)
>5	0 (0.0)	8 (8.0)	8 (7.6)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 age eval

14.341. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Evaluable Efficacy (14 Days) Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=44)	Total (N[a]=47)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	20 (45.5)	22 (46.8)
New or increased cough	0 (0.0)	35 (79.5)	35 (74.5)
New or increased shortness of breath	0 (0.0)	6 (13.6)	6 (12.8)
Chills	1 (33.3)	17 (38.6)	18 (38.3)
New or increased muscle pain	1 (33.3)	16 (36.4)	17 (36.2)
New loss of taste or smell	1 (33.3)	7 (15.9)	8 (17.0)
Sore throat	0 (0.0)	14 (31.8)	14 (29.8)
Diarrhea	1 (33.3)	3 (6.8)	4 (8.5)
Vomiting	2 (66.7)	0 (0.0)	2 (4.3)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	10 (22.7)	10 (21.3)
2	1 (33.3)	13 (29.5)	14 (29.8)
3	2 (66.7)	7 (15.9)	9 (19.1)
4	0 (0.0)	10 (22.7)	10 (21.3)
5	0 (0.0)	3 (6.8)	3 (6.4)
>5	0 (0.0)	1 (2.3)	1 (2.1)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 age eval

14.342. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Evaluable Efficacy (14 Days) Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=17)	Total (N[a]=18)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	5 (29.4)	6 (33.3)
New or increased cough	0 (0.0)	13 (76.5)	13 (72.2)
New or increased shortness of breath	0 (0.0)	1 (5.9)	1 (5.6)
Chills	1 (100.0)	5 (29.4)	6 (33.3)
New or increased muscle pain	0 (0.0)	3 (17.6)	3 (16.7)
Sore throat	0 (0.0)	6 (35.3)	6 (33.3)
Vomiting	1 (100.0)	0 (0.0)	1 (5.6)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	6 (35.3)	6 (33.3)
2	0 (0.0)	7 (41.2)	7 (38.9)
3	1 (100.0)	3 (17.6)	4 (22.2)
4	0 (0.0)	1 (5.9)	1 (5.6)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 age eval

14.343. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=146)	Total (N[a]=154)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	68 (46.6)	70 (45.5)
New or increased cough	3 (37.5)	105 (71.9)	108 (70.1)
New or increased shortness of breath	0 (0.0)	21 (14.4)	21 (13.6)
Chills	2 (25.0)	49 (33.6)	51 (33.1)
New or increased muscle pain	1 (12.5)	68 (46.6)	69 (44.8)
New loss of taste or smell	5 (62.5)	38 (26.0)	43 (27.9)
Sore throat	3 (37.5)	61 (41.8)	64 (41.6)
Diarrhea	1 (12.5)	18 (12.3)	19 (12.3)
Vomiting	2 (25.0)	5 (3.4)	7 (4.5)
Subjects with specific number of signs and symptoms			
1	1 (12.5)	21 (14.4)	22 (14.3)
2	3 (37.5)	43 (29.5)	46 (29.9)
3	4 (50.0)	34 (23.3)	38 (24.7)
4	0 (0.0)	29 (19.9)	29 (18.8)
5	0 (0.0)	10 (6.8)	10 (6.5)
>5	0 (0.0)	9 (6.2)	9 (5.8)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 aai

14.344. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5)	Placebo (N[a]=102)	Total (N[a]=107)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	0 (0.0)	48 (47.1)	48 (44.9)
New or increased cough	3 (60.0)	70 (68.6)	73 (68.2)
New or increased shortness of breath	0 (0.0)	15 (14.7)	15 (14.0)
Chills	1 (20.0)	32 (31.4)	33 (30.8)
New or increased muscle pain	0 (0.0)	52 (51.0)	52 (48.6)
New loss of taste or smell	4 (80.0)	31 (30.4)	35 (32.7)
Sore throat	3 (60.0)	47 (46.1)	50 (46.7)
Diarrhea	0 (0.0)	15 (14.7)	15 (14.0)
Vomiting	0 (0.0)	5 (4.9)	5 (4.7)
Subjects with specific number of signs and symptoms			
1	1 (20.0)	11 (10.8)	12 (11.2)
2	2 (40.0)	30 (29.4)	32 (29.9)
3	2 (40.0)	27 (26.5)	29 (27.1)
4	0 (0.0)	19 (18.6)	19 (17.8)
5	0 (0.0)	7 (6.9)	7 (6.5)
>5	0 (0.0)	8 (7.8)	8 (7.5)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 age aai

14.345. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=3)	Placebo (N[a]=44)	Total (N[a]=47)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (66.7)	20 (45.5)	22 (46.8)
New or increased cough	0 (0.0)	35 (79.5)	35 (74.5)
New or increased shortness of breath	0 (0.0)	6 (13.6)	6 (12.8)
Chills	1 (33.3)	17 (38.6)	18 (38.3)
New or increased muscle pain	1 (33.3)	16 (36.4)	17 (36.2)
New loss of taste or smell	1 (33.3)	7 (15.9)	8 (17.0)
Sore throat	0 (0.0)	14 (31.8)	14 (29.8)
Diarrhea	1 (33.3)	3 (6.8)	4 (8.5)
Vomiting	2 (66.7)	0 (0.0)	2 (4.3)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	10 (22.7)	10 (21.3)
2	1 (33.3)	13 (29.5)	14 (29.8)
3	2 (66.7)	7 (15.9)	9 (19.1)
4	0 (0.0)	10 (22.7)	10 (21.3)
5	0 (0.0)	3 (6.8)	3 (6.4)
>5	0 (0.0)	1 (2.3)	1 (2.1)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 age aai

14.346. Summary of Signs and Symptoms for COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – by Age Group – Dose 2 All-Available Efficacy Population Age Group: ≥65 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=17)	Total (N[a]=18)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	1 (100.0)	5 (29.4)	6 (33.3)
New or increased cough	0 (0.0)	13 (76.5)	13 (72.2)
New or increased shortness of breath	0 (0.0)	1 (5.9)	1 (5.6)
Chills	1 (100.0)	5 (29.4)	6 (33.3)
New or increased muscle pain	0 (0.0)	3 (17.6)	3 (16.7)
Sore throat	0 (0.0)	6 (35.3)	6 (33.3)
Vomiting	1 (100.0)	0 (0.0)	1 (5.6)
Subjects with specific number of signs and symptoms			
1	0 (0.0)	6 (35.3)	6 (33.3)
2	0 (0.0)	7 (41.2)	7 (38.9)
3	1 (100.0)	3 (17.6)	4 (22.2)
4	0 (0.0)	1 (5.9)	1 (5.6)

a. N = number of subjects with COVID-19 occurrence from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov 14d2 age aai

14.347. Summary of Signs and Symptoms for COVID-19 Occurrence Based on CDC-Defined Symptoms After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=54)	Placebo (N[a]=282)	Total (N[a]=336)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	20 (37.0)	122 (43.3)	142 (42.3)
New or increased cough	22 (40.7)	186 (66.0)	208 (61.9)
New or increased shortness of breath	4 (7.4)	44 (15.6)	48 (14.3)
Chills	10 (18.5)	86 (30.5)	96 (28.6)
New or increased muscle pain	12 (22.2)	121 (42.9)	133 (39.6)
New loss of taste or smell	24 (44.4)	91 (32.3)	115 (34.2)
Sore throat	18 (33.3)	111 (39.4)	129 (38.4)
Diarrhea	4 (7.4)	35 (12.4)	39 (11.6)
Vomiting	5 (9.3)	11 (3.9)	16 (4.8)
Additional CDC-defined symptoms			
Fatigue	6 (11.1)	65 (23.0)	71 (21.1)
Headache	14 (25.9)	96 (34.0)	110 (32.7)
Nasal congestion	7 (13.0)	56 (19.9)	63 (18.8)
Runny nose	7 (13.0)	31 (11.0)	38 (11.3)
Nausea	2 (3.7)	8 (2.8)	10 (3.0)

a. N = number of subjects with COVID-19 occurrence based on CDC-defined symptoms after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:50)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov cdc d1 aai

14.348. Summary of Signs and Symptoms for COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=165)	Total (N[a]=173)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	76 (46.1)	78 (45.1)
New or increased cough	3 (37.5)	114 (69.1)	117 (67.6)
New or increased shortness of breath	0 (0.0)	25 (15.2)	25 (14.5)
Chills	2 (25.0)	57 (34.5)	59 (34.1)
New or increased muscle pain	1 (12.5)	81 (49.1)	82 (47.4)
New loss of taste or smell	5 (62.5)	43 (26.1)	48 (27.7)
Sore throat	3 (37.5)	68 (41.2)	71 (41.0)
Diarrhea	1 (12.5)	18 (10.9)	19 (11.0)
Vomiting	2 (25.0)	6 (3.6)	8 (4.6)
Additional CDC-defined symptoms			
Fatigue	0 (0.0)	44 (26.7)	44 (25.4)
Headache	2 (25.0)	63 (38.2)	65 (37.6)
Nasal congestion	1 (12.5)	33 (20.0)	34 (19.7)
Runny nose	0 (0.0)	21 (12.7)	21 (12.1)
Nausea	1 (12.5)	3 (1.8)	4 (2.3)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence based on CDC-defined symptoms from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:50)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov cdc 7d2 wo eval

14.349. Summary of Signs and Symptoms for COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=9)	Placebo (N[a]=172)	Total (N[a]=181)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (22.2)	77 (44.8)	79 (43.6)
New or increased cough	3 (33.3)	120 (69.8)	123 (68.0)
New or increased shortness of breath	0 (0.0)	26 (15.1)	26 (14.4)
Chills	2 (22.2)	58 (33.7)	60 (33.1)
New or increased muscle pain	1 (11.1)	82 (47.7)	83 (45.9)
New loss of taste or smell	5 (55.6)	46 (26.7)	51 (28.2)
Sore throat	4 (44.4)	71 (41.3)	75 (41.4)
Diarrhea	1 (11.1)	19 (11.0)	20 (11.0)
Vomiting	2 (22.2)	6 (3.5)	8 (4.4)
Additional CDC-defined symptoms			
Fatigue	0 (0.0)	45 (26.2)	45 (24.9)
Headache	2 (22.2)	65 (37.8)	67 (37.0)
Nasal congestion	1 (11.1)	36 (20.9)	37 (20.4)
Runny nose	0 (0.0)	22 (12.8)	22 (12.2)
Nausea	1 (11.1)	3 (1.7)	4 (2.2)

a. N = number of subjects with COVID-19 occurrence based on CDC-defined symptoms from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:50)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_cdc_7d2_eval

14.350. Summary of Signs and Symptoms for COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=141)	Total (N[a]=149)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	65 (46.1)	67 (45.0)
New or increased cough	3 (37.5)	101 (71.6)	104 (69.8)
New or increased shortness of breath	0 (0.0)	20 (14.2)	20 (13.4)
Chills	2 (25.0)	48 (34.0)	50 (33.6)
New or increased muscle pain	1 (12.5)	67 (47.5)	68 (45.6)
New loss of taste or smell	5 (62.5)	36 (25.5)	41 (27.5)
Sore throat	3 (37.5)	57 (40.4)	60 (40.3)
Diarrhea	1 (12.5)	17 (12.1)	18 (12.1)
Vomiting	2 (25.0)	5 (3.5)	7 (4.7)
Additional CDC-defined symptoms			
Fatigue	0 (0.0)	36 (25.5)	36 (24.2)
Headache	2 (25.0)	54 (38.3)	56 (37.6)
Nasal congestion	1 (12.5)	29 (20.6)	30 (20.1)
Runny nose	0 (0.0)	18 (12.8)	18 (12.1)
Nausea	1 (12.5)	3 (2.1)	4 (2.7)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence based on CDC-defined symptoms from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:50)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adsympt symp cov cdc 14d2 wo eva

14.351. Summary of Signs and Symptoms for COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=146)	Total (N[a]=154)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	66 (45.2)	68 (44.2)
New or increased cough	3 (37.5)	105 (71.9)	108 (70.1)
New or increased shortness of breath	0 (0.0)	21 (14.4)	21 (13.6)
Chills	2 (25.0)	48 (32.9)	50 (32.5)
New or increased muscle pain	1 (12.5)	68 (46.6)	69 (44.8)
New loss of taste or smell	5 (62.5)	38 (26.0)	43 (27.9)
Sore throat	3 (37.5)	60 (41.1)	63 (40.9)
Diarrhea	1 (12.5)	17 (11.6)	18 (11.7)
Vomiting	2 (25.0)	5 (3.4)	7 (4.5)
Additional CDC-defined symptoms			
Fatigue	0 (0.0)	37 (25.3)	37 (24.0)
Headache	2 (25.0)	56 (38.4)	58 (37.7)
Nasal congestion	1 (12.5)	32 (21.9)	33 (21.4)
Runny nose	0 (0.0)	19 (13.0)	19 (12.3)
Nausea	1 (12.5)	3 (2.1)	4 (2.6)

a. N = number of subjects with COVID-19 occurrence based on CDC-defined symptoms from 14 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:50)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_cdc_14d2_eval

14.352. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18650)		Placebo (N[a]=18570)			
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	8	2.266 (17852)	165	2.244 (17746)	95.2	(90.3, 98.0)
Age group (years)						
16 to 55	5	1.262 (10145)	117	1.251 (10087)	95.8	(89.8, 98.6)
>55	3	1.004 (7693)	48	0.993 (7646)	93.8	(80.8, 98.8)
≥65	1	0.523 (3965)	19	0.516 (3936)	94.8	(67.3, 99.9)
Sex						
Male	3	1.150 (9100)	84	1.120 (8886)	96.5	(89.5, 99.3)
Female	5	1.116 (8752)	81	1.124 (8860)	93.8	(84.9, 98.0)
Race						
White	7	1.937 (14912)	149	1.922 (14879)	95.3	(90.2, 98.2)
Black or African American	0	0.168 (1525)	7	0.165 (1495)	100.0	(31.8, 100.0)
All others[f]	1	0.162 (1415)	9	0.157 (1372)	89.2	(22.3, 99.8)
Ethnicity						
Hispanic/Latino	3	0.615 (4882)	54	0.608 (4849)	94.5	(83.1, 98.9)
Non-Hispanic/non-Latino	5	1.637 (12866)	111	1.623 (12793)	95.5	(89.3, 98.6)
Country						
Argentina	1	0.358 (2628)	36	0.351 (2599)	97.3	(83.8, 99.9)
Brazil	1	0.119 (1130)	8	0.117 (1123)	87.7	(8.0, 99.7)
USA	6	1.777 (13709)	121	1.764 (13656)	95.1	(89.0, 98.2)

14.352. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18650)		Placebo (N[a]=18570)			
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. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:58)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 wo sg aai

14.353. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)			
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	9	2.389 (19049)	172	2.370 (18971)	94.8	(89.9, 97.7)
Age group (years)						
16 to 55	6	1.341 (10931)	123	1.331 (10890)	95.2	(89.2, 98.3)
>55	3	1.048 (8104)	49	1.039 (8067)	93.9	(81.2, 98.8)
≥65	1	0.545 (4168)	19	0.537 (4126)	94.8	(67.4, 99.9)
Sex						
Male	4	1.212 (9717)	88	1.183 (9477)	95.6	(88.2, 98.8)
Female	5	1.176 (9332)	84	1.187 (9494)	94.0	(85.4, 98.1)
Race						
White	7	2.027 (15749)	156	2.012 (15709)	95.5	(90.6, 98.2)
Black or African American	0	0.189 (1781)	7	0.189 (1768)	100.0	(30.8, 100.0)
All others[f]	2	0.172 (1519)	9	0.169 (1494)	78.1	(-5.6, 97.7)
Ethnicity						
Hispanic/Latino	3	0.649 (5213)	56	0.647 (5214)	94.7	(83.6, 98.9)
Non-Hispanic/non-Latino	6	1.725 (13726)	116	1.708 (13648)	94.9	(88.5, 98.2)
Country						
Argentina	1	0.375 (2765)	37	0.373 (2776)	97.3	(84.1, 99.9)
Brazil	2	0.134 (1277)	8	0.132 (1259)	75.4	(-23.5, 97.5)
USA	6	1.863 (14520)	126	1.849 (14451)	95.3	(89.4, 98.3)
South Africa	0	0.015 (363)	1	0.015 (363)	100.0	(-3802.8, 100.0)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	1	0.058 (541)	1	0.061 (579)	-6.4	(-8250.5, 98.6)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.003 (29)	1	0.004 (35)	100.0	(-5553.6, 100.0)
Negative prior to 7 days after Dose 2[i]	8	2.266 (17852)	165	2.244 (17746)	95.2	(90.3, 98.0)
Unknown	0	0.063 (627)	5	0.061 (611)	100.0	(-5.9, 100.0)

14.353. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:58)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 sg aai

14.354. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
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	50	4.015 (21314)	275	3.982 (21258)	82.0	(75.6, 86.9)
Age group (years)						
12 to 15	1	0.004 (49)	2	0.004 (51)	48.3	(-893.5, 99.1)
16 to 55	38	2.294 (12488)	200	2.274 (12469)	81.2	(73.2, 87.0)
>55	11	1.718 (8777)	73	1.704 (8738)	85.1	(71.7, 92.9)
≥65	6	0.887 (4467)	24	0.877 (4461)	75.3	(37.9, 91.7)
Sex						
Male	25	2.047 (10968)	149	1.992 (10702)	83.7	(74.9, 89.8)
Female	25	1.969 (10346)	126	1.990 (10556)	79.9	(69.0, 87.5)
Race						
White	45	3.366 (17544)	250	3.338 (17508)	82.1	(75.4, 87.3)
Black or African American	2	0.345 (2023)	10	0.344 (2024)	80.0	(6.4, 97.9)
All others[c]	3	0.304 (1747)	15	0.299 (1726)	80.3	(30.3, 96.3)
Ethnicity						
Hispanic/Latino	21	1.085 (5590)	101	1.076 (5582)	79.4	(66.8, 87.8)
Non-Hispanic/non-Latino	29	2.907 (15606)	172	2.883 (15558)	83.3	(75.1, 89.1)
Not reported	0	0.023 (118)	2	0.023 (118)	100.0	(-441.9, 100.0)
Country						
Argentina	16	0.600 (2856)	70	0.592 (2855)	77.5	(60.8, 87.8)
Brazil	2	0.244 (1439)	18	0.241 (1425)	89.0	(54.2, 98.8)
Germany	2	0.018 (246)	0	0.018 (249)	-∞	(NA, NA)
South Africa	0	0.044 (372)	2	0.044 (368)	100.0	(-427.5, 100.0)
Turkey	2	0.009 (245)	0	0.009 (240)	-∞	(NA, NA)
USA	28	3.099 (16156)	185	3.079 (16121)	85.0	(77.5, 90.3)
Baseline SARS-CoV-2 status						
Positive[d]	10	0.106 (633)	9	0.113 (670)	-17.9	(-227.9, 56.9)
Negative[e]	36	3.814 (19913)	259	3.777 (19818)	86.2	(80.4, 90.6)
Unknown	4	0.095 (768)	7	0.093 (770)	44.2	(-119.6, 88.0)

14.354. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
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 Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (17:11)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_pd1_sg_aai

14.355. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)			
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 14 days after Dose 2						
Overall	8	1.887 (16612)	139	1.893 (16663)	94.2	(88.3, 97.6)
Age group (years)						
16 to 55	5	1.048 (9440)	96	1.052 (9453)	94.8	(87.4, 98.3)
>55	3	0.839 (7172)	43	0.841 (7210)	93.0	(78.2, 98.6)
≥65	1	0.436 (3663)	17	0.438 (3709)	94.1	(62.3, 99.9)
Sex						
Male	3	0.958 (8467)	68	0.944 (8334)	95.7	(86.7, 99.1)
Female	5	0.930 (8145)	71	0.950 (8329)	92.8	(82.4, 97.7)
Race						
White	7	1.616 (13908)	124	1.628 (14025)	94.3	(87.9, 97.8)
Black or African American	0	0.138 (1378)	7	0.136 (1370)	100.0	(31.2, 100.0)
All others[f]	1	0.134 (1326)	8	0.129 (1268)	87.9	(10.1, 99.7)
Ethnicity						
Hispanic/Latino	3	0.515 (4613)	39	0.511 (4575)	92.4	(76.0, 98.5)
Non-Hispanic/non-Latino	5	1.361 (11901)	100	1.371 (11988)	95.0	(87.9, 98.4)
Country						
Argentina	1	0.303 (2545)	25	0.298 (2510)	96.1	(76.0, 99.9)
Brazil	1	0.098 (994)	4	0.097 (974)	75.3	(-149.2, 99.5)
USA	6	1.480 (12815)	110	1.492 (12931)	94.5	(87.6, 98.0)

14.355. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)			
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 14 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 14 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:58)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 wo sg eval

14.356. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18627)		Placebo (N[a]=18506)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First COVID-19 occurrence from 14 days after Dose 2	8	1.931 (17032)	141	1.911 (16876)	94.4	(89.0, 97.3)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 14 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 14 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 wo aai

14.357. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18627)		Placebo (N[a]=18506)			
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 14 days after Dose 2						
Overall	8	1.931 (17032)	141	1.911 (16876)	94.4	(88.6, 97.6)
Age group (years)						
16 to 55	5	1.072 (9674)	98	1.062 (9572)	94.9	(87.8, 98.4)
>55	3	0.859 (7358)	43	0.849 (7304)	93.1	(78.5, 98.6)
≥65	1	0.448 (3776)	17	0.442 (3759)	94.2	(63.0, 99.9)
Sex						
Male	3	0.980 (8680)	70	0.954 (8447)	95.8	(87.3, 99.2)
Female	5	0.951 (8352)	71	0.957 (8429)	92.9	(82.7, 97.8)
Race						
White	7	1.656 (14298)	126	1.643 (14213)	94.5	(88.3, 97.8)
Black or African American	0	0.139 (1398)	7	0.137 (1378)	100.0	(31.7, 100.0)
All others[f]	1	0.135 (1336)	8	0.131 (1285)	87.9	(9.7, 99.7)
Ethnicity						
Hispanic/Latino	3	0.523 (4726)	39	0.516 (4672)	92.4	(76.1, 98.5)
Non-Hispanic/non-Latino	5	1.397 (12203)	102	1.383 (12104)	95.1	(88.3, 98.5)
Country						
Argentina	1	0.308 (2627)	25	0.301 (2585)	96.1	(76.1, 99.9)
Brazil	1	0.098 (994)	4	0.097 (976)	75.3	(-149.4, 99.5)
USA	6	1.518 (13152)	112	1.507 (13067)	94.7	(88.1, 98.1)

14.357. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18627)		Placebo (N[a]=18506)			
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 14 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 14 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:58)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 wo sg aai

14.358. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)			
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 14 days after Dose 2						
Overall	8	1.984 (17645)	144	1.995 (17746)	94.4	(88.7, 97.6)
Age group (years)						
16 to 55	5	1.110 (10114)	100	1.117 (10157)	95.0	(87.9, 98.4)
>55	3	0.874 (7531)	44	0.879 (7589)	93.1	(78.6, 98.6)
≥65	1	0.455 (3842)	17	0.455 (3881)	94.1	(62.4, 99.9)
Sex						
Male	3	1.006 (8991)	71	0.995 (8860)	95.8	(87.3, 99.2)
Female	5	0.979 (8654)	73	1.000 (8886)	93.0	(82.9, 97.8)
Race						
White	7	1.688 (14621)	129	1.700 (14750)	94.5	(88.4, 97.8)
Black or African American	0	0.155 (1605)	7	0.155 (1616)	100.0	(30.4, 100.0)
All others[f]	1	0.142 (1419)	8	0.140 (1380)	87.7	(8.4, 99.7)
Ethnicity						
Hispanic/Latino	3	0.542 (4896)	41	0.542 (4900)	92.7	(77.0, 98.5)
Non-Hispanic/non-Latino	5	1.431 (12645)	103	1.440 (12741)	95.1	(88.2, 98.4)
Country						
Argentina	1	0.315 (2664)	26	0.315 (2673)	96.2	(76.6, 99.9)
Brazil	1	0.111 (1122)	4	0.110 (1101)	75.3	(-149.2, 99.5)
USA	6	1.549 (13518)	114	1.562 (13631)	94.7	(88.1, 98.1)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	0	0.046 (486)	1	0.050 (527)	100.0	(-4066.9, 100.0)
Negative prior to 14 days after Dose 2[i]	8	1.887 (16612)	139	1.893 (16663)	94.2	(88.3, 97.6)
Unknown	0	0.049 (522)	4	0.049 (523)	100.0	(-53.1, 100.0)

14.358. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)			
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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:58)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 sg eval

14.359. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 14 days after Dose 2	8	2.032 (18111)	146	2.015 (17985)	94.6	(89.4, 97.4)	>0.9999

Abbreviations: 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 aai

14.360. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)			
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 14 days after Dose 2						
Overall	8	2.032 (18111)	146	2.015 (17985)	94.6	(89.0, 97.7)
Age group (years)						
16 to 55	5	1.136 (10376)	102	1.127 (10294)	95.1	(88.3, 98.5)
>55	3	0.896 (7735)	44	0.888 (7691)	93.2	(78.9, 98.7)
≥65	1	0.467 (3962)	17	0.459 (3934)	94.2	(63.1, 99.9)
Sex						
Male	3	1.030 (9238)	73	1.005 (8983)	96.0	(87.8, 99.2)
Female	5	1.001 (8873)	73	1.010 (9002)	93.1	(83.1, 97.8)
Race						
White	7	1.732 (15055)	131	1.717 (14963)	94.7	(88.8, 97.9)
Black or African American	0	0.157 (1625)	7	0.156 (1625)	100.0	(30.8, 100.0)
All others[f]	1	0.143 (1431)	8	0.141 (1397)	87.7	(8.2, 99.7)
Ethnicity						
Hispanic/Latino	3	0.551 (5030)	41	0.549 (5016)	92.7	(77.2, 98.6)
Non-Hispanic/non-Latino	5	1.469 (12972)	105	1.454 (12864)	95.3	(88.6, 98.5)
Country						
Argentina	1	0.322 (2764)	26	0.320 (2762)	96.2	(76.8, 99.9)
Brazil	1	0.111 (1123)	4	0.110 (1103)	75.3	(-149.2, 99.5)
USA	6	1.590 (13882)	116	1.577 (13779)	94.9	(88.5, 98.2)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	0	0.047 (500)	1	0.050 (537)	100.0	(-4038.2, 100.0)
Negative prior to 14 days after Dose 2[i]	8	1.931 (17032)	141	1.911 (16876)	94.4	(88.6, 97.6)
Unknown	0	0.051 (552)	4	0.050 (538)	100.0	(-47.7, 100.0)

14.360. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)			
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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (16:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 sg aai

14.361. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC-defined symptoms from 14 days after Dose 2	8	1.983 (17630)	146	1.993 (17727)	94.5	(88.9, 97.7)

Abbreviations: 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 cdc eval

14.362. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC-defined symptoms from 14 days after Dose 2	8	1.886 (16600)	141	1.891 (16647)	94.3	(88.5, 97.6)

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 14 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 14 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 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 wo cdc eval

14.363. COVID-19 Occurrence After Dose 1 Based on CDC-Defined Symptoms – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=21669)	Placebo (N[a]=21686)
Efficacy Endpoint	**n[b]**	**n[b]**
COVID-19 occurrence after Dose 1 based on CDC-defined symptoms	54	282
After Dose 1 and before Dose 2	42	85
Dose 2 to 7 days after Dose 2	3	22
≥7 days after Dose 2	9	175

a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (18:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov pd1 cdc aai

Local Reactions

14.364. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	4093	189 (4.6)	(4.0, 5.3)	4090	45 (1.1)	(0.8, 1.5)
	Mild	4093	125 (3.1)	(2.5, 3.6)	4090	28 (0.7)	(0.5, 1.0)
	Moderate	4093	55 (1.3)	(1.0, 1.7)	4090	11 (0.3)	(0.1, 0.5)
	Severe	4093	9 (0.2)	(0.1, 0.4)	4090	6 (0.1)	(0.1, 0.3)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Swelling[d]						
	Any	4093	250 (6.1)	(5.4, 6.9)	4090	32 (0.8)	(0.5, 1.1)
	Mild	4093	159 (3.9)	(3.3, 4.5)	4090	13 (0.3)	(0.2, 0.5)
	Moderate	4093	84 (2.1)	(1.6, 2.5)	4090	16 (0.4)	(0.2, 0.6)
	Severe	4093	7 (0.2)	(0.1, 0.4)	4090	3 (0.1)	(0.0, 0.2)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Pain at the injection site[e]						
	Any	4093	3186 (77.8)	(76.5, 79.1)	4090	488 (11.9)	(11.0, 13.0)
	Mild	4093	2178 (53.2)	(51.7, 54.8)	4090	468 (11.4)	(10.5, 12.5)
	Moderate	4093	980 (23.9)	(22.6, 25.3)	4090	18 (0.4)	(0.3, 0.7)
	Severe	4093	28 (0.7)	(0.5, 1.0)	4090	2 (0.0)	(0.0, 0.2)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Any local reaction[f]	4093	3216 (78.6)	(77.3, 79.8)	4090	525 (12.8)	(11.8, 13.9)
2	Redness[d]						
	Any	3758	243 (6.5)	(5.7, 7.3)	3749	26 (0.7)	(0.5, 1.0)
	Mild	3758	132 (3.5)	(2.9, 4.2)	3749	16 (0.4)	(0.2, 0.7)
	Moderate	3758	93 (2.5)	(2.0, 3.0)	3749	9 (0.2)	(0.1, 0.5)
	Severe	3758	18 (0.5)	(0.3, 0.8)	3749	1 (0.0)	(0.0, 0.1)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Swelling[d]						
	Any	3758	256 (6.8)	(6.0, 7.7)	3749	16 (0.4)	(0.2, 0.7)
	Mild	3758	148 (3.9)	(3.3, 4.6)	3749	8 (0.2)	(0.1, 0.4)
	Moderate	3758	98 (2.6)	(2.1, 3.2)	3749	7 (0.2)	(0.1, 0.4)
	Severe	3758	10 (0.3)	(0.1, 0.5)	3749	1 (0.0)	(0.0, 0.1)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Pain at the injection site[e]						
	Any	3758	2730 (72.6)	(71.2, 74.1)	3749	372 (9.9)	(9.0, 10.9)
	Mild	3758	1831 (48.7)	(47.1, 50.3)	3749	350 (9.3)	(8.4, 10.3)
	Moderate	3758	866 (23.0)	(21.7, 24.4)	3749	22 (0.6)	(0.4, 0.9)

14.364. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	3758	33 (0.9)	(0.6, 1.2)	3749	0	(0.0, 0.1)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Any local reaction[f]	3758	2748 (73.1)	(71.7, 74.5)	3749	396 (10.6)	(9.6, 11.6)
Any dose	Redness[d]						
	Any	4108	389 (9.5)	(8.6, 10.4)	4106	64 (1.6)	(1.2, 2.0)
	Mild	4108	233 (5.7)	(5.0, 6.4)	4106	38 (0.9)	(0.7, 1.3)
	Moderate	4108	129 (3.1)	(2.6, 3.7)	4106	20 (0.5)	(0.3, 0.8)
	Severe	4108	27 (0.7)	(0.4, 1.0)	4106	6 (0.1)	(0.1, 0.3)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Swelling[d]						
	Any	4108	430 (10.5)	(9.5, 11.4)	4106	42 (1.0)	(0.7, 1.4)
	Mild	4108	257 (6.3)	(5.5, 7.0)	4106	17 (0.4)	(0.2, 0.7)
	Moderate	4108	156 (3.8)	(3.2, 4.4)	4106	21 (0.5)	(0.3, 0.8)
	Severe	4108	17 (0.4)	(0.2, 0.7)	4106	4 (0.1)	(0.0, 0.2)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Pain at the injection site[e]						
	Any	4108	3455 (84.1)	(82.9, 85.2)	4106	700 (17.0)	(15.9, 18.2)
	Mild	4108	2041 (49.7)	(48.1, 51.2)	4106	660 (16.1)	(15.0, 17.2)
	Moderate	4108	1355 (33.0)	(31.5, 34.4)	4106	38 (0.9)	(0.7, 1.3)
	Severe	4108	59 (1.4)	(1.1, 1.8)	4106	2 (0.0)	(0.0, 0.2)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Any local reaction[f]	4108	3481 (84.7)	(83.6, 85.8)	4106	748 (18.2)	(17.0, 19.4)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s010 lr p3 saf

14.365. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
16-55 Years	1	Redness[d]						
		Any	2291	104 (4.5)	(3.7, 5.5)	2298	26 (1.1)	(0.7, 1.7)
		Mild	2291	70 (3.1)	(2.4, 3.8)	2298	16 (0.7)	(0.4, 1.1)
		Moderate	2291	28 (1.2)	(0.8, 1.8)	2298	6 (0.3)	(0.1, 0.6)
		Severe	2291	6 (0.3)	(0.1, 0.6)	2298	4 (0.2)	(0.0, 0.4)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Swelling[d]						
		Any	2291	132 (5.8)	(4.8, 6.8)	2298	11 (0.5)	(0.2, 0.9)
		Mild	2291	88 (3.8)	(3.1, 4.7)	2298	3 (0.1)	(0.0, 0.4)
		Moderate	2291	39 (1.7)	(1.2, 2.3)	2298	5 (0.2)	(0.1, 0.5)
		Severe	2291	5 (0.2)	(0.1, 0.5)	2298	3 (0.1)	(0.0, 0.4)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	2291	1904 (83.1)	(81.5, 84.6)	2298	322 (14.0)	(12.6, 15.5)
		Mild	2291	1170 (51.1)	(49.0, 53.1)	2298	308 (13.4)	(12.0, 14.9)
		Moderate	2291	710 (31.0)	(29.1, 32.9)	2298	12 (0.5)	(0.3, 0.9)
		Severe	2291	24 (1.0)	(0.7, 1.6)	2298	2 (0.1)	(0.0, 0.3)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Any local reaction[f]	2291	1916 (83.6)	(82.1, 85.1)	2298	338 (14.7)	(13.3, 16.2)
	2	Redness[d]						
		Any	2098	123 (5.9)	(4.9, 7.0)	2103	14 (0.7)	(0.4, 1.1)
		Mild	2098	73 (3.5)	(2.7, 4.4)	2103	8 (0.4)	(0.2, 0.7)
		Moderate	2098	40 (1.9)	(1.4, 2.6)	2103	6 (0.3)	(0.1, 0.6)
		Severe	2098	10 (0.5)	(0.2, 0.9)	2103	0	(0.0, 0.2)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Swelling[d]						
		Any	2098	132 (6.3)	(5.3, 7.4)	2103	5 (0.2)	(0.1, 0.6)
		Mild	2098	80 (3.8)	(3.0, 4.7)	2103	3 (0.1)	(0.0, 0.4)
		Moderate	2098	45 (2.1)	(1.6, 2.9)	2103	2 (0.1)	(0.0, 0.3)
		Severe	2098	7 (0.3)	(0.1, 0.7)	2103	0	(0.0, 0.2)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	2098	1632 (77.8)	(75.9, 79.6)	2103	245 (11.7)	(10.3, 13.1)

14.365. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	2098	1039 (49.5)	(47.4, 51.7)	2103	225 (10.7)	(9.4, 12.1)
		Moderate	2098	568 (27.1)	(25.2, 29.0)	2103	20 (1.0)	(0.6, 1.5)
		Severe	2098	25 (1.2)	(0.8, 1.8)	2103	0	(0.0, 0.2)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Any local reaction[f]	2098	1638 (78.1)	(76.2, 79.8)	2103	256 (12.2)	(10.8, 13.6)
	Any dose	Redness[d]						
		Any	2299	210 (9.1)	(8.0, 10.4)	2310	37 (1.6)	(1.1, 2.2)
		Mild	2299	132 (5.7)	(4.8, 6.8)	2310	21 (0.9)	(0.6, 1.4)
		Moderate	2299	62 (2.7)	(2.1, 3.4)	2310	12 (0.5)	(0.3, 0.9)
		Severe	2299	16 (0.7)	(0.4, 1.1)	2310	4 (0.2)	(0.0, 0.4)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Swelling[d]						
		Any	2299	229 (10.0)	(8.8, 11.3)	2310	15 (0.6)	(0.4, 1.1)
		Mild	2299	144 (6.3)	(5.3, 7.3)	2310	6 (0.3)	(0.1, 0.6)
		Moderate	2299	73 (3.2)	(2.5, 4.0)	2310	6 (0.3)	(0.1, 0.6)
		Severe	2299	12 (0.5)	(0.3, 0.9)	2310	3 (0.1)	(0.0, 0.4)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	2299	2032 (88.4)	(87.0, 89.7)	2310	462 (20.0)	(18.4, 21.7)
		Mild	2299	1057 (46.0)	(43.9, 48.0)	2310	430 (18.6)	(17.0, 20.3)
		Moderate	2299	928 (40.4)	(38.4, 42.4)	2310	30 (1.3)	(0.9, 1.8)
		Severe	2299	47 (2.0)	(1.5, 2.7)	2310	2 (0.1)	(0.0, 0.3)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Any local reaction[f]	2299	2040 (88.7)	(87.4, 90.0)	2310	483 (20.9)	(19.3, 22.6)
>55 Years	1	Redness[d]						
		Any	1802	85 (4.7)	(3.8, 5.8)	1792	19 (1.1)	(0.6, 1.7)
		Mild	1802	55 (3.1)	(2.3, 4.0)	1792	12 (0.7)	(0.3, 1.2)
		Moderate	1802	27 (1.5)	(1.0, 2.2)	1792	5 (0.3)	(0.1, 0.6)
		Severe	1802	3 (0.2)	(0.0, 0.5)	1792	2 (0.1)	(0.0, 0.4)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Swelling[d]						
		Any	1802	118 (6.5)	(5.4, 7.8)	1792	21 (1.2)	(0.7, 1.8)
		Mild	1802	71 (3.9)	(3.1, 4.9)	1792	10 (0.6)	(0.3, 1.0)
		Moderate	1802	45 (2.5)	(1.8, 3.3)	1792	11 (0.6)	(0.3, 1.1)
		Severe	1802	2 (0.1)	(0.0, 0.4)	1792	0	(0.0, 0.2)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)

14.365. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Pain at the injection site[e]						
		Any	1802	1282 (71.1)	(69.0, 73.2)	1792	166 (9.3)	(8.0, 10.7)
		Mild	1802	1008 (55.9)	(53.6, 58.2)	1792	160 (8.9)	(7.6, 10.3)
		Moderate	1802	270 (15.0)	(13.4, 16.7)	1792	6 (0.3)	(0.1, 0.7)
		Severe	1802	4 (0.2)	(0.1, 0.6)	1792	0	(0.0, 0.2)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Any local reaction[f]	1802	1300 (72.1)	(70.0, 74.2)	1792	187 (10.4)	(9.1, 11.9)
	2	Redness[d]						
		Any	1660	120 (7.2)	(6.0, 8.6)	1646	12 (0.7)	(0.4, 1.3)
		Mild	1660	59 (3.6)	(2.7, 4.6)	1646	8 (0.5)	(0.2, 1.0)
		Moderate	1660	53 (3.2)	(2.4, 4.2)	1646	3 (0.2)	(0.0, 0.5)
		Severe	1660	8 (0.5)	(0.2, 0.9)	1646	1 (0.1)	(0.0, 0.3)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Swelling[d]						
		Any	1660	124 (7.5)	(6.3, 8.8)	1646	11 (0.7)	(0.3, 1.2)
		Mild	1660	68 (4.1)	(3.2, 5.2)	1646	5 (0.3)	(0.1, 0.7)
		Moderate	1660	53 (3.2)	(2.4, 4.2)	1646	5 (0.3)	(0.1, 0.7)
		Severe	1660	3 (0.2)	(0.0, 0.5)	1646	1 (0.1)	(0.0, 0.3)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	1660	1098 (66.1)	(63.8, 68.4)	1646	127 (7.7)	(6.5, 9.1)
		Mild	1660	792 (47.7)	(45.3, 50.1)	1646	125 (7.6)	(6.4, 9.0)
		Moderate	1660	298 (18.0)	(16.1, 19.9)	1646	2 (0.1)	(0.0, 0.4)
		Severe	1660	8 (0.5)	(0.2, 0.9)	1646	0	(0.0, 0.2)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Any local reaction[f]	1660	1110 (66.9)	(64.5, 69.1)	1646	140 (8.5)	(7.2, 10.0)
	Any dose	Redness[d]						
		Any	1809	179 (9.9)	(8.6, 11.4)	1796	27 (1.5)	(1.0, 2.2)
		Mild	1809	101 (5.6)	(4.6, 6.7)	1796	17 (0.9)	(0.6, 1.5)
		Moderate	1809	67 (3.7)	(2.9, 4.7)	1796	8 (0.4)	(0.2, 0.9)
		Severe	1809	11 (0.6)	(0.3, 1.1)	1796	2 (0.1)	(0.0, 0.4)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Swelling[d]						
		Any	1809	201 (11.1)	(9.7, 12.7)	1796	27 (1.5)	(1.0, 2.2)
		Mild	1809	113 (6.2)	(5.2, 7.5)	1796	11 (0.6)	(0.3, 1.1)
		Moderate	1809	83 (4.6)	(3.7, 5.7)	1796	15 (0.8)	(0.5, 1.4)

14.365. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	1809	5 (0.3)	(0.1, 0.6)	1796	1 (0.1)	(0.0, 0.3)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	1809	1423 (78.7)	(76.7, 80.5)	1796	238 (13.3)	(11.7, 14.9)
		Mild	1809	984 (54.4)	(52.1, 56.7)	1796	230 (12.8)	(11.3, 14.4)
		Moderate	1809	427 (23.6)	(21.7, 25.6)	1796	8 (0.4)	(0.2, 0.9)
		Severe	1809	12 (0.7)	(0.3, 1.2)	1796	0	(0.0, 0.2)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Any local reaction[f]	1809	1441 (79.7)	(77.7, 81.5)	1796	265 (14.8)	(13.1, 16.5)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s010 lr age p3 saf

14.366. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	1	Redness[d]						
		Any	154	8 (5.2)	(2.3, 10.0)	164	5 (3.0)	(1.0, 7.0)
		Mild	154	2 (1.3)	(0.2, 4.6)	164	2 (1.2)	(0.1, 4.3)
		Moderate	154	4 (2.6)	(0.7, 6.5)	164	1 (0.6)	(0.0, 3.4)
		Severe	154	2 (1.3)	(0.2, 4.6)	164	2 (1.2)	(0.1, 4.3)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Swelling[d]						
		Any	154	13 (8.4)	(4.6, 14.0)	164	1 (0.6)	(0.0, 3.4)
		Mild	154	5 (3.2)	(1.1, 7.4)	164	0	(0.0, 2.2)
		Moderate	154	7 (4.5)	(1.8, 9.1)	164	0	(0.0, 2.2)
		Severe	154	1 (0.6)	(0.0, 3.6)	164	1 (0.6)	(0.0, 3.4)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Pain at the injection site[e]						
		Any	154	110 (71.4)	(63.6, 78.4)	164	25 (15.2)	(10.1, 21.7)
		Mild	154	63 (40.9)	(33.1, 49.1)	164	21 (12.8)	(8.1, 18.9)
		Moderate	154	44 (28.6)	(21.6, 36.4)	164	3 (1.8)	(0.4, 5.3)
		Severe	154	3 (1.9)	(0.4, 5.6)	164	1 (0.6)	(0.0, 3.4)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Any local reaction[f]	154	114 (74.0)	(66.4, 80.8)	164	27 (16.5)	(11.1, 23.0)
	2	Redness[d]						
		Any	133	5 (3.8)	(1.2, 8.6)	145	1 (0.7)	(0.0, 3.8)
		Mild	133	4 (3.0)	(0.8, 7.5)	145	0	(0.0, 2.5)
		Moderate	133	1 (0.8)	(0.0, 4.1)	145	0	(0.0, 2.5)
		Severe	133	0	(0.0, 2.7)	145	1 (0.7)	(0.0, 3.8)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Swelling[d]						
		Any	133	7 (5.3)	(2.1, 10.5)	145	1 (0.7)	(0.0, 3.8)
		Mild	133	2 (1.5)	(0.2, 5.3)	145	1 (0.7)	(0.0, 3.8)
		Moderate	133	5 (3.8)	(1.2, 8.6)	145	0	(0.0, 2.5)
		Severe	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Pain at the injection site[e]						
		Any	133	79 (59.4)	(50.5, 67.8)	145	11 (7.6)	(3.8, 13.2)

14.366. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	133	47 (35.3)	(27.3, 44.1)	145	9 (6.2)	(2.9, 11.5)
		Moderate	133	28 (21.1)	(14.5, 29.0)	145	2 (1.4)	(0.2, 4.9)
		Severe	133	4 (3.0)	(0.8, 7.5)	145	0	(0.0, 2.5)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Any local reaction[f]	133	81 (60.9)	(52.1, 69.2)	145	12 (8.3)	(4.3, 14.0)
	Any dose	Redness[d]						
		Any	154	13 (8.4)	(4.6, 14.0)	164	5 (3.0)	(1.0, 7.0)
		Mild	154	6 (3.9)	(1.4, 8.3)	164	2 (1.2)	(0.1, 4.3)
		Moderate	154	5 (3.2)	(1.1, 7.4)	164	1 (0.6)	(0.0, 3.4)
		Severe	154	2 (1.3)	(0.2, 4.6)	164	2 (1.2)	(0.1, 4.3)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Swelling[d]						
		Any	154	16 (10.4)	(6.1, 16.3)	164	2 (1.2)	(0.1, 4.3)
		Mild	154	5 (3.2)	(1.1, 7.4)	164	1 (0.6)	(0.0, 3.4)
		Moderate	154	10 (6.5)	(3.2, 11.6)	164	0	(0.0, 2.2)
		Severe	154	1 (0.6)	(0.0, 3.6)	164	1 (0.6)	(0.0, 3.4)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Pain at the injection site[e]						
		Any	154	121 (78.6)	(71.2, 84.8)	164	31 (18.9)	(13.2, 25.7)
		Mild	154	61 (39.6)	(31.8, 47.8)	164	25 (15.2)	(10.1, 21.7)
		Moderate	154	53 (34.4)	(27.0, 42.5)	164	5 (3.0)	(1.0, 7.0)
		Severe	154	7 (4.5)	(1.8, 9.1)	164	1 (0.6)	(0.0, 3.4)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Any local reaction[f]	154	124 (80.5)	(73.4, 86.5)	164	33 (20.1)	(14.3, 27.1)
Negative	1	Redness[d]						
		Any	3893	179 (4.6)	(4.0, 5.3)	3886	39 (1.0)	(0.7, 1.4)
		Mild	3893	121 (3.1)	(2.6, 3.7)	3886	26 (0.7)	(0.4, 1.0)
		Moderate	3893	51 (1.3)	(1.0, 1.7)	3886	10 (0.3)	(0.1, 0.5)
		Severe	3893	7 (0.2)	(0.1, 0.4)	3886	3 (0.1)	(0.0, 0.2)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Swelling[d]						
		Any	3893	235 (6.0)	(5.3, 6.8)	3886	30 (0.8)	(0.5, 1.1)
		Mild	3893	153 (3.9)	(3.3, 4.6)	3886	13 (0.3)	(0.2, 0.6)
		Moderate	3893	76 (2.0)	(1.5, 2.4)	3886	16 (0.4)	(0.2, 0.7)
		Severe	3893	6 (0.2)	(0.1, 0.3)	3886	1 (0.0)	(0.0, 0.1)

14.366. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	3893	3041 (78.1)	(76.8, 79.4)	3886	460 (11.8)	(10.8, 12.9)
		Mild	3893	2093 (53.8)	(52.2, 55.3)	3886	445 (11.5)	(10.5, 12.5)
		Moderate	3893	925 (23.8)	(22.4, 25.1)	3886	14 (0.4)	(0.2, 0.6)
		Severe	3893	23 (0.6)	(0.4, 0.9)	3886	1 (0.0)	(0.0, 0.1)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Any local reaction[f]	3893	3067 (78.8)	(77.5, 80.1)	3886	495 (12.7)	(11.7, 13.8)
	2	Redness[d]						
		Any	3590	237 (6.6)	(5.8, 7.5)	3568	25 (0.7)	(0.5, 1.0)
		Mild	3590	127 (3.5)	(3.0, 4.2)	3568	16 (0.4)	(0.3, 0.7)
		Moderate	3590	92 (2.6)	(2.1, 3.1)	3568	9 (0.3)	(0.1, 0.5)
		Severe	3590	18 (0.5)	(0.3, 0.8)	3568	0	(0.0, 0.1)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Swelling[d]						
		Any	3590	247 (6.9)	(6.1, 7.8)	3568	15 (0.4)	(0.2, 0.7)
		Mild	3590	144 (4.0)	(3.4, 4.7)	3568	7 (0.2)	(0.1, 0.4)
		Moderate	3590	93 (2.6)	(2.1, 3.2)	3568	7 (0.2)	(0.1, 0.4)
		Severe	3590	10 (0.3)	(0.1, 0.5)	3568	1 (0.0)	(0.0, 0.2)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	3590	2629 (73.2)	(71.8, 74.7)	3568	360 (10.1)	(9.1, 11.1)
		Mild	3590	1771 (49.3)	(47.7, 51.0)	3568	340 (9.5)	(8.6, 10.5)
		Moderate	3590	829 (23.1)	(21.7, 24.5)	3568	20 (0.6)	(0.3, 0.9)
		Severe	3590	29 (0.8)	(0.5, 1.2)	3568	0	(0.0, 0.1)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Any local reaction[f]	3590	2645 (73.7)	(72.2, 75.1)	3568	383 (10.7)	(9.7, 11.8)
	Any dose	Redness[d]						
		Any	3908	373 (9.5)	(8.6, 10.5)	3902	58 (1.5)	(1.1, 1.9)
		Mild	3908	224 (5.7)	(5.0, 6.5)	3902	36 (0.9)	(0.6, 1.3)
		Moderate	3908	124 (3.2)	(2.6, 3.8)	3902	19 (0.5)	(0.3, 0.8)
		Severe	3908	25 (0.6)	(0.4, 0.9)	3902	3 (0.1)	(0.0, 0.2)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		Swelling[d]						

14.366. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	3908	410 (10.5)	(9.5, 11.5)	3902	39 (1.0)	(0.7, 1.4)
		Mild	3908	249 (6.4)	(5.6, 7.2)	3902	16 (0.4)	(0.2, 0.7)
		Moderate	3908	145 (3.7)	(3.1, 4.4)	3902	21 (0.5)	(0.3, 0.8)
		Severe	3908	16 (0.4)	(0.2, 0.7)	3902	2 (0.1)	(0.0, 0.2)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	3908	3297 (84.4)	(83.2, 85.5)	3902	665 (17.0)	(15.9, 18.3)
		Mild	3908	1961 (50.2)	(48.6, 51.8)	3902	632 (16.2)	(15.1, 17.4)
		Moderate	3908	1286 (32.9)	(31.4, 34.4)	3902	32 (0.8)	(0.6, 1.2)
		Severe	3908	50 (1.3)	(1.0, 1.7)	3902	1 (0.0)	(0.0, 0.1)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		Any local reaction[f]	3908	3320 (85.0)	(83.8, 86.1)	3902	711 (18.2)	(17.0, 19.5)

Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (21:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s010 lr bs p3 saf

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	16-55 Years	1	Redness[d]						
			Any	114	4 (3.5)	(1.0, 8.7)	130	4 (3.1)	(0.8, 7.7)
			Mild	114	2 (1.8)	(0.2, 6.2)	130	2 (1.5)	(0.2, 5.4)
			Moderate	114	1 (0.9)	(0.0, 4.8)	130	1 (0.8)	(0.0, 4.2)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	1 (0.8)	(0.0, 4.2)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Swelling[d]						
			Any	114	10 (8.8)	(4.3, 15.5)	130	1 (0.8)	(0.0, 4.2)
			Mild	114	4 (3.5)	(1.0, 8.7)	130	0	(0.0, 2.8)
			Moderate	114	5 (4.4)	(1.4, 9.9)	130	0	(0.0, 2.8)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	1 (0.8)	(0.0, 4.2)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Pain at the injection site[e]						
			Any	114	88 (77.2)	(68.4, 84.5)	130	22 (16.9)	(10.9, 24.5)
			Mild	114	48 (42.1)	(32.9, 51.7)	130	19 (14.6)	(9.0, 21.9)
			Moderate	114	37 (32.5)	(24.0, 41.9)	130	2 (1.5)	(0.2, 5.4)
			Severe	114	3 (2.6)	(0.5, 7.5)	130	1 (0.8)	(0.0, 4.2)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Any local reaction[f]	114	89 (78.1)	(69.4, 85.3)	130	24 (18.5)	(12.2, 26.2)
		2	Redness[d]						
			Any	97	4 (4.1)	(1.1, 10.2)	114	0	(0.0, 3.2)
			Mild	97	3 (3.1)	(0.6, 8.8)	114	0	(0.0, 3.2)
			Moderate	97	1 (1.0)	(0.0, 5.6)	114	0	(0.0, 3.2)
			Severe	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Swelling[d]						
			Any	97	5 (5.2)	(1.7, 11.6)	114	1 (0.9)	(0.0, 4.8)
			Mild	97	2 (2.1)	(0.3, 7.3)	114	1 (0.9)	(0.0, 4.8)
			Moderate	97	3 (3.1)	(0.6, 8.8)	114	0	(0.0, 3.2)
			Severe	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Pain at the injection site[e]						
			Any	97	62 (63.9)	(53.5, 73.4)	114	10 (8.8)	(4.3, 15.5)
			Mild	97	36 (37.1)	(27.5, 47.5)	114	8 (7.0)	(3.1, 13.4)
			Moderate	97	23 (23.7)	(15.7, 33.4)	114	2 (1.8)	(0.2, 6.2)
			Severe	97	3 (3.1)	(0.6, 8.8)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Any local reaction[f]	97	64 (66.0)	(55.7, 75.3)	114	10 (8.8)	(4.3, 15.5)
		Any dose	Redness[d]						
			Any	114	8 (7.0)	(3.1, 13.4)	130	4 (3.1)	(0.8, 7.7)
			Mild	114	5 (4.4)	(1.4, 9.9)	130	2 (1.5)	(0.2, 5.4)
			Moderate	114	2 (1.8)	(0.2, 6.2)	130	1 (0.8)	(0.0, 4.2)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	1 (0.8)	(0.0, 4.2)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Swelling[d]						
			Any	114	13 (11.4)	(6.2, 18.7)	130	2 (1.5)	(0.2, 5.4)
			Mild	114	5 (4.4)	(1.4, 9.9)	130	1 (0.8)	(0.0, 4.2)
			Moderate	114	7 (6.1)	(2.5, 12.2)	130	0	(0.0, 2.8)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	1 (0.8)	(0.0, 4.2)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Pain at the injection site[e]						
			Any	114	94 (82.5)	(74.2, 88.9)	130	27 (20.8)	(14.2, 28.8)
			Mild	114	44 (38.6)	(29.6, 48.2)	130	22 (16.9)	(10.9, 24.5)
			Moderate	114	44 (38.6)	(29.6, 48.2)	130	4 (3.1)	(0.8, 7.7)
			Severe	114	6 (5.3)	(2.0, 11.1)	130	1 (0.8)	(0.0, 4.2)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Any local reaction[f]	114	95 (83.3)	(75.2, 89.7)	130	29 (22.3)	(15.5, 30.4)
	>55 Years	1	Redness[d]						
			Any	40	4 (10.0)	(2.8, 23.7)	34	1 (2.9)	(0.1, 15.3)
			Mild	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Moderate	40	3 (7.5)	(1.6, 20.4)	34	0	(0.0, 10.3)
			Severe	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Swelling[d]						
			Any	40	3 (7.5)	(1.6, 20.4)	34	0	(0.0, 10.3)
			Mild	40	1 (2.5)	(0.1, 13.2)	34	0	(0.0, 10.3)
			Moderate	40	2 (5.0)	(0.6, 16.9)	34	0	(0.0, 10.3)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Pain at the injection site[e]						
			Any	40	22 (55.0)	(38.5, 70.7)	34	3 (8.8)	(1.9, 23.7)
			Mild	40	15 (37.5)	(22.7, 54.2)	34	2 (5.9)	(0.7, 19.7)
			Moderate	40	7 (17.5)	(7.3, 32.8)	34	1 (2.9)	(0.1, 15.3)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Any local reaction[f]	40	25 (62.5)	(45.8, 77.3)	34	3 (8.8)	(1.9, 23.7)
		2	Redness[d]						
			Any	36	1 (2.8)	(0.1, 14.5)	31	1 (3.2)	(0.1, 16.7)
			Mild	36	1 (2.8)	(0.1, 14.5)	31	0	(0.0, 11.2)
			Moderate	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Severe	36	0	(0.0, 9.7)	31	1 (3.2)	(0.1, 16.7)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Swelling[d]						
			Any	36	2 (5.6)	(0.7, 18.7)	31	0	(0.0, 11.2)
			Mild	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Moderate	36	2 (5.6)	(0.7, 18.7)	31	0	(0.0, 11.2)
			Severe	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Pain at the injection site[e]						
			Any	36	17 (47.2)	(30.4, 64.5)	31	1 (3.2)	(0.1, 16.7)
			Mild	36	11 (30.6)	(16.3, 48.1)	31	1 (3.2)	(0.1, 16.7)
			Moderate	36	5 (13.9)	(4.7, 29.5)	31	0	(0.0, 11.2)
			Severe	36	1 (2.8)	(0.1, 14.5)	31	0	(0.0, 11.2)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Any local reaction[f]	36	17 (47.2)	(30.4, 64.5)	31	2 (6.5)	(0.8, 21.4)

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any dose	Redness[d]						
			Any	40	5 (12.5)	(4.2, 26.8)	34	1 (2.9)	(0.1, 15.3)
			Mild	40	1 (2.5)	(0.1, 13.2)	34	0	(0.0, 10.3)
			Moderate	40	3 (7.5)	(1.6, 20.4)	34	0	(0.0, 10.3)
			Severe	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Swelling[d]						
			Any	40	3 (7.5)	(1.6, 20.4)	34	0	(0.0, 10.3)
			Mild	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Moderate	40	3 (7.5)	(1.6, 20.4)	34	0	(0.0, 10.3)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Pain at the injection site[e]						
			Any	40	27 (67.5)	(50.9, 81.4)	34	4 (11.8)	(3.3, 27.5)
			Mild	40	17 (42.5)	(27.0, 59.1)	34	3 (8.8)	(1.9, 23.7)
			Moderate	40	9 (22.5)	(10.8, 38.5)	34	1 (2.9)	(0.1, 15.3)
			Severe	40	1 (2.5)	(0.1, 13.2)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Any local reaction[f]	40	29 (72.5)	(56.1, 85.4)	34	4 (11.8)	(3.3, 27.5)
Negative	16-55 Years	1	Redness[d]						
			Any	2147	100 (4.7)	(3.8, 5.6)	2148	21 (1.0)	(0.6, 1.5)
			Mild	2147	68 (3.2)	(2.5, 4.0)	2148	14 (0.7)	(0.4, 1.1)
			Moderate	2147	27 (1.3)	(0.8, 1.8)	2148	5 (0.2)	(0.1, 0.5)
			Severe	2147	5 (0.2)	(0.1, 0.5)	2148	2 (0.1)	(0.0, 0.3)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Swelling[d]						
			Any	2147	121 (5.6)	(4.7, 6.7)	2148	9 (0.4)	(0.2, 0.8)
			Mild	2147	84 (3.9)	(3.1, 4.8)	2148	3 (0.1)	(0.0, 0.4)
			Moderate	2147	33 (1.5)	(1.1, 2.2)	2148	5 (0.2)	(0.1, 0.5)
			Severe	2147	4 (0.2)	(0.1, 0.5)	2148	1 (0.0)	(0.0, 0.3)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Pain at the injection site[e]						

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Any	2147	1794 (83.6)	(81.9, 85.1)	2148	298 (13.9)	(12.4, 15.4)
			Mild	2147	1109 (51.7)	(49.5, 53.8)	2148	288 (13.4)	(12.0, 14.9)
			Moderate	2147	666 (31.0)	(29.1, 33.0)	2148	9 (0.4)	(0.2, 0.8)
			Severe	2147	19 (0.9)	(0.5, 1.4)	2148	1 (0.0)	(0.0, 0.3)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Any local reaction[f]	2147	1805 (84.1)	(82.5, 85.6)	2148	312 (14.5)	(13.1, 16.1)
		2	Redness[d]						
			Any	1982	119 (6.0)	(5.0, 7.1)	1970	14 (0.7)	(0.4, 1.2)
			Mild	1982	70 (3.5)	(2.8, 4.4)	1970	8 (0.4)	(0.2, 0.8)
			Moderate	1982	39 (2.0)	(1.4, 2.7)	1970	6 (0.3)	(0.1, 0.7)
			Severe	1982	10 (0.5)	(0.2, 0.9)	1970	0	(0.0, 0.2)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Swelling[d]						
			Any	1982	126 (6.4)	(5.3, 7.5)	1970	4 (0.2)	(0.1, 0.5)
			Mild	1982	77 (3.9)	(3.1, 4.8)	1970	2 (0.1)	(0.0, 0.4)
			Moderate	1982	42 (2.1)	(1.5, 2.9)	1970	2 (0.1)	(0.0, 0.4)
			Severe	1982	7 (0.4)	(0.1, 0.7)	1970	0	(0.0, 0.2)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Pain at the injection site[e]						
			Any	1982	1559 (78.7)	(76.8, 80.4)	1970	234 (11.9)	(10.5, 13.4)
			Mild	1982	998 (50.4)	(48.1, 52.6)	1970	216 (11.0)	(9.6, 12.4)
			Moderate	1982	539 (27.2)	(25.2, 29.2)	1970	18 (0.9)	(0.5, 1.4)
			Severe	1982	22 (1.1)	(0.7, 1.7)	1970	0	(0.0, 0.2)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Any local reaction[f]	1982	1563 (78.9)	(77.0, 80.6)	1970	245 (12.4)	(11.0, 14.0)
		Any dose	Redness[d]						
			Any	2155	202 (9.4)	(8.2, 10.7)	2160	32 (1.5)	(1.0, 2.1)
			Mild	2155	127 (5.9)	(4.9, 7.0)	2160	19 (0.9)	(0.5, 1.4)
			Moderate	2155	60 (2.8)	(2.1, 3.6)	2160	11 (0.5)	(0.3, 0.9)
			Severe	2155	15 (0.7)	(0.4, 1.1)	2160	2 (0.1)	(0.0, 0.3)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Swelling[d]						
			Any	2155	214 (9.9)	(8.7, 11.3)	2160	12 (0.6)	(0.3, 1.0)

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Mild	2155	138 (6.4)	(5.4, 7.5)	2160	5 (0.2)	(0.1, 0.5)
			Moderate	2155	65 (3.0)	(2.3, 3.8)	2160	6 (0.3)	(0.1, 0.6)
			Severe	2155	11 (0.5)	(0.3, 0.9)	2160	1 (0.0)	(0.0, 0.3)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Pain at the injection site[e]						
			Any	2155	1915 (88.9)	(87.5, 90.2)	2160	432 (20.0)	(18.3, 21.8)
			Mild	2155	1002 (46.5)	(44.4, 48.6)	2160	406 (18.8)	(17.2, 20.5)
			Moderate	2155	874 (40.6)	(38.5, 42.7)	2160	25 (1.2)	(0.8, 1.7)
			Severe	2155	39 (1.8)	(1.3, 2.5)	2160	1 (0.0)	(0.0, 0.3)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Any local reaction[f]	2155	1922 (89.2)	(87.8, 90.5)	2160	451 (20.9)	(19.2, 22.7)
	>55 Years	1	Redness[d]						
			Any	1746	79 (4.5)	(3.6, 5.6)	1738	18 (1.0)	(0.6, 1.6)
			Mild	1746	53 (3.0)	(2.3, 4.0)	1738	12 (0.7)	(0.4, 1.2)
			Moderate	1746	24 (1.4)	(0.9, 2.0)	1738	5 (0.3)	(0.1, 0.7)
			Severe	1746	2 (0.1)	(0.0, 0.4)	1738	1 (0.1)	(0.0, 0.3)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Swelling[d]						
			Any	1746	114 (6.5)	(5.4, 7.8)	1738	21 (1.2)	(0.7, 1.8)
			Mild	1746	69 (4.0)	(3.1, 5.0)	1738	10 (0.6)	(0.3, 1.1)
			Moderate	1746	43 (2.5)	(1.8, 3.3)	1738	11 (0.6)	(0.3, 1.1)
			Severe	1746	2 (0.1)	(0.0, 0.4)	1738	0	(0.0, 0.2)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Pain at the injection site[e]						
			Any	1746	1247 (71.4)	(69.2, 73.5)	1738	162 (9.3)	(8.0, 10.8)
			Mild	1746	984 (56.4)	(54.0, 58.7)	1738	157 (9.0)	(7.7, 10.5)
			Moderate	1746	259 (14.8)	(13.2, 16.6)	1738	5 (0.3)	(0.1, 0.7)
			Severe	1746	4 (0.2)	(0.1, 0.6)	1738	0	(0.0, 0.2)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Any local reaction[f]	1746	1262 (72.3)	(70.1, 74.4)	1738	183 (10.5)	(9.1, 12.1)
		2	Redness[d]						
			Any	1608	118 (7.3)	(6.1, 8.7)	1598	11 (0.7)	(0.3, 1.2)
			Mild	1608	57 (3.5)	(2.7, 4.6)	1598	8 (0.5)	(0.2, 1.0)

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Moderate	1608	53 (3.3)	(2.5, 4.3)	1598	3 (0.2)	(0.0, 0.5)
			Severe	1608	8 (0.5)	(0.2, 1.0)	1598	0	(0.0, 0.2)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Swelling[d]						
			Any	1608	121 (7.5)	(6.3, 8.9)	1598	11 (0.7)	(0.3, 1.2)
			Mild	1608	67 (4.2)	(3.2, 5.3)	1598	5 (0.3)	(0.1, 0.7)
			Moderate	1608	51 (3.2)	(2.4, 4.1)	1598	5 (0.3)	(0.1, 0.7)
			Severe	1608	3 (0.2)	(0.0, 0.5)	1598	1 (0.1)	(0.0, 0.3)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Pain at the injection site[e]						
			Any	1608	1070 (66.5)	(64.2, 68.8)	1598	126 (7.9)	(6.6, 9.3)
			Mild	1608	773 (48.1)	(45.6, 50.5)	1598	124 (7.8)	(6.5, 9.2)
			Moderate	1608	290 (18.0)	(16.2, 20.0)	1598	2 (0.1)	(0.0, 0.5)
			Severe	1608	7 (0.4)	(0.2, 0.9)	1598	0	(0.0, 0.2)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Any local reaction[f]	1608	1082 (67.3)	(64.9, 69.6)	1598	138 (8.6)	(7.3, 10.1)
		Any dose	Redness[d]						
			Any	1753	171 (9.8)	(8.4, 11.2)	1742	26 (1.5)	(1.0, 2.2)
			Mild	1753	97 (5.5)	(4.5, 6.7)	1742	17 (1.0)	(0.6, 1.6)
			Moderate	1753	64 (3.7)	(2.8, 4.6)	1742	8 (0.5)	(0.2, 0.9)
			Severe	1753	10 (0.6)	(0.3, 1.0)	1742	1 (0.1)	(0.0, 0.3)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Swelling[d]						
			Any	1753	196 (11.2)	(9.7, 12.7)	1742	27 (1.5)	(1.0, 2.2)
			Mild	1753	111 (6.3)	(5.2, 7.6)	1742	11 (0.6)	(0.3, 1.1)
			Moderate	1753	80 (4.6)	(3.6, 5.6)	1742	15 (0.9)	(0.5, 1.4)
			Severe	1753	5 (0.3)	(0.1, 0.7)	1742	1 (0.1)	(0.0, 0.3)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Pain at the injection site[e]						
			Any	1753	1382 (78.8)	(76.8, 80.7)	1742	233 (13.4)	(11.8, 15.1)
			Mild	1753	959 (54.7)	(52.3, 57.1)	1742	226 (13.0)	(11.4, 14.6)
			Moderate	1753	412 (23.5)	(21.5, 25.6)	1742	7 (0.4)	(0.2, 0.8)

14.367. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Severe	1753	11 (0.6)	(0.3, 1.1)	1742	0	(0.0, 0.2)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Any local reaction[f]	1753	1398 (79.7)	(77.8, 81.6)	1742	260 (14.9)	(13.3, 16.7)

Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (21:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s010 lr bsage p3 saf

14.368. Onset Days for Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	189	45
	Mean (SD)	2.3 (0.94)	1.7 (1.02)
	Median	2.0	1.0
	Min, max	(1, 7)	(1, 5)
	Swelling		
	n[a]	250	32
	Mean (SD)	2.0 (0.72)	1.6 (1.04)
	Median	2.0	1.0
	Min, max	(1, 5)	(1, 5)
	Pain at the injection site		
	n[a]	3186	488
	Mean (SD)	1.5 (0.56)	1.7 (1.21)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 7)
	Any local reaction[b]		
	n[a]	3216	525
	Mean (SD)	1.5 (0.55)	1.7 (1.18)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 7)
2	Redness		
	n[a]	243	26
	Mean (SD)	2.7 (0.98)	2.2 (1.44)
	Median	3.0	2.0
	Min, max	(1, 6)	(1, 6)
	Swelling		
	n[a]	256	16
	Mean (SD)	2.1 (0.83)	1.8 (1.13)
	Median	2.0	1.0
	Min, max	(1, 5)	(1, 5)
	Pain at the injection site		
	n[a]	2730	372
	Mean (SD)	1.5 (0.63)	1.5 (1.01)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 7)
	Any local reaction[b]		
	n[a]	2748	396

14.368. Onset Days for Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
	Mean (SD)	1.5 (0.63)	1.6 (1.07)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 7)

Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (21:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s050 lr onset p3 saf

14.369. Onset Days for Local Reactions, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Redness		
		n[a]	104	26
		Mean (SD)	2.3 (1.01)	1.8 (1.27)
		Median	2.0	1.0
		Min, max	(1, 7)	(1, 5)
		Swelling		
		n[a]	132	11
		Mean (SD)	2.0 (0.82)	2.0 (1.41)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 5)
		Pain at the injection site		
		n[a]	1904	322
		Mean (SD)	1.4 (0.57)	1.6 (1.21)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		
		n[a]	1916	338
		Mean (SD)	1.4 (0.55)	1.6 (1.19)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
	2	Redness		
		n[a]	123	14
		Mean (SD)	2.6 (0.97)	2.3 (1.54)
		Median	3.0	2.0
		Min, max	(1, 6)	(1, 6)
		Swelling		
		n[a]	132	5
		Mean (SD)	2.2 (0.87)	2.0 (1.00)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 3)
		Pain at the injection site		
		n[a]	1632	245
		Mean (SD)	1.4 (0.59)	1.4 (0.85)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)
		Any local reaction[b]		
		n[a]	1638	256

14.369. Onset Days for Local Reactions, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	1.4 (0.60)	1.4 (0.92)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)
>55 Years	1	Redness		
		n[a]	85	19
		Mean (SD)	2.3 (0.86)	1.6 (0.51)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 2)
		Swelling		
		n[a]	118	21
		Mean (SD)	1.9 (0.59)	1.4 (0.75)
		Median	2.0	1.0
		Min, max	(1, 4)	(1, 4)
		Pain at the injection site		
		n[a]	1282	166
		Mean (SD)	1.6 (0.52)	1.8 (1.22)
		Median	2.0	1.0
		Min, max	(1, 4)	(1, 7)
		Any local reaction[b]		
		n[a]	1300	187
		Mean (SD)	1.6 (0.52)	1.8 (1.17)
		Median	2.0	1.0
		Min, max	(1, 4)	(1, 7)
	2	Redness		
		n[a]	120	12
		Mean (SD)	2.8 (0.99)	2.1 (1.38)
		Median	3.0	2.0
		Min, max	(1, 5)	(1, 6)
		Swelling		
		n[a]	124	11
		Mean (SD)	2.1 (0.80)	1.6 (1.21)
		Median	2.0	1.0
		Min, max	(1, 4)	(1, 5)
		Pain at the injection site		
		n[a]	1098	127
		Mean (SD)	1.6 (0.66)	1.8 (1.23)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		

14.369. Onset Days for Local Reactions, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	1110	140
		Mean (SD)	1.6 (0.66)	1.8 (1.26)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)

Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (21:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s050 lr onset age p3 saf

14.370. Duration (Days) From First to Last Day of Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	189	45
	Mean (SD)	2.3 (2.26)	1.8 (1.75)
	Median	1.0	1.0
	Min, max	(1, 20)	(1, 10)
	Swelling		
	n[a]	250	32
	Mean (SD)	1.8 (1.30)	2.3 (2.29)
	Median	1.0	1.0
	Min, max	(1, 12)	(1, 11)
	Pain at the injection site		
	n[a]	3186	488
	Mean (SD)	2.1 (1.45)	1.6 (1.70)
	Median	2.0	1.0
	Min, max	(1, 22)	(1, 19)
	Unknown[b]	4	1
2	Redness		
	n[a]	243	26
	Mean (SD)	2.6 (3.10)	1.5 (1.24)
	Median	2.0	1.0
	Min, max	(1, 34)	(1, 7)
	Unknown[b]	3	0
	Swelling		
	n[a]	256	16
	Mean (SD)	2.3 (2.54)	1.9 (1.24)
	Median	2.0	1.5
	Min, max	(1, 34)	(1, 5)
	Unknown[b]	1	0
	Pain at the injection site		
	n[a]	2730	372
	Mean (SD)	2.5 (1.69)	1.7 (1.99)
	Median	2.0	1.0
	Min, max	(1, 36)	(1, 31)
	Unknown[b]	10	2

14.370. Duration (Days) From First to Last Day of Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

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

Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. For symptoms that are ongoing at the time of next dose, stop date is computed as the next dose date.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adcevd Table Generation: 17NOV2020 (21:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_s030_lr_dur_p3_saf

14.371. Duration (Days) From First to Last Day of Local Reactions, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Redness		
		n[a]	104	26
		Mean (SD)	2.1 (2.04)	1.7 (1.44)
		Median	1.0	1.0
		Min, max	(1, 14)	(1, 6)
		Swelling		
		n[a]	132	11
		Mean (SD)	1.9 (1.53)	1.6 (1.50)
		Median	1.0	1.0
		Min, max	(1, 12)	(1, 6)
		Pain at the injection site		
		n[a]	1904	322
		Mean (SD)	2.2 (1.40)	1.5 (1.42)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 17)
		Unknown[b]	4	1
	2	Redness		
		n[a]	123	14
		Mean (SD)	2.2 (1.58)	1.2 (0.43)
		Median	2.0	1.0
		Min, max	(1, 9)	(1, 2)
		Unknown[b]	1	0
		Swelling		
		n[a]	132	5
		Mean (SD)	2.1 (1.37)	2.2 (0.84)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 3)
		Unknown[b]	1	0
		Pain at the injection site		
		n[a]	1632	245
		Mean (SD)	2.4 (1.37)	1.8 (2.29)
		Median	2.0	1.0
		Min, max	(1, 10)	(1, 31)
		Unknown[b]	6	1
>55 Years	1	Redness		
		n[a]	85	19
		Mean (SD)	2.4 (2.50)	1.9 (2.15)

14.371. Duration (Days) From First to Last Day of Local Reactions, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Median	2.0	1.0
		Min, max	(1, 20)	(1, 10)
		Swelling		
		n[a]	118	21
		Mean (SD)	1.7 (0.98)	2.7 (2.57)
		Median	1.0	2.0
		Min, max	(1, 6)	(1, 11)
		Pain at the injection site		
		n[a]	1282	166
		Mean (SD)	1.9 (1.50)	1.7 (2.14)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 19)
	2	Redness		
		n[a]	120	12
		Mean (SD)	3.0 (4.08)	1.8 (1.76)
		Median	2.0	1.0
		Min, max	(1, 34)	(1, 7)
		Unknown[b]	2	0
		Swelling		
		n[a]	124	11
		Mean (SD)	2.6 (3.34)	1.8 (1.40)
		Median	2.0	1.0
		Min, max	(1, 34)	(1, 5)
		Pain at the injection site		
		n[a]	1098	127
		Mean (SD)	2.5 (2.07)	1.6 (1.20)
		Median	2.0	1.0
		Min, max	(1, 36)	(1, 7)
		Unknown[b]	4	1

Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. For symptoms that are ongoing at the time of next dose, stop date is computed as the next dose date.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adcevd Table Generation: 17NOV2020 (16:33)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_s030_lr_dur_age_p3_saf

Systemic Events

14.372. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	≥38.0°C	4093	111 (2.7)	(2.2, 3.3)	4090	27 (0.7)	(0.4, 1.0)
	≥38.0°C to 38.4°C	4093	87 (2.1)	(1.7, 2.6)	4090	12 (0.3)	(0.2, 0.5)
	>38.4°C to 38.9°C	4093	16 (0.4)	(0.2, 0.6)	4090	8 (0.2)	(0.1, 0.4)
	>38.9°C to 40.0°C	4093	7 (0.2)	(0.1, 0.4)	4090	5 (0.1)	(0.0, 0.3)
	>40.0°C	4093	1 (0.0)	(0.0, 0.1)	4090	2 (0.0)	(0.0, 0.2)
	Fatigue[d]						
	Any	4093	1700 (41.5)	(40.0, 43.1)	4090	1172 (28.7)	(27.3, 30.1)
	Mild	4093	970 (23.7)	(22.4, 25.0)	4090	719 (17.6)	(16.4, 18.8)
	Moderate	4093	695 (17.0)	(15.8, 18.2)	4090	439 (10.7)	(9.8, 11.7)
	Severe	4093	35 (0.9)	(0.6, 1.2)	4090	14 (0.3)	(0.2, 0.6)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Headache[d]						
	Any	4093	1413 (34.5)	(33.1, 36.0)	4090	1100 (26.9)	(25.5, 28.3)
	Mild	4093	976 (23.8)	(22.5, 25.2)	4090	747 (18.3)	(17.1, 19.5)
	Moderate	4093	412 (10.1)	(9.2, 11.0)	4090	331 (8.1)	(7.3, 9.0)
	Severe	4093	25 (0.6)	(0.4, 0.9)	4090	22 (0.5)	(0.3, 0.8)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Chills[d]						
	Any	4093	434 (10.6)	(9.7, 11.6)	4090	203 (5.0)	(4.3, 5.7)
	Mild	4093	317 (7.7)	(6.9, 8.6)	4090	151 (3.7)	(3.1, 4.3)
	Moderate	4093	108 (2.6)	(2.2, 3.2)	4090	49 (1.2)	(0.9, 1.6)
	Severe	4093	9 (0.2)	(0.1, 0.4)	4090	3 (0.1)	(0.0, 0.2)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Vomiting[e]						
	Any	4093	37 (0.9)	(0.6, 1.2)	4090	37 (0.9)	(0.6, 1.2)
	Mild	4093	32 (0.8)	(0.5, 1.1)	4090	31 (0.8)	(0.5, 1.1)
	Moderate	4093	5 (0.1)	(0.0, 0.3)	4090	5 (0.1)	(0.0, 0.3)
	Severe	4093	0	(0.0, 0.1)	4090	1 (0.0)	(0.0, 0.1)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Diarrhea[f]						
	Any	4093	402 (9.8)	(8.9, 10.8)	4090	388 (9.5)	(8.6, 10.4)
	Mild	4093	324 (7.9)	(7.1, 8.8)	4090	317 (7.8)	(6.9, 8.6)
	Moderate	4093	72 (1.8)	(1.4, 2.2)	4090	69 (1.7)	(1.3, 2.1)
	Severe	4093	6 (0.1)	(0.1, 0.3)	4090	2 (0.0)	(0.0, 0.2)

14.372. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	New or worsened muscle pain[d]						
	Any	4093	738 (18.0)	(16.9, 19.2)	4090	398 (9.7)	(8.8, 10.7)
	Mild	4093	424 (10.4)	(9.4, 11.3)	4090	275 (6.7)	(6.0, 7.5)
	Moderate	4093	300 (7.3)	(6.5, 8.2)	4090	118 (2.9)	(2.4, 3.4)
	Severe	4093	14 (0.3)	(0.2, 0.6)	4090	5 (0.1)	(0.0, 0.3)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	New or worsened joint pain[d]						
	Any	4093	406 (9.9)	(9.0, 10.9)	4090	247 (6.0)	(5.3, 6.8)
	Mild	4093	248 (6.1)	(5.3, 6.8)	4090	163 (4.0)	(3.4, 4.6)
	Moderate	4093	151 (3.7)	(3.1, 4.3)	4090	83 (2.0)	(1.6, 2.5)
	Severe	4093	7 (0.2)	(0.1, 0.4)	4090	1 (0.0)	(0.0, 0.1)
	Grade 4	4093	0	(0.0, 0.1)	4090	0	(0.0, 0.1)
	Any systemic event[g]	4093	2421 (59.1)	(57.6, 60.7)	4090	1922 (47.0)	(45.5, 48.5)
	Use of antipyretic or pain medication[h]	4093	996 (24.3)	(23.0, 25.7)	4090	545 (13.3)	(12.3, 14.4)
2	Fever						
	≥38.0°C	3758	512 (13.6)	(12.5, 14.8)	3749	14 (0.4)	(0.2, 0.6)
	≥38.0°C to 38.4°C	3758	325 (8.6)	(7.8, 9.6)	3749	7 (0.2)	(0.1, 0.4)
	>38.4°C to 38.9°C	3758	155 (4.1)	(3.5, 4.8)	3749	4 (0.1)	(0.0, 0.3)
	>38.9°C to 40.0°C	3758	31 (0.8)	(0.6, 1.2)	3749	3 (0.1)	(0.0, 0.2)
	>40.0°C	3758	1 (0.0)	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Fatigue[d]						
	Any	3758	2086 (55.5)	(53.9, 57.1)	3749	756 (20.2)	(18.9, 21.5)
	Mild	3758	793 (21.1)	(19.8, 22.4)	3749	409 (10.9)	(9.9, 12.0)
	Moderate	3758	1150 (30.6)	(29.1, 32.1)	3749	331 (8.8)	(7.9, 9.8)
	Severe	3758	143 (3.8)	(3.2, 4.5)	3749	16 (0.4)	(0.2, 0.7)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Headache[d]						
	Any	3758	1732 (46.1)	(44.5, 47.7)	3749	735 (19.6)	(18.3, 20.9)
	Mild	3758	960 (25.5)	(24.2, 27.0)	3749	486 (13.0)	(11.9, 14.1)
	Moderate	3758	696 (18.5)	(17.3, 19.8)	3749	230 (6.1)	(5.4, 7.0)
	Severe	3758	76 (2.0)	(1.6, 2.5)	3749	19 (0.5)	(0.3, 0.8)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Chills[d]						
	Any	3758	1114 (29.6)	(28.2, 31.1)	3749	125 (3.3)	(2.8, 4.0)
	Mild	3758	558 (14.8)	(13.7, 16.0)	3749	100 (2.7)	(2.2, 3.2)
	Moderate	3758	494 (13.1)	(12.1, 14.3)	3749	25 (0.7)	(0.4, 1.0)

14.372. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	3758	62 (1.6)	(1.3, 2.1)	3749	0	(0.0, 0.1)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Vomiting[e]						
	Any	3758	51 (1.4)	(1.0, 1.8)	3749	30 (0.8)	(0.5, 1.1)
	Mild	3758	37 (1.0)	(0.7, 1.4)	3749	21 (0.6)	(0.3, 0.9)
	Moderate	3758	9 (0.2)	(0.1, 0.5)	3749	9 (0.2)	(0.1, 0.5)
	Severe	3758	5 (0.1)	(0.0, 0.3)	3749	0	(0.0, 0.1)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Diarrhea[f]						
	Any	3758	356 (9.5)	(8.6, 10.5)	3749	276 (7.4)	(6.5, 8.2)
	Mild	3758	293 (7.8)	(7.0, 8.7)	3749	217 (5.8)	(5.1, 6.6)
	Moderate	3758	57 (1.5)	(1.2, 2.0)	3749	54 (1.4)	(1.1, 1.9)
	Severe	3758	6 (0.2)	(0.1, 0.3)	3749	5 (0.1)	(0.0, 0.3)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	New or worsened muscle pain[d]						
	Any	3758	1260 (33.5)	(32.0, 35.1)	3749	260 (6.9)	(6.1, 7.8)
	Mild	3758	528 (14.1)	(13.0, 15.2)	3749	168 (4.5)	(3.8, 5.2)
	Moderate	3758	669 (17.8)	(16.6, 19.1)	3749	88 (2.3)	(1.9, 2.9)
	Severe	3758	63 (1.7)	(1.3, 2.1)	3749	4 (0.1)	(0.0, 0.3)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	New or worsened joint pain[d]						
	Any	3758	772 (20.5)	(19.3, 21.9)	3749	170 (4.5)	(3.9, 5.3)
	Mild	3758	366 (9.7)	(8.8, 10.7)	3749	89 (2.4)	(1.9, 2.9)
	Moderate	3758	379 (10.1)	(9.1, 11.1)	3749	76 (2.0)	(1.6, 2.5)
	Severe	3758	27 (0.7)	(0.5, 1.0)	3749	5 (0.1)	(0.0, 0.3)
	Grade 4	3758	0	(0.0, 0.1)	3749	0	(0.0, 0.1)
	Any systemic event[g]	3758	2627 (69.9)	(68.4, 71.4)	3749	1267 (33.8)	(32.3, 35.3)
	Use of antipyretic or pain medication[h]	3758	1570 (41.8)	(40.2, 43.4)	3749	427 (11.4)	(10.4, 12.5)
Any dose	Fever						
	≥38.0°C	4108	582 (14.2)	(13.1, 15.3)	4106	38 (0.9)	(0.7, 1.3)
	≥38.0°C to 38.4°C	4108	378 (9.2)	(8.3, 10.1)	4106	18 (0.4)	(0.3, 0.7)
	>38.4°C to 38.9°C	4108	167 (4.1)	(3.5, 4.7)	4106	11 (0.3)	(0.1, 0.5)
	>38.9°C to 40.0°C	4108	35 (0.9)	(0.6, 1.2)	4106	7 (0.2)	(0.1, 0.4)
	>40.0°C	4108	2 (0.0)	(0.0, 0.2)	4106	2 (0.0)	(0.0, 0.2)
	Fatigue[d]						
	Any	4108	2585 (62.9)	(61.4, 64.4)	4106	1461 (35.6)	(34.1, 37.1)

14.372. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	4108	984 (24.0)	(22.7, 25.3)	4106	800 (19.5)	(18.3, 20.7)
	Moderate	4108	1429 (34.8)	(33.3, 36.3)	4106	635 (15.5)	(14.4, 16.6)
	Severe	4108	172 (4.2)	(3.6, 4.8)	4106	26 (0.6)	(0.4, 0.9)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Headache[d]						
	Any	4108	2265 (55.1)	(53.6, 56.7)	4106	1402 (34.1)	(32.7, 35.6)
	Mild	4108	1237 (30.1)	(28.7, 31.5)	4106	887 (21.6)	(20.4, 22.9)
	Moderate	4108	930 (22.6)	(21.4, 23.9)	4106	475 (11.6)	(10.6, 12.6)
	Severe	4108	98 (2.4)	(1.9, 2.9)	4106	40 (1.0)	(0.7, 1.3)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Chills[d]						
	Any	4108	1312 (31.9)	(30.5, 33.4)	4106	289 (7.0)	(6.3, 7.9)
	Mild	4108	688 (16.7)	(15.6, 17.9)	4106	219 (5.3)	(4.7, 6.1)
	Moderate	4108	553 (13.5)	(12.4, 14.5)	4106	67 (1.6)	(1.3, 2.1)
	Severe	4108	71 (1.7)	(1.4, 2.2)	4106	3 (0.1)	(0.0, 0.2)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Vomiting[e]						
	Any	4108	84 (2.0)	(1.6, 2.5)	4106	62 (1.5)	(1.2, 1.9)
	Mild	4108	66 (1.6)	(1.2, 2.0)	4106	47 (1.1)	(0.8, 1.5)
	Moderate	4108	13 (0.3)	(0.2, 0.5)	4106	14 (0.3)	(0.2, 0.6)
	Severe	4108	5 (0.1)	(0.0, 0.3)	4106	1 (0.0)	(0.0, 0.1)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Diarrhea[f]						
	Any	4108	644 (15.7)	(14.6, 16.8)	4106	576 (14.0)	(13.0, 15.1)
	Mild	4108	511 (12.4)	(11.4, 13.5)	4106	453 (11.0)	(10.1, 12.0)
	Moderate	4108	121 (2.9)	(2.4, 3.5)	4106	116 (2.8)	(2.3, 3.4)
	Severe	4108	12 (0.3)	(0.2, 0.5)	4106	7 (0.2)	(0.1, 0.4)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	New or worsened muscle pain[d]						
	Any	4108	1573 (38.3)	(36.8, 39.8)	4106	549 (13.4)	(12.3, 14.4)
	Mild	4108	659 (16.0)	(14.9, 17.2)	4106	350 (8.5)	(7.7, 9.4)
	Moderate	4108	840 (20.4)	(19.2, 21.7)	4106	190 (4.6)	(4.0, 5.3)
	Severe	4108	74 (1.8)	(1.4, 2.3)	4106	9 (0.2)	(0.1, 0.4)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	New or worsened joint pain[d]						
	Any	4108	968 (23.6)	(22.3, 24.9)	4106	360 (8.8)	(7.9, 9.7)
	Mild	4108	458 (11.1)	(10.2, 12.2)	4106	206 (5.0)	(4.4, 5.7)
	Moderate	4108	476 (11.6)	(10.6, 12.6)	4106	148 (3.6)	(3.1, 4.2)

14.372. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	4108	34 (0.8)	(0.6, 1.2)	4106	6 (0.1)	(0.1, 0.3)
	Grade 4	4108	0	(0.0, 0.1)	4106	0	(0.0, 0.1)
	Any systemic event[g]	4108	3181 (77.4)	(76.1, 78.7)	4106	2255 (54.9)	(53.4, 56.4)
	Use of antipyretic or pain medication[h]	4108	1909 (46.5)	(44.9, 48.0)	4106	810 (19.7)	(18.5, 21.0)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (21:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s020 se p3 saf

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
16-55 Years	1	Fever						
		≥38.0°C	2291	85 (3.7)	(3.0, 4.6)	2298	20 (0.9)	(0.5, 1.3)
		≥38.0°C to 38.4°C	2291	64 (2.8)	(2.2, 3.6)	2298	10 (0.4)	(0.2, 0.8)
		>38.4°C to 38.9°C	2291	15 (0.7)	(0.4, 1.1)	2298	5 (0.2)	(0.1, 0.5)
		>38.9°C to 40.0°C	2291	6 (0.3)	(0.1, 0.6)	2298	3 (0.1)	(0.0, 0.4)
		>40.0°C	2291	0	(0.0, 0.2)	2298	2 (0.1)	(0.0, 0.3)
		Fatigue[d]						
		Any	2291	1085 (47.4)	(45.3, 49.4)	2298	767 (33.4)	(31.4, 35.3)
		Mild	2291	597 (26.1)	(24.3, 27.9)	2298	467 (20.3)	(18.7, 22.0)
		Moderate	2291	455 (19.9)	(18.2, 21.6)	2298	289 (12.6)	(11.2, 14.0)
		Severe	2291	33 (1.4)	(1.0, 2.0)	2298	11 (0.5)	(0.2, 0.9)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Headache[d]						
		Any	2291	959 (41.9)	(39.8, 43.9)	2298	775 (33.7)	(31.8, 35.7)
		Mild	2291	628 (27.4)	(25.6, 29.3)	2298	505 (22.0)	(20.3, 23.7)
		Moderate	2291	308 (13.4)	(12.1, 14.9)	2298	251 (10.9)	(9.7, 12.3)
		Severe	2291	23 (1.0)	(0.6, 1.5)	2298	19 (0.8)	(0.5, 1.3)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Chills[d]						
		Any	2291	321 (14.0)	(12.6, 15.5)	2298	146 (6.4)	(5.4, 7.4)
		Mild	2291	230 (10.0)	(8.8, 11.3)	2298	111 (4.8)	(4.0, 5.8)
		Moderate	2291	82 (3.6)	(2.9, 4.4)	2298	33 (1.4)	(1.0, 2.0)
		Severe	2291	9 (0.4)	(0.2, 0.7)	2298	2 (0.1)	(0.0, 0.3)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Vomiting[e]						
		Any	2291	28 (1.2)	(0.8, 1.8)	2298	28 (1.2)	(0.8, 1.8)
		Mild	2291	24 (1.0)	(0.7, 1.6)	2298	22 (1.0)	(0.6, 1.4)
		Moderate	2291	4 (0.2)	(0.0, 0.4)	2298	5 (0.2)	(0.1, 0.5)
		Severe	2291	0	(0.0, 0.2)	2298	1 (0.0)	(0.0, 0.2)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	2291	255 (11.1)	(9.9, 12.5)	2298	270 (11.7)	(10.5, 13.1)
		Mild	2291	206 (9.0)	(7.9, 10.2)	2298	217 (9.4)	(8.3, 10.7)
		Moderate	2291	46 (2.0)	(1.5, 2.7)	2298	52 (2.3)	(1.7, 3.0)
		Severe	2291	3 (0.1)	(0.0, 0.4)	2298	1 (0.0)	(0.0, 0.2)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		New or worsened muscle pain[d]						
		Any	2291	487 (21.3)	(19.6, 23.0)	2298	249 (10.8)	(9.6, 12.2)
		Mild	2291	256 (11.2)	(9.9, 12.5)	2298	175 (7.6)	(6.6, 8.8)
		Moderate	2291	218 (9.5)	(8.3, 10.8)	2298	72 (3.1)	(2.5, 3.9)
		Severe	2291	13 (0.6)	(0.3, 1.0)	2298	2 (0.1)	(0.0, 0.3)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	2291	251 (11.0)	(9.7, 12.3)	2298	138 (6.0)	(5.1, 7.1)
		Mild	2291	147 (6.4)	(5.4, 7.5)	2298	95 (4.1)	(3.4, 5.0)
		Moderate	2291	99 (4.3)	(3.5, 5.2)	2298	43 (1.9)	(1.4, 2.5)
		Severe	2291	5 (0.2)	(0.1, 0.5)	2298	0	(0.0, 0.2)
		Grade 4	2291	0	(0.0, 0.2)	2298	0	(0.0, 0.2)
		Any systemic event[g]	2291	1538 (67.1)	(65.2, 69.1)	2298	1243 (54.1)	(52.0, 56.1)
		Use of antipyretic or pain medication[h]	2291	638 (27.8)	(26.0, 29.7)	2298	332 (14.4)	(13.0, 16.0)
	2	Fever						
		≥38.0°C	2098	331 (15.8)	(14.2, 17.4)	2103	10 (0.5)	(0.2, 0.9)
		≥38.0°C to 38.4°C	2098	194 (9.2)	(8.0, 10.6)	2103	5 (0.2)	(0.1, 0.6)
		>38.4°C to 38.9°C	2098	110 (5.2)	(4.3, 6.3)	2103	3 (0.1)	(0.0, 0.4)
		>38.9°C to 40.0°C	2098	26 (1.2)	(0.8, 1.8)	2103	2 (0.1)	(0.0, 0.3)
		>40.0°C	2098	1 (0.0)	(0.0, 0.3)	2103	0	(0.0, 0.2)
		Fatigue[d]						
		Any	2098	1247 (59.4)	(57.3, 61.5)	2103	479 (22.8)	(21.0, 24.6)
		Mild	2098	442 (21.1)	(19.3, 22.9)	2103	248 (11.8)	(10.4, 13.2)
		Moderate	2098	708 (33.7)	(31.7, 35.8)	2103	217 (10.3)	(9.1, 11.7)
		Severe	2098	97 (4.6)	(3.8, 5.6)	2103	14 (0.7)	(0.4, 1.1)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Headache[d]						
		Any	2098	1085 (51.7)	(49.6, 53.9)	2103	506 (24.1)	(22.2, 25.9)
		Mild	2098	538 (25.6)	(23.8, 27.6)	2103	321 (15.3)	(13.8, 16.9)
		Moderate	2098	480 (22.9)	(21.1, 24.7)	2103	170 (8.1)	(7.0, 9.3)
		Severe	2098	67 (3.2)	(2.5, 4.0)	2103	15 (0.7)	(0.4, 1.2)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Chills[d]						
		Any	2098	737 (35.1)	(33.1, 37.2)	2103	79 (3.8)	(3.0, 4.7)
		Mild	2098	359 (17.1)	(15.5, 18.8)	2103	65 (3.1)	(2.4, 3.9)
		Moderate	2098	333 (15.9)	(14.3, 17.5)	2103	14 (0.7)	(0.4, 1.1)

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	2098	45 (2.1)	(1.6, 2.9)	2103	0	(0.0, 0.2)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Vomiting[e]						
		Any	2098	40 (1.9)	(1.4, 2.6)	2103	25 (1.2)	(0.8, 1.7)
		Mild	2098	28 (1.3)	(0.9, 1.9)	2103	16 (0.8)	(0.4, 1.2)
		Moderate	2098	8 (0.4)	(0.2, 0.7)	2103	9 (0.4)	(0.2, 0.8)
		Severe	2098	4 (0.2)	(0.1, 0.5)	2103	0	(0.0, 0.2)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	2098	219 (10.4)	(9.2, 11.8)	2103	177 (8.4)	(7.3, 9.7)
		Mild	2098	179 (8.5)	(7.4, 9.8)	2103	144 (6.8)	(5.8, 8.0)
		Moderate	2098	36 (1.7)	(1.2, 2.4)	2103	32 (1.5)	(1.0, 2.1)
		Severe	2098	4 (0.2)	(0.1, 0.5)	2103	1 (0.0)	(0.0, 0.3)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		New or worsened muscle pain[d]						
		Any	2098	783 (37.3)	(35.2, 39.4)	2103	173 (8.2)	(7.1, 9.5)
		Mild	2098	326 (15.5)	(14.0, 17.2)	2103	111 (5.3)	(4.4, 6.3)
		Moderate	2098	410 (19.5)	(17.9, 21.3)	2103	59 (2.8)	(2.1, 3.6)
		Severe	2098	47 (2.2)	(1.7, 3.0)	2103	3 (0.1)	(0.0, 0.4)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	2098	459 (21.9)	(20.1, 23.7)	2103	109 (5.2)	(4.3, 6.2)
		Mild	2098	205 (9.8)	(8.5, 11.1)	2103	54 (2.6)	(1.9, 3.3)
		Moderate	2098	234 (11.2)	(9.8, 12.6)	2103	51 (2.4)	(1.8, 3.2)
		Severe	2098	20 (1.0)	(0.6, 1.5)	2103	4 (0.2)	(0.1, 0.5)
		Grade 4	2098	0	(0.0, 0.2)	2103	0	(0.0, 0.2)
		Any systemic event[g]	2098	1557 (74.2)	(72.3, 76.1)	2103	803 (38.2)	(36.1, 40.3)
		Use of antipyretic or pain medication[h]	2098	945 (45.0)	(42.9, 47.2)	2103	266 (12.6)	(11.3, 14.1)
	Any dose	Fever						
		≥38.0°C	2299	388 (16.9)	(15.4, 18.5)	2310	28 (1.2)	(0.8, 1.7)
		≥38.0°C to 38.4°C	2299	237 (10.3)	(9.1, 11.6)	2310	14 (0.6)	(0.3, 1.0)
		>38.4°C to 38.9°C	2299	121 (5.3)	(4.4, 6.3)	2310	8 (0.3)	(0.1, 0.7)
		>38.9°C to 40.0°C	2299	29 (1.3)	(0.8, 1.8)	2310	4 (0.2)	(0.0, 0.4)
		>40.0°C	2299	1 (0.0)	(0.0, 0.2)	2310	2 (0.1)	(0.0, 0.3)
		Fatigue[d]						

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	2299	1566 (68.1)	(66.2, 70.0)	2310	935 (40.5)	(38.5, 42.5)
		Mild	2299	547 (23.8)	(22.1, 25.6)	2310	502 (21.7)	(20.1, 23.5)
		Moderate	2299	895 (38.9)	(36.9, 41.0)	2310	412 (17.8)	(16.3, 19.5)
		Severe	2299	124 (5.4)	(4.5, 6.4)	2310	21 (0.9)	(0.6, 1.4)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Headache[d]						
		Any	2299	1441 (62.7)	(60.7, 64.7)	2310	964 (41.7)	(39.7, 43.8)
		Mild	2299	699 (30.4)	(28.5, 32.3)	2310	579 (25.1)	(23.3, 26.9)
		Moderate	2299	655 (28.5)	(26.7, 30.4)	2310	352 (15.2)	(13.8, 16.8)
		Severe	2299	87 (3.8)	(3.0, 4.6)	2310	33 (1.4)	(1.0, 2.0)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Chills[d]						
		Any	2299	877 (38.1)	(36.2, 40.2)	2310	197 (8.5)	(7.4, 9.7)
		Mild	2299	447 (19.4)	(17.8, 21.1)	2310	154 (6.7)	(5.7, 7.8)
		Moderate	2299	376 (16.4)	(14.9, 17.9)	2310	41 (1.8)	(1.3, 2.4)
		Severe	2299	54 (2.3)	(1.8, 3.1)	2310	2 (0.1)	(0.0, 0.3)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Vomiting[e]						
		Any	2299	64 (2.8)	(2.2, 3.5)	2310	48 (2.1)	(1.5, 2.7)
		Mild	2299	49 (2.1)	(1.6, 2.8)	2310	33 (1.4)	(1.0, 2.0)
		Moderate	2299	11 (0.5)	(0.2, 0.9)	2310	14 (0.6)	(0.3, 1.0)
		Severe	2299	4 (0.2)	(0.0, 0.4)	2310	1 (0.0)	(0.0, 0.2)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	2299	408 (17.7)	(16.2, 19.4)	2310	391 (16.9)	(15.4, 18.5)
		Mild	2299	325 (14.1)	(12.7, 15.6)	2310	309 (13.4)	(12.0, 14.8)
		Moderate	2299	76 (3.3)	(2.6, 4.1)	2310	80 (3.5)	(2.8, 4.3)
		Severe	2299	7 (0.3)	(0.1, 0.6)	2310	2 (0.1)	(0.0, 0.3)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		New or worsened muscle pain[d]						
		Any	2299	987 (42.9)	(40.9, 45.0)	2310	352 (15.2)	(13.8, 16.8)
		Mild	2299	394 (17.1)	(15.6, 18.7)	2310	227 (9.8)	(8.6, 11.1)
		Moderate	2299	536 (23.3)	(21.6, 25.1)	2310	120 (5.2)	(4.3, 6.2)
		Severe	2299	57 (2.5)	(1.9, 3.2)	2310	5 (0.2)	(0.1, 0.5)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	2299	587 (25.5)	(23.8, 27.4)	2310	213 (9.2)	(8.1, 10.5)

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	2299	263 (11.4)	(10.2, 12.8)	2310	124 (5.4)	(4.5, 6.4)
		Moderate	2299	299 (13.0)	(11.7, 14.4)	2310	85 (3.7)	(2.9, 4.5)
		Severe	2299	25 (1.1)	(0.7, 1.6)	2310	4 (0.2)	(0.0, 0.4)
		Grade 4	2299	0	(0.0, 0.2)	2310	0	(0.0, 0.2)
		Any systemic event[g]	2299	1903 (82.8)	(81.2, 84.3)	2310	1427 (61.8)	(59.8, 63.8)
		Use of antipyretic or pain medication[h]	2299	1163 (50.6)	(48.5, 52.7)	2310	508 (22.0)	(20.3, 23.7)
>55 Years	1	Fever						
		≥38.0°C	1802	26 (1.4)	(0.9, 2.1)	1792	7 (0.4)	(0.2, 0.8)
		≥38.0°C to 38.4°C	1802	23 (1.3)	(0.8, 1.9)	1792	2 (0.1)	(0.0, 0.4)
		>38.4°C to 38.9°C	1802	1 (0.1)	(0.0, 0.3)	1792	3 (0.2)	(0.0, 0.5)
		>38.9°C to 40.0°C	1802	1 (0.1)	(0.0, 0.3)	1792	2 (0.1)	(0.0, 0.4)
		>40.0°C	1802	1 (0.1)	(0.0, 0.3)	1792	0	(0.0, 0.2)
		Fatigue[d]						
		Any	1802	615 (34.1)	(31.9, 36.4)	1792	405 (22.6)	(20.7, 24.6)
		Mild	1802	373 (20.7)	(18.8, 22.6)	1792	252 (14.1)	(12.5, 15.8)
		Moderate	1802	240 (13.3)	(11.8, 15.0)	1792	150 (8.4)	(7.1, 9.7)
		Severe	1802	2 (0.1)	(0.0, 0.4)	1792	3 (0.2)	(0.0, 0.5)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Headache[d]						
		Any	1802	454 (25.2)	(23.2, 27.3)	1792	325 (18.1)	(16.4, 20.0)
		Mild	1802	348 (19.3)	(17.5, 21.2)	1792	242 (13.5)	(12.0, 15.2)
		Moderate	1802	104 (5.8)	(4.7, 6.9)	1792	80 (4.5)	(3.6, 5.5)
		Severe	1802	2 (0.1)	(0.0, 0.4)	1792	3 (0.2)	(0.0, 0.5)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Chills[d]						
		Any	1802	113 (6.3)	(5.2, 7.5)	1792	57 (3.2)	(2.4, 4.1)
		Mild	1802	87 (4.8)	(3.9, 5.9)	1792	40 (2.2)	(1.6, 3.0)
		Moderate	1802	26 (1.4)	(0.9, 2.1)	1792	16 (0.9)	(0.5, 1.4)
		Severe	1802	0	(0.0, 0.2)	1792	1 (0.1)	(0.0, 0.3)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Vomiting[e]						
		Any	1802	9 (0.5)	(0.2, 0.9)	1792	9 (0.5)	(0.2, 1.0)
		Mild	1802	8 (0.4)	(0.2, 0.9)	1792	9 (0.5)	(0.2, 1.0)
		Moderate	1802	1 (0.1)	(0.0, 0.3)	1792	0	(0.0, 0.2)
		Severe	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Diarrhea[f]						

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	1802	147 (8.2)	(6.9, 9.5)	1792	118 (6.6)	(5.5, 7.8)
		Mild	1802	118 (6.5)	(5.4, 7.8)	1792	100 (5.6)	(4.6, 6.7)
		Moderate	1802	26 (1.4)	(0.9, 2.1)	1792	17 (0.9)	(0.6, 1.5)
		Severe	1802	3 (0.2)	(0.0, 0.5)	1792	1 (0.1)	(0.0, 0.3)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		New or worsened muscle pain[d]						
		Any	1802	251 (13.9)	(12.4, 15.6)	1792	149 (8.3)	(7.1, 9.7)
		Mild	1802	168 (9.3)	(8.0, 10.8)	1792	100 (5.6)	(4.6, 6.7)
		Moderate	1802	82 (4.6)	(3.6, 5.6)	1792	46 (2.6)	(1.9, 3.4)
		Severe	1802	1 (0.1)	(0.0, 0.3)	1792	3 (0.2)	(0.0, 0.5)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	1802	155 (8.6)	(7.3, 10.0)	1792	109 (6.1)	(5.0, 7.3)
		Mild	1802	101 (5.6)	(4.6, 6.8)	1792	68 (3.8)	(3.0, 4.8)
		Moderate	1802	52 (2.9)	(2.2, 3.8)	1792	40 (2.2)	(1.6, 3.0)
		Severe	1802	2 (0.1)	(0.0, 0.4)	1792	1 (0.1)	(0.0, 0.3)
		Grade 4	1802	0	(0.0, 0.2)	1792	0	(0.0, 0.2)
		Any systemic event[g]	1802	883 (49.0)	(46.7, 51.3)	1792	679 (37.9)	(35.6, 40.2)
		Use of antipyretic or pain medication[h]	1802	358 (19.9)	(18.0, 21.8)	1792	213 (11.9)	(10.4, 13.5)
	2	Fever						
		≥38.0°C	1660	181 (10.9)	(9.4, 12.5)	1646	4 (0.2)	(0.1, 0.6)
		≥38.0°C to 38.4°C	1660	131 (7.9)	(6.6, 9.3)	1646	2 (0.1)	(0.0, 0.4)
		>38.4°C to 38.9°C	1660	45 (2.7)	(2.0, 3.6)	1646	1 (0.1)	(0.0, 0.3)
		>38.9°C to 40.0°C	1660	5 (0.3)	(0.1, 0.7)	1646	1 (0.1)	(0.0, 0.3)
		>40.0°C	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Fatigue[d]						
		Any	1660	839 (50.5)	(48.1, 53.0)	1646	277 (16.8)	(15.1, 18.7)
		Mild	1660	351 (21.1)	(19.2, 23.2)	1646	161 (9.8)	(8.4, 11.3)
		Moderate	1660	442 (26.6)	(24.5, 28.8)	1646	114 (6.9)	(5.7, 8.3)
		Severe	1660	46 (2.8)	(2.0, 3.7)	1646	2 (0.1)	(0.0, 0.4)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Headache[d]						
		Any	1660	647 (39.0)	(36.6, 41.4)	1646	229 (13.9)	(12.3, 15.7)
		Mild	1660	422 (25.4)	(23.3, 27.6)	1646	165 (10.0)	(8.6, 11.6)
		Moderate	1660	216 (13.0)	(11.4, 14.7)	1646	60 (3.6)	(2.8, 4.7)
		Severe	1660	9 (0.5)	(0.2, 1.0)	1646	4 (0.2)	(0.1, 0.6)

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Chills[d]						
		Any	1660	377 (22.7)	(20.7, 24.8)	1646	46 (2.8)	(2.1, 3.7)
		Mild	1660	199 (12.0)	(10.5, 13.6)	1646	35 (2.1)	(1.5, 2.9)
		Moderate	1660	161 (9.7)	(8.3, 11.2)	1646	11 (0.7)	(0.3, 1.2)
		Severe	1660	17 (1.0)	(0.6, 1.6)	1646	0	(0.0, 0.2)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Vomiting[e]						
		Any	1660	11 (0.7)	(0.3, 1.2)	1646	5 (0.3)	(0.1, 0.7)
		Mild	1660	9 (0.5)	(0.2, 1.0)	1646	5 (0.3)	(0.1, 0.7)
		Moderate	1660	1 (0.1)	(0.0, 0.3)	1646	0	(0.0, 0.2)
		Severe	1660	1 (0.1)	(0.0, 0.3)	1646	0	(0.0, 0.2)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	1660	137 (8.3)	(7.0, 9.7)	1646	99 (6.0)	(4.9, 7.3)
		Mild	1660	114 (6.9)	(5.7, 8.2)	1646	73 (4.4)	(3.5, 5.5)
		Moderate	1660	21 (1.3)	(0.8, 1.9)	1646	22 (1.3)	(0.8, 2.0)
		Severe	1660	2 (0.1)	(0.0, 0.4)	1646	4 (0.2)	(0.1, 0.6)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		New or worsened muscle pain[d]						
		Any	1660	477 (28.7)	(26.6, 31.0)	1646	87 (5.3)	(4.3, 6.5)
		Mild	1660	202 (12.2)	(10.6, 13.8)	1646	57 (3.5)	(2.6, 4.5)
		Moderate	1660	259 (15.6)	(13.9, 17.4)	1646	29 (1.8)	(1.2, 2.5)
		Severe	1660	16 (1.0)	(0.6, 1.6)	1646	1 (0.1)	(0.0, 0.3)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	1660	313 (18.9)	(17.0, 20.8)	1646	61 (3.7)	(2.8, 4.7)
		Mild	1660	161 (9.7)	(8.3, 11.2)	1646	35 (2.1)	(1.5, 2.9)
		Moderate	1660	145 (8.7)	(7.4, 10.2)	1646	25 (1.5)	(1.0, 2.2)
		Severe	1660	7 (0.4)	(0.2, 0.9)	1646	1 (0.1)	(0.0, 0.3)
		Grade 4	1660	0	(0.0, 0.2)	1646	0	(0.0, 0.2)
		Any systemic event[g]	1660	1070 (64.5)	(62.1, 66.8)	1646	464 (28.2)	(26.0, 30.4)
		Use of antipyretic or pain medication[h]	1660	625 (37.7)	(35.3, 40.0)	1646	161 (9.8)	(8.4, 11.3)
	Any dose	Fever						
		≥38.0°C	1809	194 (10.7)	(9.3, 12.2)	1796	10 (0.6)	(0.3, 1.0)

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		≥38.0°C to 38.4°C	1809	141 (7.8)	(6.6, 9.1)	1796	4 (0.2)	(0.1, 0.6)
		>38.4°C to 38.9°C	1809	46 (2.5)	(1.9, 3.4)	1796	3 (0.2)	(0.0, 0.5)
		>38.9°C to 40.0°C	1809	6 (0.3)	(0.1, 0.7)	1796	3 (0.2)	(0.0, 0.5)
		>40.0°C	1809	1 (0.1)	(0.0, 0.3)	1796	0	(0.0, 0.2)
		Fatigue[d]						
		Any	1809	1019 (56.3)	(54.0, 58.6)	1796	526 (29.3)	(27.2, 31.5)
		Mild	1809	437 (24.2)	(22.2, 26.2)	1796	298 (16.6)	(14.9, 18.4)
		Moderate	1809	534 (29.5)	(27.4, 31.7)	1796	223 (12.4)	(10.9, 14.0)
		Severe	1809	48 (2.7)	(2.0, 3.5)	1796	5 (0.3)	(0.1, 0.6)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Headache[d]						
		Any	1809	824 (45.6)	(43.2, 47.9)	1796	438 (24.4)	(22.4, 26.4)
		Mild	1809	538 (29.7)	(27.6, 31.9)	1796	308 (17.1)	(15.4, 19.0)
		Moderate	1809	275 (15.2)	(13.6, 16.9)	1796	123 (6.8)	(5.7, 8.1)
		Severe	1809	11 (0.6)	(0.3, 1.1)	1796	7 (0.4)	(0.2, 0.8)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Chills[d]						
		Any	1809	435 (24.0)	(22.1, 26.1)	1796	92 (5.1)	(4.1, 6.2)
		Mild	1809	241 (13.3)	(11.8, 15.0)	1796	65 (3.6)	(2.8, 4.6)
		Moderate	1809	177 (9.8)	(8.5, 11.2)	1796	26 (1.4)	(0.9, 2.1)
		Severe	1809	17 (0.9)	(0.5, 1.5)	1796	1 (0.1)	(0.0, 0.3)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Vomiting[e]						
		Any	1809	20 (1.1)	(0.7, 1.7)	1796	14 (0.8)	(0.4, 1.3)
		Mild	1809	17 (0.9)	(0.5, 1.5)	1796	14 (0.8)	(0.4, 1.3)
		Moderate	1809	2 (0.1)	(0.0, 0.4)	1796	0	(0.0, 0.2)
		Severe	1809	1 (0.1)	(0.0, 0.3)	1796	0	(0.0, 0.2)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	1809	236 (13.0)	(11.5, 14.7)	1796	185 (10.3)	(8.9, 11.8)
		Mild	1809	186 (10.3)	(8.9, 11.8)	1796	144 (8.0)	(6.8, 9.4)
		Moderate	1809	45 (2.5)	(1.8, 3.3)	1796	36 (2.0)	(1.4, 2.8)
		Severe	1809	5 (0.3)	(0.1, 0.6)	1796	5 (0.3)	(0.1, 0.6)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		New or worsened muscle pain[d]						
		Any	1809	586 (32.4)	(30.2, 34.6)	1796	197 (11.0)	(9.6, 12.5)
		Mild	1809	265 (14.6)	(13.1, 16.4)	1796	123 (6.8)	(5.7, 8.1)

14.373. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	1809	304 (16.8)	(15.1, 18.6)	1796	70 (3.9)	(3.1, 4.9)
		Severe	1809	17 (0.9)	(0.5, 1.5)	1796	4 (0.2)	(0.1, 0.6)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	1809	381 (21.1)	(19.2, 23.0)	1796	147 (8.2)	(7.0, 9.5)
		Mild	1809	195 (10.8)	(9.4, 12.3)	1796	82 (4.6)	(3.6, 5.6)
		Moderate	1809	177 (9.8)	(8.5, 11.2)	1796	63 (3.5)	(2.7, 4.5)
		Severe	1809	9 (0.5)	(0.2, 0.9)	1796	2 (0.1)	(0.0, 0.4)
		Grade 4	1809	0	(0.0, 0.2)	1796	0	(0.0, 0.2)
		Any systemic event[g]	1809	1278 (70.6)	(68.5, 72.7)	1796	828 (46.1)	(43.8, 48.4)
		Use of antipyretic or pain medication[h]	1809	746 (41.2)	(39.0, 43.5)	1796	302 (16.8)	(15.1, 18.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s020 se age p3 saf

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	1	Fever						
		≥38.0°C	154	19 (12.3)	(7.6, 18.6)	164	4 (2.4)	(0.7, 6.1)
		≥38.0°C to 38.4°C	154	15 (9.7)	(5.6, 15.6)	164	1 (0.6)	(0.0, 3.4)
		>38.4°C to 38.9°C	154	3 (1.9)	(0.4, 5.6)	164	1 (0.6)	(0.0, 3.4)
		>38.9°C to 40.0°C	154	1 (0.6)	(0.0, 3.6)	164	1 (0.6)	(0.0, 3.4)
		>40.0°C	154	0	(0.0, 2.4)	164	1 (0.6)	(0.0, 3.4)
		Fatigue[d]						
		Any	154	64 (41.6)	(33.7, 49.8)	164	32 (19.5)	(13.7, 26.4)
		Mild	154	24 (15.6)	(10.2, 22.3)	164	17 (10.4)	(6.2, 16.1)
		Moderate	154	39 (25.3)	(18.7, 33.0)	164	15 (9.1)	(5.2, 14.6)
		Severe	154	1 (0.6)	(0.0, 3.6)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Headache[d]						
		Any	154	56 (36.4)	(28.8, 44.5)	164	37 (22.6)	(16.4, 29.7)
		Mild	154	29 (18.8)	(13.0, 25.9)	164	27 (16.5)	(11.1, 23.0)
		Moderate	154	26 (16.9)	(11.3, 23.8)	164	7 (4.3)	(1.7, 8.6)
		Severe	154	1 (0.6)	(0.0, 3.6)	164	3 (1.8)	(0.4, 5.3)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Chills[d]						
		Any	154	36 (23.4)	(16.9, 30.9)	164	4 (2.4)	(0.7, 6.1)
		Mild	154	22 (14.3)	(9.2, 20.8)	164	2 (1.2)	(0.1, 4.3)
		Moderate	154	12 (7.8)	(4.1, 13.2)	164	2 (1.2)	(0.1, 4.3)
		Severe	154	2 (1.3)	(0.2, 4.6)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Vomiting[e]						
		Any	154	3 (1.9)	(0.4, 5.6)	164	3 (1.8)	(0.4, 5.3)
		Mild	154	3 (1.9)	(0.4, 5.6)	164	3 (1.8)	(0.4, 5.3)
		Moderate	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Severe	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Diarrhea[f]						
		Any	154	9 (5.8)	(2.7, 10.8)	164	13 (7.9)	(4.3, 13.2)
		Mild	154	8 (5.2)	(2.3, 10.0)	164	10 (6.1)	(3.0, 10.9)
		Moderate	154	1 (0.6)	(0.0, 3.6)	164	3 (1.8)	(0.4, 5.3)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		New or worsened muscle pain[d]						
		Any	154	46 (29.9)	(22.8, 37.8)	164	14 (8.5)	(4.7, 13.9)
		Mild	154	16 (10.4)	(6.1, 16.3)	164	9 (5.5)	(2.5, 10.2)
		Moderate	154	28 (18.2)	(12.4, 25.2)	164	5 (3.0)	(1.0, 7.0)
		Severe	154	2 (1.3)	(0.2, 4.6)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		New or worsened joint pain[d]						
		Any	154	27 (17.5)	(11.9, 24.5)	164	10 (6.1)	(3.0, 10.9)
		Mild	154	14 (9.1)	(5.1, 14.8)	164	4 (2.4)	(0.7, 6.1)
		Moderate	154	12 (7.8)	(4.1, 13.2)	164	6 (3.7)	(1.4, 7.8)
		Severe	154	1 (0.6)	(0.0, 3.6)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Any systemic event[g]	154	96 (62.3)	(54.2, 70.0)	164	67 (40.9)	(33.3, 48.8)
		Use of antipyretic or pain medication[h]	154	55 (35.7)	(28.2, 43.8)	164	26 (15.9)	(10.6, 22.4)
	2	Fever						
		≥38.0°C	133	10 (7.5)	(3.7, 13.4)	145	2 (1.4)	(0.2, 4.9)
		≥38.0°C to 38.4°C	133	9 (6.8)	(3.1, 12.5)	145	1 (0.7)	(0.0, 3.8)
		>38.4°C to 38.9°C	133	1 (0.8)	(0.0, 4.1)	145	1 (0.7)	(0.0, 3.8)
		>38.9°C to 40.0°C	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		>40.0°C	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Fatigue[d]						
		Any	133	44 (33.1)	(25.2, 41.8)	145	25 (17.2)	(11.5, 24.4)
		Mild	133	17 (12.8)	(7.6, 19.7)	145	11 (7.6)	(3.8, 13.2)
		Moderate	133	23 (17.3)	(11.3, 24.8)	145	13 (9.0)	(4.9, 14.8)
		Severe	133	4 (3.0)	(0.8, 7.5)	145	1 (0.7)	(0.0, 3.8)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Headache[d]						
		Any	133	43 (32.3)	(24.5, 41.0)	145	27 (18.6)	(12.6, 25.9)
		Mild	133	20 (15.0)	(9.4, 22.3)	145	16 (11.0)	(6.4, 17.3)
		Moderate	133	20 (15.0)	(9.4, 22.3)	145	8 (5.5)	(2.4, 10.6)
		Severe	133	3 (2.3)	(0.5, 6.5)	145	3 (2.1)	(0.4, 5.9)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Chills[d]						
		Any	133	23 (17.3)	(11.3, 24.8)	145	1 (0.7)	(0.0, 3.8)
		Mild	133	13 (9.8)	(5.3, 16.1)	145	1 (0.7)	(0.0, 3.8)
		Moderate	133	10 (7.5)	(3.7, 13.4)	145	0	(0.0, 2.5)
		Severe	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Vomiting[e]						
		Any	133	2 (1.5)	(0.2, 5.3)	145	3 (2.1)	(0.4, 5.9)
		Mild	133	1 (0.8)	(0.0, 4.1)	145	2 (1.4)	(0.2, 4.9)
		Moderate	133	0	(0.0, 2.7)	145	1 (0.7)	(0.0, 3.8)
		Severe	133	1 (0.8)	(0.0, 4.1)	145	0	(0.0, 2.5)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Diarrhea[f]						
		Any	133	9 (6.8)	(3.1, 12.5)	145	14 (9.7)	(5.4, 15.7)
		Mild	133	5 (3.8)	(1.2, 8.6)	145	8 (5.5)	(2.4, 10.6)
		Moderate	133	4 (3.0)	(0.8, 7.5)	145	4 (2.8)	(0.8, 6.9)
		Severe	133	0	(0.0, 2.7)	145	2 (1.4)	(0.2, 4.9)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		New or worsened muscle pain[d]						
		Any	133	37 (27.8)	(20.4, 36.3)	145	13 (9.0)	(4.9, 14.8)
		Mild	133	14 (10.5)	(5.9, 17.0)	145	6 (4.1)	(1.5, 8.8)
		Moderate	133	18 (13.5)	(8.2, 20.5)	145	7 (4.8)	(2.0, 9.7)
		Severe	133	5 (3.8)	(1.2, 8.6)	145	0	(0.0, 2.5)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		New or worsened joint pain[d]						
		Any	133	24 (18.0)	(11.9, 25.6)	145	8 (5.5)	(2.4, 10.6)
		Mild	133	10 (7.5)	(3.7, 13.4)	145	7 (4.8)	(2.0, 9.7)
		Moderate	133	14 (10.5)	(5.9, 17.0)	145	1 (0.7)	(0.0, 3.8)
		Severe	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Grade 4	133	0	(0.0, 2.7)	145	0	(0.0, 2.5)
		Any systemic event[g]	133	73 (54.9)	(46.0, 63.5)	145	45 (31.0)	(23.6, 39.2)
		Use of antipyretic or pain medication[h]	133	41 (30.8)	(23.1, 39.4)	145	14 (9.7)	(5.4, 15.7)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any dose	Fever						
		≥38.0°C	154	26 (16.9)	(11.3, 23.8)	164	6 (3.7)	(1.4, 7.8)
		≥38.0°C to 38.4°C	154	21 (13.6)	(8.6, 20.1)	164	2 (1.2)	(0.1, 4.3)
		>38.4°C to 38.9°C	154	4 (2.6)	(0.7, 6.5)	164	2 (1.2)	(0.1, 4.3)
		>38.9°C to 40.0°C	154	1 (0.6)	(0.0, 3.6)	164	1 (0.6)	(0.0, 3.4)
		>40.0°C	154	0	(0.0, 2.4)	164	1 (0.6)	(0.0, 3.4)
		Fatigue[d]						
		Any	154	78 (50.6)	(42.5, 58.8)	164	46 (28.0)	(21.3, 35.6)
		Mild	154	27 (17.5)	(11.9, 24.5)	164	22 (13.4)	(8.6, 19.6)
		Moderate	154	47 (30.5)	(23.4, 38.4)	164	23 (14.0)	(9.1, 20.3)
		Severe	154	4 (2.6)	(0.7, 6.5)	164	1 (0.6)	(0.0, 3.4)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Headache[d]						
		Any	154	72 (46.8)	(38.7, 55.0)	164	49 (29.9)	(23.0, 37.5)
		Mild	154	31 (20.1)	(14.1, 27.3)	164	30 (18.3)	(12.7, 25.1)
		Moderate	154	37 (24.0)	(17.5, 31.6)	164	13 (7.9)	(4.3, 13.2)
		Severe	154	4 (2.6)	(0.7, 6.5)	164	6 (3.7)	(1.4, 7.8)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Chills[d]						
		Any	154	45 (29.2)	(22.2, 37.1)	164	5 (3.0)	(1.0, 7.0)
		Mild	154	26 (16.9)	(11.3, 23.8)	164	3 (1.8)	(0.4, 5.3)
		Moderate	154	17 (11.0)	(6.6, 17.1)	164	2 (1.2)	(0.1, 4.3)
		Severe	154	2 (1.3)	(0.2, 4.6)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Vomiting[e]						
		Any	154	5 (3.2)	(1.1, 7.4)	164	5 (3.0)	(1.0, 7.0)
		Mild	154	4 (2.6)	(0.7, 6.5)	164	4 (2.4)	(0.7, 6.1)
		Moderate	154	0	(0.0, 2.4)	164	1 (0.6)	(0.0, 3.4)
		Severe	154	1 (0.6)	(0.0, 3.6)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Diarrhea[f]						
		Any	154	16 (10.4)	(6.1, 16.3)	164	25 (15.2)	(10.1, 21.7)
		Mild	154	11 (7.1)	(3.6, 12.4)	164	16 (9.8)	(5.7, 15.4)
		Moderate	154	5 (3.2)	(1.1, 7.4)	164	7 (4.3)	(1.7, 8.6)
		Severe	154	0	(0.0, 2.4)	164	2 (1.2)	(0.1, 4.3)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		New or worsened muscle pain[d]						
		Any	154	61 (39.6)	(31.8, 47.8)	164	23 (14.0)	(9.1, 20.3)
		Mild	154	21 (13.6)	(8.6, 20.1)	164	11 (6.7)	(3.4, 11.7)
		Moderate	154	34 (22.1)	(15.8, 29.5)	164	12 (7.3)	(3.8, 12.4)
		Severe	154	6 (3.9)	(1.4, 8.3)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		New or worsened joint pain[d]						
		Any	154	40 (26.0)	(19.2, 33.6)	164	18 (11.0)	(6.6, 16.8)
		Mild	154	18 (11.7)	(7.1, 17.8)	164	11 (6.7)	(3.4, 11.7)
		Moderate	154	21 (13.6)	(8.6, 20.1)	164	7 (4.3)	(1.7, 8.6)
		Severe	154	1 (0.6)	(0.0, 3.6)	164	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	164	0	(0.0, 2.2)
		Any systemic event[g]	154	108 (70.1)	(62.2, 77.2)	164	82 (50.0)	(42.1, 57.9)
		Use of antipyretic or pain medication[h]	154	63 (40.9)	(33.1, 49.1)	164	34 (20.7)	(14.8, 27.7)
Negative	1	Fever						
		≥38.0°C	3893	89 (2.3)	(1.8, 2.8)	3886	22 (0.6)	(0.4, 0.9)
		≥38.0°C to 38.4°C	3893	72 (1.8)	(1.4, 2.3)	3886	10 (0.3)	(0.1, 0.5)
		>38.4°C to 38.9°C	3893	11 (0.3)	(0.1, 0.5)	3886	7 (0.2)	(0.1, 0.4)
		>38.9°C to 40.0°C	3893	5 (0.1)	(0.0, 0.3)	3886	4 (0.1)	(0.0, 0.3)
		>40.0°C	3893	1 (0.0)	(0.0, 0.1)	3886	1 (0.0)	(0.0, 0.1)
		Fatigue[d]						
		Any	3893	1615 (41.5)	(39.9, 43.1)	3886	1134 (29.2)	(27.8, 30.6)
		Mild	3893	937 (24.1)	(22.7, 25.4)	3886	698 (18.0)	(16.8, 19.2)
		Moderate	3893	647 (16.6)	(15.5, 17.8)	3886	422 (10.9)	(9.9, 11.9)
		Severe	3893	31 (0.8)	(0.5, 1.1)	3886	14 (0.4)	(0.2, 0.6)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Headache[d]						
		Any	3893	1343 (34.5)	(33.0, 36.0)	3886	1056 (27.2)	(25.8, 28.6)
		Mild	3893	939 (24.1)	(22.8, 25.5)	3886	716 (18.4)	(17.2, 19.7)
		Moderate	3893	383 (9.8)	(8.9, 10.8)	3886	322 (8.3)	(7.4, 9.2)
		Severe	3893	21 (0.5)	(0.3, 0.8)	3886	18 (0.5)	(0.3, 0.7)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Chills[d]						
		Any	3893	388 (10.0)	(9.0, 11.0)	3886	198 (5.1)	(4.4, 5.8)
		Mild	3893	290 (7.4)	(6.6, 8.3)	3886	149 (3.8)	(3.3, 4.5)
		Moderate	3893	93 (2.4)	(1.9, 2.9)	3886	46 (1.2)	(0.9, 1.6)
		Severe	3893	5 (0.1)	(0.0, 0.3)	3886	3 (0.1)	(0.0, 0.2)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Vomiting[e]						
		Any	3893	33 (0.8)	(0.6, 1.2)	3886	32 (0.8)	(0.6, 1.2)
		Mild	3893	29 (0.7)	(0.5, 1.1)	3886	27 (0.7)	(0.5, 1.0)
		Moderate	3893	4 (0.1)	(0.0, 0.3)	3886	5 (0.1)	(0.0, 0.3)
		Severe	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	3893	389 (10.0)	(9.1, 11.0)	3886	372 (9.6)	(8.7, 10.5)
		Mild	3893	313 (8.0)	(7.2, 8.9)	3886	305 (7.8)	(7.0, 8.7)
		Moderate	3893	70 (1.8)	(1.4, 2.3)	3886	66 (1.7)	(1.3, 2.2)
		Severe	3893	6 (0.2)	(0.1, 0.3)	3886	1 (0.0)	(0.0, 0.1)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	3893	680 (17.5)	(16.3, 18.7)	3886	381 (9.8)	(8.9, 10.8)
		Mild	3893	404 (10.4)	(9.4, 11.4)	3886	265 (6.8)	(6.0, 7.7)
		Moderate	3893	266 (6.8)	(6.1, 7.7)	3886	111 (2.9)	(2.4, 3.4)
		Severe	3893	10 (0.3)	(0.1, 0.5)	3886	5 (0.1)	(0.0, 0.3)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	3893	375 (9.6)	(8.7, 10.6)	3886	236 (6.1)	(5.3, 6.9)
		Mild	3893	233 (6.0)	(5.3, 6.8)	3886	159 (4.1)	(3.5, 4.8)
		Moderate	3893	138 (3.5)	(3.0, 4.2)	3886	76 (2.0)	(1.5, 2.4)
		Severe	3893	4 (0.1)	(0.0, 0.3)	3886	1 (0.0)	(0.0, 0.1)
		Grade 4	3893	0	(0.0, 0.1)	3886	0	(0.0, 0.1)
		Any systemic event[g]	3893	2296 (59.0)	(57.4, 60.5)	3886	1842 (47.4)	(45.8, 49.0)
		Use of antipyretic or pain medication[h]	3893	925 (23.8)	(22.4, 25.1)	3886	512 (13.2)	(12.1, 14.3)
	2	Fever						

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		≥38.0°C	3590	500 (13.9)	(12.8, 15.1)	3568	11 (0.3)	(0.2, 0.6)
		≥38.0°C to 38.4°C	3590	315 (8.8)	(7.9, 9.7)	3568	6 (0.2)	(0.1, 0.4)
		>38.4°C to 38.9°C	3590	154 (4.3)	(3.7, 5.0)	3568	2 (0.1)	(0.0, 0.2)
		>38.9°C to 40.0°C	3590	30 (0.8)	(0.6, 1.2)	3568	3 (0.1)	(0.0, 0.2)
		>40.0°C	3590	1 (0.0)	(0.0, 0.2)	3568	0	(0.0, 0.1)
		Fatigue[d]						
		Any	3590	2025 (56.4)	(54.8, 58.0)	3568	728 (20.4)	(19.1, 21.8)
		Mild	3590	770 (21.4)	(20.1, 22.8)	3568	398 (11.2)	(10.1, 12.2)
		Moderate	3590	1117 (31.1)	(29.6, 32.7)	3568	315 (8.8)	(7.9, 9.8)
		Severe	3590	138 (3.8)	(3.2, 4.5)	3568	15 (0.4)	(0.2, 0.7)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Headache[d]						
		Any	3590	1675 (46.7)	(45.0, 48.3)	3568	702 (19.7)	(18.4, 21.0)
		Mild	3590	932 (26.0)	(24.5, 27.4)	3568	469 (13.1)	(12.1, 14.3)
		Moderate	3590	670 (18.7)	(17.4, 20.0)	3568	217 (6.1)	(5.3, 6.9)
		Severe	3590	73 (2.0)	(1.6, 2.6)	3568	16 (0.4)	(0.3, 0.7)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Chills[d]						
		Any	3590	1083 (30.2)	(28.7, 31.7)	3568	123 (3.4)	(2.9, 4.1)
		Mild	3590	542 (15.1)	(13.9, 16.3)	3568	99 (2.8)	(2.3, 3.4)
		Moderate	3590	480 (13.4)	(12.3, 14.5)	3568	24 (0.7)	(0.4, 1.0)
		Severe	3590	61 (1.7)	(1.3, 2.2)	3568	0	(0.0, 0.1)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Vomiting[e]						
		Any	3590	49 (1.4)	(1.0, 1.8)	3568	27 (0.8)	(0.5, 1.1)
		Mild	3590	36 (1.0)	(0.7, 1.4)	3568	19 (0.5)	(0.3, 0.8)
		Moderate	3590	9 (0.3)	(0.1, 0.5)	3568	8 (0.2)	(0.1, 0.4)
		Severe	3590	4 (0.1)	(0.0, 0.3)	3568	0	(0.0, 0.1)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	3590	344 (9.6)	(8.6, 10.6)	3568	260 (7.3)	(6.5, 8.2)
		Mild	3590	285 (7.9)	(7.1, 8.9)	3568	207 (5.8)	(5.1, 6.6)
		Moderate	3590	53 (1.5)	(1.1, 1.9)	3568	50 (1.4)	(1.0, 1.8)
		Severe	3590	6 (0.2)	(0.1, 0.4)	3568	3 (0.1)	(0.0, 0.2)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		New or worsened muscle pain[d]						
		Any	3590	1213 (33.8)	(32.2, 35.4)	3568	245 (6.9)	(6.1, 7.7)
		Mild	3590	511 (14.2)	(13.1, 15.4)	3568	161 (4.5)	(3.9, 5.2)
		Moderate	3590	644 (17.9)	(16.7, 19.2)	3568	80 (2.2)	(1.8, 2.8)
		Severe	3590	58 (1.6)	(1.2, 2.1)	3568	4 (0.1)	(0.0, 0.3)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	3590	740 (20.6)	(19.3, 22.0)	3568	162 (4.5)	(3.9, 5.3)
		Mild	3590	354 (9.9)	(8.9, 10.9)	3568	82 (2.3)	(1.8, 2.8)
		Moderate	3590	360 (10.0)	(9.1, 11.1)	3568	75 (2.1)	(1.7, 2.6)
		Severe	3590	26 (0.7)	(0.5, 1.1)	3568	5 (0.1)	(0.0, 0.3)
		Grade 4	3590	0	(0.0, 0.1)	3568	0	(0.0, 0.1)
		Any systemic event[g]	3590	2532 (70.5)	(69.0, 72.0)	3568	1213 (34.0)	(32.4, 35.6)
		Use of antipyretic or pain medication[h]	3590	1515 (42.2)	(40.6, 43.8)	3568	405 (11.4)	(10.3, 12.4)
	Any dose	Fever						
		≥38.0°C	3908	551 (14.1)	(13.0, 15.2)	3902	30 (0.8)	(0.5, 1.1)
		≥38.0°C to 38.4°C	3908	356 (9.1)	(8.2, 10.1)	3902	15 (0.4)	(0.2, 0.6)
		>38.4°C to 38.9°C	3908	161 (4.1)	(3.5, 4.8)	3902	8 (0.2)	(0.1, 0.4)
		>38.9°C to 40.0°C	3908	32 (0.8)	(0.6, 1.2)	3902	6 (0.2)	(0.1, 0.3)
		>40.0°C	3908	2 (0.1)	(0.0, 0.2)	3902	1 (0.0)	(0.0, 0.1)
		Fatigue[d]						
		Any	3908	2478 (63.4)	(61.9, 64.9)	3902	1407 (36.1)	(34.5, 37.6)
		Mild	3908	947 (24.2)	(22.9, 25.6)	3902	774 (19.8)	(18.6, 21.1)
		Moderate	3908	1367 (35.0)	(33.5, 36.5)	3902	608 (15.6)	(14.5, 16.8)
		Severe	3908	164 (4.2)	(3.6, 4.9)	3902	25 (0.6)	(0.4, 0.9)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		Headache[d]						
		Any	3908	2168 (55.5)	(53.9, 57.0)	3902	1342 (34.4)	(32.9, 35.9)
		Mild	3908	1192 (30.5)	(29.1, 32.0)	3902	853 (21.9)	(20.6, 23.2)
		Moderate	3908	885 (22.6)	(21.3, 24.0)	3902	456 (11.7)	(10.7, 12.7)
		Severe	3908	91 (2.3)	(1.9, 2.9)	3902	33 (0.8)	(0.6, 1.2)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Chills[d]						
		Any	3908	1251 (32.0)	(30.5, 33.5)	3902	282 (7.2)	(6.4, 8.1)
		Mild	3908	655 (16.8)	(15.6, 18.0)	3902	216 (5.5)	(4.8, 6.3)
		Moderate	3908	530 (13.6)	(12.5, 14.7)	3902	63 (1.6)	(1.2, 2.1)
		Severe	3908	66 (1.7)	(1.3, 2.1)	3902	3 (0.1)	(0.0, 0.2)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		Vomiting[e]						
		Any	3908	78 (2.0)	(1.6, 2.5)	3902	55 (1.4)	(1.1, 1.8)
		Mild	3908	62 (1.6)	(1.2, 2.0)	3902	42 (1.1)	(0.8, 1.5)
		Moderate	3908	12 (0.3)	(0.2, 0.5)	3902	13 (0.3)	(0.2, 0.6)
		Severe	3908	4 (0.1)	(0.0, 0.3)	3902	0	(0.0, 0.1)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	3908	622 (15.9)	(14.8, 17.1)	3902	546 (14.0)	(12.9, 15.1)
		Mild	3908	495 (12.7)	(11.6, 13.7)	3902	433 (11.1)	(10.1, 12.1)
		Moderate	3908	115 (2.9)	(2.4, 3.5)	3902	109 (2.8)	(2.3, 3.4)
		Severe	3908	12 (0.3)	(0.2, 0.5)	3902	4 (0.1)	(0.0, 0.3)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	3908	1493 (38.2)	(36.7, 39.7)	3902	522 (13.4)	(12.3, 14.5)
		Mild	3908	634 (16.2)	(15.1, 17.4)	3902	337 (8.6)	(7.8, 9.6)
		Moderate	3908	793 (20.3)	(19.0, 21.6)	3902	176 (4.5)	(3.9, 5.2)
		Severe	3908	66 (1.7)	(1.3, 2.1)	3902	9 (0.2)	(0.1, 0.4)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	3908	917 (23.5)	(22.1, 24.8)	3902	341 (8.7)	(7.9, 9.7)
		Mild	3908	438 (11.2)	(10.2, 12.2)	3902	195 (5.0)	(4.3, 5.7)
		Moderate	3908	449 (11.5)	(10.5, 12.5)	3902	140 (3.6)	(3.0, 4.2)
		Severe	3908	30 (0.8)	(0.5, 1.1)	3902	6 (0.2)	(0.1, 0.3)
		Grade 4	3908	0	(0.0, 0.1)	3902	0	(0.0, 0.1)
		Any systemic event[g]	3908	3038 (77.7)	(76.4, 79.0)	3902	2156 (55.3)	(53.7, 56.8)
		Use of antipyretic or pain medication[h]	3908	1822 (46.6)	(45.0, 48.2)	3902	763 (19.6)	(18.3, 20.8)

14.374. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (22:35)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_s020_se_bs_p3_saf

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	16-55 Years	1	Fever						
			≥38.0°C	114	15 (13.2)	(7.6, 20.8)	130	2 (1.5)	(0.2, 5.4)
			≥38.0°C to 38.4°C	114	11 (9.6)	(4.9, 16.6)	130	0	(0.0, 2.8)
			>38.4°C to 38.9°C	114	3 (2.6)	(0.5, 7.5)	130	0	(0.0, 2.8)
			>38.9°C to 40.0°C	114	1 (0.9)	(0.0, 4.8)	130	1 (0.8)	(0.0, 4.2)
			>40.0°C	114	0	(0.0, 3.2)	130	1 (0.8)	(0.0, 4.2)
			Fatigue[d]						
			Any	114	51 (44.7)	(35.4, 54.3)	130	26 (20.0)	(13.5, 27.9)
			Mild	114	18 (15.8)	(9.6, 23.8)	130	13 (10.0)	(5.4, 16.5)
			Moderate	114	32 (28.1)	(20.1, 37.3)	130	13 (10.0)	(5.4, 16.5)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Headache[d]						
			Any	114	47 (41.2)	(32.1, 50.8)	130	30 (23.1)	(16.1, 31.3)
			Mild	114	24 (21.1)	(14.0, 29.7)	130	22 (16.9)	(10.9, 24.5)
			Moderate	114	22 (19.3)	(12.5, 27.7)	130	5 (3.8)	(1.3, 8.7)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	3 (2.3)	(0.5, 6.6)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Chills[d]						
			Any	114	29 (25.4)	(17.7, 34.4)	130	4 (3.1)	(0.8, 7.7)
			Mild	114	18 (15.8)	(9.6, 23.8)	130	2 (1.5)	(0.2, 5.4)
			Moderate	114	9 (7.9)	(3.7, 14.5)	130	2 (1.5)	(0.2, 5.4)
			Severe	114	2 (1.8)	(0.2, 6.2)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Vomiting[e]						
			Any	114	2 (1.8)	(0.2, 6.2)	130	2 (1.5)	(0.2, 5.4)
			Mild	114	2 (1.8)	(0.2, 6.2)	130	2 (1.5)	(0.2, 5.4)
			Moderate	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Severe	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Diarrhea[f]						

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Any	114	5 (4.4)	(1.4, 9.9)	130	10 (7.7)	(3.8, 13.7)
			Mild	114	5 (4.4)	(1.4, 9.9)	130	7 (5.4)	(2.2, 10.8)
			Moderate	114	0	(0.0, 3.2)	130	3 (2.3)	(0.5, 6.6)
			Severe	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			New or worsened muscle pain[d]						
			Any	114	37 (32.5)	(24.0, 41.9)	130	10 (7.7)	(3.8, 13.7)
			Mild	114	14 (12.3)	(6.9, 19.7)	130	7 (5.4)	(2.2, 10.8)
			Moderate	114	21 (18.4)	(11.8, 26.8)	130	3 (2.3)	(0.5, 6.6)
			Severe	114	2 (1.8)	(0.2, 6.2)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			New or worsened joint pain[d]						
			Any	114	19 (16.7)	(10.3, 24.8)	130	7 (5.4)	(2.2, 10.8)
			Mild	114	8 (7.0)	(3.1, 13.4)	130	4 (3.1)	(0.8, 7.7)
			Moderate	114	10 (8.8)	(4.3, 15.5)	130	3 (2.3)	(0.5, 6.6)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Any systemic event[g]	114	77 (67.5)	(58.1, 76.0)	130	54 (41.5)	(33.0, 50.5)
			Use of antipyretic or pain medication[h]	114	43 (37.7)	(28.8, 47.3)	130	19 (14.6)	(9.0, 21.9)
		2	Fever						
			≥38.0°C	97	4 (4.1)	(1.1, 10.2)	114	2 (1.8)	(0.2, 6.2)
			≥38.0°C to 38.4°C	97	4 (4.1)	(1.1, 10.2)	114	1 (0.9)	(0.0, 4.8)
			>38.4°C to 38.9°C	97	0	(0.0, 3.7)	114	1 (0.9)	(0.0, 4.8)
			>38.9°C to 40.0°C	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			>40.0°C	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Fatigue[d]						
			Any	97	28 (28.9)	(20.1, 39.0)	114	22 (19.3)	(12.5, 27.7)
			Mild	97	11 (11.3)	(5.8, 19.4)	114	9 (7.9)	(3.7, 14.5)
			Moderate	97	14 (14.4)	(8.1, 23.0)	114	13 (11.4)	(6.2, 18.7)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Severe	97	3 (3.1)	(0.6, 8.8)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Headache[d]						
			Any	97	30 (30.9)	(21.9, 41.1)	114	22 (19.3)	(12.5, 27.7)
			Mild	97	13 (13.4)	(7.3, 21.8)	114	13 (11.4)	(6.2, 18.7)
			Moderate	97	14 (14.4)	(8.1, 23.0)	114	6 (5.3)	(2.0, 11.1)
			Severe	97	3 (3.1)	(0.6, 8.8)	114	3 (2.6)	(0.5, 7.5)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Chills[d]						
			Any	97	13 (13.4)	(7.3, 21.8)	114	1 (0.9)	(0.0, 4.8)
			Mild	97	9 (9.3)	(4.3, 16.9)	114	1 (0.9)	(0.0, 4.8)
			Moderate	97	4 (4.1)	(1.1, 10.2)	114	0	(0.0, 3.2)
			Severe	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Vomiting[e]						
			Any	97	2 (2.1)	(0.3, 7.3)	114	3 (2.6)	(0.5, 7.5)
			Mild	97	1 (1.0)	(0.0, 5.6)	114	2 (1.8)	(0.2, 6.2)
			Moderate	97	0	(0.0, 3.7)	114	1 (0.9)	(0.0, 4.8)
			Severe	97	1 (1.0)	(0.0, 5.6)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Diarrhea[f]						
			Any	97	7 (7.2)	(3.0, 14.3)	114	10 (8.8)	(4.3, 15.5)
			Mild	97	4 (4.1)	(1.1, 10.2)	114	6 (5.3)	(2.0, 11.1)
			Moderate	97	3 (3.1)	(0.6, 8.8)	114	4 (3.5)	(1.0, 8.7)
			Severe	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			New or worsened muscle pain[d]						
			Any	97	24 (24.7)	(16.5, 34.5)	114	11 (9.6)	(4.9, 16.6)
			Mild	97	10 (10.3)	(5.1, 18.1)	114	4 (3.5)	(1.0, 8.7)
			Moderate	97	10 (10.3)	(5.1, 18.1)	114	7 (6.1)	(2.5, 12.2)
			Severe	97	4 (4.1)	(1.1, 10.2)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			New or worsened joint pain[d]						

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Any	97	12 (12.4)	(6.6, 20.6)	114	7 (6.1)	(2.5, 12.2)
			Mild	97	5 (5.2)	(1.7, 11.6)	114	6 (5.3)	(2.0, 11.1)
			Moderate	97	7 (7.2)	(3.0, 14.3)	114	1 (0.9)	(0.0, 4.8)
			Severe	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Grade 4	97	0	(0.0, 3.7)	114	0	(0.0, 3.2)
			Any systemic event[g]	97	50 (51.5)	(41.2, 61.8)	114	38 (33.3)	(24.8, 42.8)
			Use of antipyretic or pain medication[h]	97	28 (28.9)	(20.1, 39.0)	114	12 (10.5)	(5.6, 17.7)
		Any dose	Fever						
			≥38.0°C	114	19 (16.7)	(10.3, 24.8)	130	4 (3.1)	(0.8, 7.7)
			≥38.0°C to 38.4°C	114	15 (13.2)	(7.6, 20.8)	130	1 (0.8)	(0.0, 4.2)
			>38.4°C to 38.9°C	114	3 (2.6)	(0.5, 7.5)	130	1 (0.8)	(0.0, 4.2)
			>38.9°C to 40.0°C	114	1 (0.9)	(0.0, 4.8)	130	1 (0.8)	(0.0, 4.2)
			>40.0°C	114	0	(0.0, 3.2)	130	1 (0.8)	(0.0, 4.2)
			Fatigue[d]						
			Any	114	59 (51.8)	(42.2, 61.2)	130	39 (30.0)	(22.3, 38.7)
			Mild	114	21 (18.4)	(11.8, 26.8)	130	18 (13.8)	(8.4, 21.0)
			Moderate	114	35 (30.7)	(22.4, 40.0)	130	21 (16.2)	(10.3, 23.6)
			Severe	114	3 (2.6)	(0.5, 7.5)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Headache[d]						
			Any	114	56 (49.1)	(39.6, 58.7)	130	39 (30.0)	(22.3, 38.7)
			Mild	114	22 (19.3)	(12.5, 27.7)	130	24 (18.5)	(12.2, 26.2)
			Moderate	114	30 (26.3)	(18.5, 35.4)	130	9 (6.9)	(3.2, 12.7)
			Severe	114	4 (3.5)	(1.0, 8.7)	130	6 (4.6)	(1.7, 9.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Chills[d]						
			Any	114	33 (28.9)	(20.8, 38.2)	130	5 (3.8)	(1.3, 8.7)
			Mild	114	21 (18.4)	(11.8, 26.8)	130	3 (2.3)	(0.5, 6.6)
			Moderate	114	10 (8.8)	(4.3, 15.5)	130	2 (1.5)	(0.2, 5.4)
			Severe	114	2 (1.8)	(0.2, 6.2)	130	0	(0.0, 2.8)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Vomiting[e]						
			Any	114	4 (3.5)	(1.0, 8.7)	130	4 (3.1)	(0.8, 7.7)
			Mild	114	3 (2.6)	(0.5, 7.5)	130	3 (2.3)	(0.5, 6.6)
			Moderate	114	0	(0.0, 3.2)	130	1 (0.8)	(0.0, 4.2)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Diarrhea[f]						
			Any	114	11 (9.6)	(4.9, 16.6)	130	20 (15.4)	(9.7, 22.8)
			Mild	114	8 (7.0)	(3.1, 13.4)	130	13 (10.0)	(5.4, 16.5)
			Moderate	114	3 (2.6)	(0.5, 7.5)	130	7 (5.4)	(2.2, 10.8)
			Severe	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			New or worsened muscle pain[d]						
			Any	114	46 (40.4)	(31.3, 49.9)	130	19 (14.6)	(9.0, 21.9)
			Mild	114	18 (15.8)	(9.6, 23.8)	130	9 (6.9)	(3.2, 12.7)
			Moderate	114	23 (20.2)	(13.2, 28.7)	130	10 (7.7)	(3.8, 13.7)
			Severe	114	5 (4.4)	(1.4, 9.9)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			New or worsened joint pain[d]						
			Any	114	26 (22.8)	(15.5, 31.6)	130	14 (10.8)	(6.0, 17.4)
			Mild	114	12 (10.5)	(5.6, 17.7)	130	10 (7.7)	(3.8, 13.7)
			Moderate	114	13 (11.4)	(6.2, 18.7)	130	4 (3.1)	(0.8, 7.7)
			Severe	114	1 (0.9)	(0.0, 4.8)	130	0	(0.0, 2.8)
			Grade 4	114	0	(0.0, 3.2)	130	0	(0.0, 2.8)
			Any systemic event[g]	114	83 (72.8)	(63.7, 80.7)	130	66 (50.8)	(41.9, 59.6)
			Use of antipyretic or pain medication[h]	114	46 (40.4)	(31.3, 49.9)	130	26 (20.0)	(13.5, 27.9)
	>55 Years	1	Fever						
			≥38.0°C	40	4 (10.0)	(2.8, 23.7)	34	2 (5.9)	(0.7, 19.7)
			≥38.0°C to 38.4°C	40	4 (10.0)	(2.8, 23.7)	34	1 (2.9)	(0.1, 15.3)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			>38.4°C to 38.9°C	40	0	(0.0, 8.8)	34	1 (2.9)	(0.1, 15.3)
			>38.9°C to 40.0°C	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			>40.0°C	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Fatigue[d]						
			Any	40	13 (32.5)	(18.6, 49.1)	34	6 (17.6)	(6.8, 34.5)
			Mild	40	6 (15.0)	(5.7, 29.8)	34	4 (11.8)	(3.3, 27.5)
			Moderate	40	7 (17.5)	(7.3, 32.8)	34	2 (5.9)	(0.7, 19.7)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Headache[d]						
			Any	40	9 (22.5)	(10.8, 38.5)	34	7 (20.6)	(8.7, 37.9)
			Mild	40	5 (12.5)	(4.2, 26.8)	34	5 (14.7)	(5.0, 31.1)
			Moderate	40	4 (10.0)	(2.8, 23.7)	34	2 (5.9)	(0.7, 19.7)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Chills[d]						
			Any	40	7 (17.5)	(7.3, 32.8)	34	0	(0.0, 10.3)
			Mild	40	4 (10.0)	(2.8, 23.7)	34	0	(0.0, 10.3)
			Moderate	40	3 (7.5)	(1.6, 20.4)	34	0	(0.0, 10.3)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Vomiting[e]						
			Any	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			Mild	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			Moderate	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Diarrhea[f]						
			Any	40	4 (10.0)	(2.8, 23.7)	34	3 (8.8)	(1.9, 23.7)
			Mild	40	3 (7.5)	(1.6, 20.4)	34	3 (8.8)	(1.9, 23.7)
			Moderate	40	1 (2.5)	(0.1, 13.2)	34	0	(0.0, 10.3)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			New or worsened muscle pain[d]						
			Any	40	9 (22.5)	(10.8, 38.5)	34	4 (11.8)	(3.3, 27.5)
			Mild	40	2 (5.0)	(0.6, 16.9)	34	2 (5.9)	(0.7, 19.7)
			Moderate	40	7 (17.5)	(7.3, 32.8)	34	2 (5.9)	(0.7, 19.7)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			New or worsened joint pain[d]						
			Any	40	8 (20.0)	(9.1, 35.6)	34	3 (8.8)	(1.9, 23.7)
			Mild	40	6 (15.0)	(5.7, 29.8)	34	0	(0.0, 10.3)
			Moderate	40	2 (5.0)	(0.6, 16.9)	34	3 (8.8)	(1.9, 23.7)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Any systemic event[g]	40	19 (47.5)	(31.5, 63.9)	34	13 (38.2)	(22.2, 56.4)
			Use of antipyretic or pain medication[h]	40	12 (30.0)	(16.6, 46.5)	34	7 (20.6)	(8.7, 37.9)
		2	Fever						
			≥38.0°C	36	6 (16.7)	(6.4, 32.8)	31	0	(0.0, 11.2)
			≥38.0°C to 38.4°C	36	5 (13.9)	(4.7, 29.5)	31	0	(0.0, 11.2)
			>38.4°C to 38.9°C	36	1 (2.8)	(0.1, 14.5)	31	0	(0.0, 11.2)
			>38.9°C to 40.0°C	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			>40.0°C	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Fatigue[d]						
			Any	36	16 (44.4)	(27.9, 61.9)	31	3 (9.7)	(2.0, 25.8)
			Mild	36	6 (16.7)	(6.4, 32.8)	31	2 (6.5)	(0.8, 21.4)
			Moderate	36	9 (25.0)	(12.1, 42.2)	31	0	(0.0, 11.2)
			Severe	36	1 (2.8)	(0.1, 14.5)	31	1 (3.2)	(0.1, 16.7)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Headache[d]						
			Any	36	13 (36.1)	(20.8, 53.8)	31	5 (16.1)	(5.5, 33.7)
			Mild	36	7 (19.4)	(8.2, 36.0)	31	3 (9.7)	(2.0, 25.8)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Moderate	36	6 (16.7)	(6.4, 32.8)	31	2 (6.5)	(0.8, 21.4)
			Severe	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Chills[d]						
			Any	36	10 (27.8)	(14.2, 45.2)	31	0	(0.0, 11.2)
			Mild	36	4 (11.1)	(3.1, 26.1)	31	0	(0.0, 11.2)
			Moderate	36	6 (16.7)	(6.4, 32.8)	31	0	(0.0, 11.2)
			Severe	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Vomiting[e]						
			Any	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Mild	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Moderate	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Severe	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Diarrhea[f]						
			Any	36	2 (5.6)	(0.7, 18.7)	31	4 (12.9)	(3.6, 29.8)
			Mild	36	1 (2.8)	(0.1, 14.5)	31	2 (6.5)	(0.8, 21.4)
			Moderate	36	1 (2.8)	(0.1, 14.5)	31	0	(0.0, 11.2)
			Severe	36	0	(0.0, 9.7)	31	2 (6.5)	(0.8, 21.4)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			New or worsened muscle pain[d]						
			Any	36	13 (36.1)	(20.8, 53.8)	31	2 (6.5)	(0.8, 21.4)
			Mild	36	4 (11.1)	(3.1, 26.1)	31	2 (6.5)	(0.8, 21.4)
			Moderate	36	8 (22.2)	(10.1, 39.2)	31	0	(0.0, 11.2)
			Severe	36	1 (2.8)	(0.1, 14.5)	31	0	(0.0, 11.2)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			New or worsened joint pain[d]						
			Any	36	12 (33.3)	(18.6, 51.0)	31	1 (3.2)	(0.1, 16.7)
			Mild	36	5 (13.9)	(4.7, 29.5)	31	1 (3.2)	(0.1, 16.7)
			Moderate	36	7 (19.4)	(8.2, 36.0)	31	0	(0.0, 11.2)
			Severe	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)
			Grade 4	36	0	(0.0, 9.7)	31	0	(0.0, 11.2)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Any systemic event[g]	36	23 (63.9)	(46.2, 79.2)	31	7 (22.6)	(9.6, 41.1)
			Use of antipyretic or pain medication[h]	36	13 (36.1)	(20.8, 53.8)	31	2 (6.5)	(0.8, 21.4)
		Any dose	Fever						
			≥38.0°C	40	7 (17.5)	(7.3, 32.8)	34	2 (5.9)	(0.7, 19.7)
			≥38.0°C to 38.4°C	40	6 (15.0)	(5.7, 29.8)	34	1 (2.9)	(0.1, 15.3)
			>38.4°C to 38.9°C	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			>38.9°C to 40.0°C	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			>40.0°C	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Fatigue[d]						
			Any	40	19 (47.5)	(31.5, 63.9)	34	7 (20.6)	(8.7, 37.9)
			Mild	40	6 (15.0)	(5.7, 29.8)	34	4 (11.8)	(3.3, 27.5)
			Moderate	40	12 (30.0)	(16.6, 46.5)	34	2 (5.9)	(0.7, 19.7)
			Severe	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Headache[d]						
			Any	40	16 (40.0)	(24.9, 56.7)	34	10 (29.4)	(15.1, 47.5)
			Mild	40	9 (22.5)	(10.8, 38.5)	34	6 (17.6)	(6.8, 34.5)
			Moderate	40	7 (17.5)	(7.3, 32.8)	34	4 (11.8)	(3.3, 27.5)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Chills[d]						
			Any	40	12 (30.0)	(16.6, 46.5)	34	0	(0.0, 10.3)
			Mild	40	5 (12.5)	(4.2, 26.8)	34	0	(0.0, 10.3)
			Moderate	40	7 (17.5)	(7.3, 32.8)	34	0	(0.0, 10.3)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Vomiting[e]						
			Any	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			Mild	40	1 (2.5)	(0.1, 13.2)	34	1 (2.9)	(0.1, 15.3)
			Moderate	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Diarrhea[f]						
			Any	40	5 (12.5)	(4.2, 26.8)	34	5 (14.7)	(5.0, 31.1)
			Mild	40	3 (7.5)	(1.6, 20.4)	34	3 (8.8)	(1.9, 23.7)
			Moderate	40	2 (5.0)	(0.6, 16.9)	34	0	(0.0, 10.3)
			Severe	40	0	(0.0, 8.8)	34	2 (5.9)	(0.7, 19.7)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			New or worsened muscle pain[d]						
			Any	40	15 (37.5)	(22.7, 54.2)	34	4 (11.8)	(3.3, 27.5)
			Mild	40	3 (7.5)	(1.6, 20.4)	34	2 (5.9)	(0.7, 19.7)
			Moderate	40	11 (27.5)	(14.6, 43.9)	34	2 (5.9)	(0.7, 19.7)
			Severe	40	1 (2.5)	(0.1, 13.2)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			New or worsened joint pain[d]						
			Any	40	14 (35.0)	(20.6, 51.7)	34	4 (11.8)	(3.3, 27.5)
			Mild	40	6 (15.0)	(5.7, 29.8)	34	1 (2.9)	(0.1, 15.3)
			Moderate	40	8 (20.0)	(9.1, 35.6)	34	3 (8.8)	(1.9, 23.7)
			Severe	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Grade 4	40	0	(0.0, 8.8)	34	0	(0.0, 10.3)
			Any systemic event[g]	40	25 (62.5)	(45.8, 77.3)	34	16 (47.1)	(29.8, 64.9)
			Use of antipyretic or pain medication[h]	40	17 (42.5)	(27.0, 59.1)	34	8 (23.5)	(10.7, 41.2)
Negative	16-55 Years	1	Fever						
			≥38.0°C	2147	68 (3.2)	(2.5, 4.0)	2148	17 (0.8)	(0.5, 1.3)
			≥38.0°C to 38.4°C	2147	53 (2.5)	(1.9, 3.2)	2148	9 (0.4)	(0.2, 0.8)
			>38.4°C to 38.9°C	2147	11 (0.5)	(0.3, 0.9)	2148	5 (0.2)	(0.1, 0.5)
			>38.9°C to 40.0°C	2147	4 (0.2)	(0.1, 0.5)	2148	2 (0.1)	(0.0, 0.3)
			>40.0°C	2147	0	(0.0, 0.2)	2148	1 (0.0)	(0.0, 0.3)
			Fatigue[d]						

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Any	2147	1019 (47.5)	(45.3, 49.6)	2148	738 (34.4)	(32.3, 36.4)
			Mild	2147	573 (26.7)	(24.8, 28.6)	2148	452 (21.0)	(19.3, 22.8)
			Moderate	2147	416 (19.4)	(17.7, 21.1)	2148	275 (12.8)	(11.4, 14.3)
			Severe	2147	30 (1.4)	(0.9, 2.0)	2148	11 (0.5)	(0.3, 0.9)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Headache[d]						
			Any	2147	902 (42.0)	(39.9, 44.1)	2148	740 (34.5)	(32.4, 36.5)
			Mild	2147	598 (27.9)	(26.0, 29.8)	2148	481 (22.4)	(20.6, 24.2)
			Moderate	2147	285 (13.3)	(11.9, 14.8)	2148	244 (11.4)	(10.0, 12.8)
			Severe	2147	19 (0.9)	(0.5, 1.4)	2148	15 (0.7)	(0.4, 1.1)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Chills[d]						
			Any	2147	285 (13.3)	(11.9, 14.8)	2148	141 (6.6)	(5.6, 7.7)
			Mild	2147	208 (9.7)	(8.5, 11.0)	2148	109 (5.1)	(4.2, 6.1)
			Moderate	2147	72 (3.4)	(2.6, 4.2)	2148	30 (1.4)	(0.9, 2.0)
			Severe	2147	5 (0.2)	(0.1, 0.5)	2148	2 (0.1)	(0.0, 0.3)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Vomiting[e]						
			Any	2147	25 (1.2)	(0.8, 1.7)	2148	24 (1.1)	(0.7, 1.7)
			Mild	2147	22 (1.0)	(0.6, 1.5)	2148	19 (0.9)	(0.5, 1.4)
			Moderate	2147	3 (0.1)	(0.0, 0.4)	2148	5 (0.2)	(0.1, 0.5)
			Severe	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Diarrhea[f]						
			Any	2147	248 (11.6)	(10.2, 13.0)	2148	258 (12.0)	(10.7, 13.5)
			Mild	2147	199 (9.3)	(8.1, 10.6)	2148	209 (9.7)	(8.5, 11.1)
			Moderate	2147	46 (2.1)	(1.6, 2.8)	2148	49 (2.3)	(1.7, 3.0)
			Severe	2147	3 (0.1)	(0.0, 0.4)	2148	0	(0.0, 0.2)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			New or worsened muscle pain[d]						
			Any	2147	441 (20.5)	(18.8, 22.3)	2148	238 (11.1)	(9.8, 12.5)
			Mild	2147	239 (11.1)	(9.8, 12.5)	2148	168 (7.8)	(6.7, 9.0)
			Moderate	2147	193 (9.0)	(7.8, 10.3)	2148	68 (3.2)	(2.5, 4.0)
			Severe	2147	9 (0.4)	(0.2, 0.8)	2148	2 (0.1)	(0.0, 0.3)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			New or worsened joint pain[d]						
			Any	2147	230 (10.7)	(9.4, 12.1)	2148	130 (6.1)	(5.1, 7.1)
			Mild	2147	139 (6.5)	(5.5, 7.6)	2148	91 (4.2)	(3.4, 5.2)
			Moderate	2147	88 (4.1)	(3.3, 5.0)	2148	39 (1.8)	(1.3, 2.5)
			Severe	2147	3 (0.1)	(0.0, 0.4)	2148	0	(0.0, 0.2)
			Grade 4	2147	0	(0.0, 0.2)	2148	0	(0.0, 0.2)
			Any systemic event[g]	2147	1441 (67.1)	(65.1, 69.1)	2148	1182 (55.0)	(52.9, 57.1)
			Use of antipyretic or pain medication[h]	2147	585 (27.2)	(25.4, 29.2)	2148	309 (14.4)	(12.9, 15.9)
		2	Fever						
			≥38.0°C	1982	325 (16.4)	(14.8, 18.1)	1970	8 (0.4)	(0.2, 0.8)
			≥38.0°C to 38.4°C	1982	189 (9.5)	(8.3, 10.9)	1970	4 (0.2)	(0.1, 0.5)
			>38.4°C to 38.9°C	1982	110 (5.5)	(4.6, 6.7)	1970	2 (0.1)	(0.0, 0.4)
			>38.9°C to 40.0°C	1982	25 (1.3)	(0.8, 1.9)	1970	2 (0.1)	(0.0, 0.4)
			>40.0°C	1982	1 (0.1)	(0.0, 0.3)	1970	0	(0.0, 0.2)
			Fatigue[d]						
			Any	1982	1210 (61.0)	(58.9, 63.2)	1970	455 (23.1)	(21.3, 25.0)
			Mild	1982	430 (21.7)	(19.9, 23.6)	1970	239 (12.1)	(10.7, 13.7)
			Moderate	1982	687 (34.7)	(32.6, 36.8)	1970	202 (10.3)	(8.9, 11.7)
			Severe	1982	93 (4.7)	(3.8, 5.7)	1970	14 (0.7)	(0.4, 1.2)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Headache[d]						
			Any	1982	1048 (52.9)	(50.7, 55.1)	1970	479 (24.3)	(22.4, 26.3)
			Mild	1982	523 (26.4)	(24.5, 28.4)	1970	307 (15.6)	(14.0, 17.3)
			Moderate	1982	461 (23.3)	(21.4, 25.2)	1970	160 (8.1)	(7.0, 9.4)
			Severe	1982	64 (3.2)	(2.5, 4.1)	1970	12 (0.6)	(0.3, 1.1)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Chills[d]						
			Any	1982	718 (36.2)	(34.1, 38.4)	1970	78 (4.0)	(3.1, 4.9)
			Mild	1982	347 (17.5)	(15.9, 19.3)	1970	64 (3.2)	(2.5, 4.1)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Moderate	1982	327 (16.5)	(14.9, 18.2)	1970	14 (0.7)	(0.4, 1.2)
			Severe	1982	44 (2.2)	(1.6, 3.0)	1970	0	(0.0, 0.2)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Vomiting[e]						
			Any	1982	38 (1.9)	(1.4, 2.6)	1970	22 (1.1)	(0.7, 1.7)
			Mild	1982	27 (1.4)	(0.9, 2.0)	1970	14 (0.7)	(0.4, 1.2)
			Moderate	1982	8 (0.4)	(0.2, 0.8)	1970	8 (0.4)	(0.2, 0.8)
			Severe	1982	3 (0.2)	(0.0, 0.4)	1970	0	(0.0, 0.2)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Diarrhea[f]						
			Any	1982	209 (10.5)	(9.2, 12.0)	1970	165 (8.4)	(7.2, 9.7)
			Mild	1982	172 (8.7)	(7.5, 10.0)	1970	136 (6.9)	(5.8, 8.1)
			Moderate	1982	33 (1.7)	(1.1, 2.3)	1970	28 (1.4)	(0.9, 2.0)
			Severe	1982	4 (0.2)	(0.1, 0.5)	1970	1 (0.1)	(0.0, 0.3)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			New or worsened muscle pain[d]						
			Any	1982	752 (37.9)	(35.8, 40.1)	1970	161 (8.2)	(7.0, 9.5)
			Mild	1982	315 (15.9)	(14.3, 17.6)	1970	106 (5.4)	(4.4, 6.5)
			Moderate	1982	394 (19.9)	(18.1, 21.7)	1970	52 (2.6)	(2.0, 3.4)
			Severe	1982	43 (2.2)	(1.6, 2.9)	1970	3 (0.2)	(0.0, 0.4)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			New or worsened joint pain[d]						
			Any	1982	441 (22.3)	(20.4, 24.1)	1970	102 (5.2)	(4.2, 6.3)
			Mild	1982	199 (10.0)	(8.8, 11.4)	1970	48 (2.4)	(1.8, 3.2)
			Moderate	1982	223 (11.3)	(9.9, 12.7)	1970	50 (2.5)	(1.9, 3.3)
			Severe	1982	19 (1.0)	(0.6, 1.5)	1970	4 (0.2)	(0.1, 0.5)
			Grade 4	1982	0	(0.0, 0.2)	1970	0	(0.0, 0.2)
			Any systemic event[g]	1982	1495 (75.4)	(73.5, 77.3)	1970	758 (38.5)	(36.3, 40.7)
			Use of antipyretic or pain medication[h]	1982	910 (45.9)	(43.7, 48.1)	1970	248 (12.6)	(11.2, 14.1)
		Any dose	Fever						
			≥38.0°C	2155	365 (16.9)	(15.4, 18.6)	2160	23 (1.1)	(0.7, 1.6)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			≥38.0°C to 38.4°C	2155	221 (10.3)	(9.0, 11.6)	2160	12 (0.6)	(0.3, 1.0)
			>38.4°C to 38.9°C	2155	117 (5.4)	(4.5, 6.5)	2160	7 (0.3)	(0.1, 0.7)
			>38.9°C to 40.0°C	2155	26 (1.2)	(0.8, 1.8)	2160	3 (0.1)	(0.0, 0.4)
			>40.0°C	2155	1 (0.0)	(0.0, 0.3)	2160	1 (0.0)	(0.0, 0.3)
			Fatigue[d]						
			Any	2155	1488 (69.0)	(67.0, 71.0)	2160	891 (41.3)	(39.2, 43.4)
			Mild	2155	521 (24.2)	(22.4, 26.0)	2160	482 (22.3)	(20.6, 24.1)
			Moderate	2155	849 (39.4)	(37.3, 41.5)	2160	388 (18.0)	(16.4, 19.6)
			Severe	2155	118 (5.5)	(4.6, 6.5)	2160	21 (1.0)	(0.6, 1.5)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Headache[d]						
			Any	2155	1369 (63.5)	(61.5, 65.6)	2160	917 (42.5)	(40.4, 44.6)
			Mild	2155	670 (31.1)	(29.1, 33.1)	2160	553 (25.6)	(23.8, 27.5)
			Moderate	2155	619 (28.7)	(26.8, 30.7)	2160	338 (15.6)	(14.1, 17.2)
			Severe	2155	80 (3.7)	(3.0, 4.6)	2160	26 (1.2)	(0.8, 1.8)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Chills[d]						
			Any	2155	832 (38.6)	(36.5, 40.7)	2160	191 (8.8)	(7.7, 10.1)
			Mild	2155	420 (19.5)	(17.8, 21.2)	2160	151 (7.0)	(6.0, 8.1)
			Moderate	2155	363 (16.8)	(15.3, 18.5)	2160	38 (1.8)	(1.2, 2.4)
			Severe	2155	49 (2.3)	(1.7, 3.0)	2160	2 (0.1)	(0.0, 0.3)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Vomiting[e]						
			Any	2155	59 (2.7)	(2.1, 3.5)	2160	42 (1.9)	(1.4, 2.6)
			Mild	2155	46 (2.1)	(1.6, 2.8)	2160	29 (1.3)	(0.9, 1.9)
			Moderate	2155	10 (0.5)	(0.2, 0.9)	2160	13 (0.6)	(0.3, 1.0)
			Severe	2155	3 (0.1)	(0.0, 0.4)	2160	0	(0.0, 0.2)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Diarrhea[f]						
			Any	2155	393 (18.2)	(16.6, 19.9)	2160	367 (17.0)	(15.4, 18.6)
			Mild	2155	313 (14.5)	(13.1, 16.1)	2160	293 (13.6)	(12.1, 15.1)
			Moderate	2155	73 (3.4)	(2.7, 4.2)	2160	73 (3.4)	(2.7, 4.2)
			Severe	2155	7 (0.3)	(0.1, 0.7)	2160	1 (0.0)	(0.0, 0.3)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			New or worsened muscle pain[d]						
			Any	2155	927 (43.0)	(40.9, 45.1)	2160	331 (15.3)	(13.8, 16.9)
			Mild	2155	374 (17.4)	(15.8, 19.0)	2160	217 (10.0)	(8.8, 11.4)
			Moderate	2155	503 (23.3)	(21.6, 25.2)	2160	109 (5.0)	(4.2, 6.1)
			Severe	2155	50 (2.3)	(1.7, 3.0)	2160	5 (0.2)	(0.1, 0.5)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			New or worsened joint pain[d]						
			Any	2155	553 (25.7)	(23.8, 27.6)	2160	198 (9.2)	(8.0, 10.5)
			Mild	2155	250 (11.6)	(10.3, 13.0)	2160	114 (5.3)	(4.4, 6.3)
			Moderate	2155	281 (13.0)	(11.6, 14.5)	2160	80 (3.7)	(2.9, 4.6)
			Severe	2155	22 (1.0)	(0.6, 1.5)	2160	4 (0.2)	(0.1, 0.5)
			Grade 4	2155	0	(0.0, 0.2)	2160	0	(0.0, 0.2)
			Any systemic event[g]	2155	1796 (83.3)	(81.7, 84.9)	2160	1350 (62.5)	(60.4, 64.5)
			Use of antipyretic or pain medication[h]	2155	1103 (51.2)	(49.0, 53.3)	2160	473 (21.9)	(20.2, 23.7)
	>55 Years	1	Fever						
			≥38.0°C	1746	21 (1.2)	(0.7, 1.8)	1738	5 (0.3)	(0.1, 0.7)
			≥38.0°C to 38.4°C	1746	19 (1.1)	(0.7, 1.7)	1738	1 (0.1)	(0.0, 0.3)
			>38.4°C to 38.9°C	1746	0	(0.0, 0.2)	1738	2 (0.1)	(0.0, 0.4)
			>38.9°C to 40.0°C	1746	1 (0.1)	(0.0, 0.3)	1738	2 (0.1)	(0.0, 0.4)
			>40.0°C	1746	1 (0.1)	(0.0, 0.3)	1738	0	(0.0, 0.2)
			Fatigue[d]						
			Any	1746	596 (34.1)	(31.9, 36.4)	1738	396 (22.8)	(20.8, 24.8)
			Mild	1746	364 (20.8)	(19.0, 22.8)	1738	246 (14.2)	(12.5, 15.9)
			Moderate	1746	231 (13.2)	(11.7, 14.9)	1738	147 (8.5)	(7.2, 9.9)
			Severe	1746	1 (0.1)	(0.0, 0.3)	1738	3 (0.2)	(0.0, 0.5)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Headache[d]						
			Any	1746	441 (25.3)	(23.2, 27.4)	1738	316 (18.2)	(16.4, 20.1)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Mild	1746	341 (19.5)	(17.7, 21.5)	1738	235 (13.5)	(11.9, 15.2)
			Moderate	1746	98 (5.6)	(4.6, 6.8)	1738	78 (4.5)	(3.6, 5.6)
			Severe	1746	2 (0.1)	(0.0, 0.4)	1738	3 (0.2)	(0.0, 0.5)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Chills[d]						
			Any	1746	103 (5.9)	(4.8, 7.1)	1738	57 (3.3)	(2.5, 4.2)
			Mild	1746	82 (4.7)	(3.8, 5.8)	1738	40 (2.3)	(1.6, 3.1)
			Moderate	1746	21 (1.2)	(0.7, 1.8)	1738	16 (0.9)	(0.5, 1.5)
			Severe	1746	0	(0.0, 0.2)	1738	1 (0.1)	(0.0, 0.3)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Vomiting[e]						
			Any	1746	8 (0.5)	(0.2, 0.9)	1738	8 (0.5)	(0.2, 0.9)
			Mild	1746	7 (0.4)	(0.2, 0.8)	1738	8 (0.5)	(0.2, 0.9)
			Moderate	1746	1 (0.1)	(0.0, 0.3)	1738	0	(0.0, 0.2)
			Severe	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Diarrhea[f]						
			Any	1746	141 (8.1)	(6.8, 9.5)	1738	114 (6.6)	(5.4, 7.8)
			Mild	1746	114 (6.5)	(5.4, 7.8)	1738	96 (5.5)	(4.5, 6.7)
			Moderate	1746	24 (1.4)	(0.9, 2.0)	1738	17 (1.0)	(0.6, 1.6)
			Severe	1746	3 (0.2)	(0.0, 0.5)	1738	1 (0.1)	(0.0, 0.3)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			New or worsened muscle pain[d]						
			Any	1746	239 (13.7)	(12.1, 15.4)	1738	143 (8.2)	(7.0, 9.6)
			Mild	1746	165 (9.5)	(8.1, 10.9)	1738	97 (5.6)	(4.5, 6.8)
			Moderate	1746	73 (4.2)	(3.3, 5.2)	1738	43 (2.5)	(1.8, 3.3)
			Severe	1746	1 (0.1)	(0.0, 0.3)	1738	3 (0.2)	(0.0, 0.5)
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			New or worsened joint pain[d]						
			Any	1746	145 (8.3)	(7.1, 9.7)	1738	106 (6.1)	(5.0, 7.3)
			Mild	1746	94 (5.4)	(4.4, 6.5)	1738	68 (3.9)	(3.1, 4.9)
			Moderate	1746	50 (2.9)	(2.1, 3.8)	1738	37 (2.1)	(1.5, 2.9)
			Severe	1746	1 (0.1)	(0.0, 0.3)	1738	1 (0.1)	(0.0, 0.3)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Grade 4	1746	0	(0.0, 0.2)	1738	0	(0.0, 0.2)
			Any systemic event[g]	1746	855 (49.0)	(46.6, 51.3)	1738	660 (38.0)	(35.7, 40.3)
			Use of antipyretic or pain medication[h]	1746	340 (19.5)	(17.6, 21.4)	1738	203 (11.7)	(10.2, 13.3)
		2	Fever						
			≥38.0°C	1608	175 (10.9)	(9.4, 12.5)	1598	3 (0.2)	(0.0, 0.5)
			≥38.0°C to 38.4°C	1608	126 (7.8)	(6.6, 9.3)	1598	2 (0.1)	(0.0, 0.5)
			>38.4°C to 38.9°C	1608	44 (2.7)	(2.0, 3.7)	1598	0	(0.0, 0.2)
			>38.9°C to 40.0°C	1608	5 (0.3)	(0.1, 0.7)	1598	1 (0.1)	(0.0, 0.3)
			>40.0°C	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Fatigue[d]						
			Any	1608	815 (50.7)	(48.2, 53.2)	1598	273 (17.1)	(15.3, 19.0)
			Mild	1608	340 (21.1)	(19.2, 23.2)	1598	159 (9.9)	(8.5, 11.5)
			Moderate	1608	430 (26.7)	(24.6, 29.0)	1598	113 (7.1)	(5.9, 8.4)
			Severe	1608	45 (2.8)	(2.0, 3.7)	1598	1 (0.1)	(0.0, 0.3)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Headache[d]						
			Any	1608	627 (39.0)	(36.6, 41.4)	1598	223 (14.0)	(12.3, 15.8)
			Mild	1608	409 (25.4)	(23.3, 27.6)	1598	162 (10.1)	(8.7, 11.7)
			Moderate	1608	209 (13.0)	(11.4, 14.7)	1598	57 (3.6)	(2.7, 4.6)
			Severe	1608	9 (0.6)	(0.3, 1.1)	1598	4 (0.3)	(0.1, 0.6)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Chills[d]						
			Any	1608	365 (22.7)	(20.7, 24.8)	1598	45 (2.8)	(2.1, 3.8)
			Mild	1608	195 (12.1)	(10.6, 13.8)	1598	35 (2.2)	(1.5, 3.0)
			Moderate	1608	153 (9.5)	(8.1, 11.1)	1598	10 (0.6)	(0.3, 1.1)
			Severe	1608	17 (1.1)	(0.6, 1.7)	1598	0	(0.0, 0.2)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Vomiting[e]						
			Any	1608	11 (0.7)	(0.3, 1.2)	1598	5 (0.3)	(0.1, 0.7)
			Mild	1608	9 (0.6)	(0.3, 1.1)	1598	5 (0.3)	(0.1, 0.7)
			Moderate	1608	1 (0.1)	(0.0, 0.3)	1598	0	(0.0, 0.2)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Severe	1608	1 (0.1)	(0.0, 0.3)	1598	0	(0.0, 0.2)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Diarrhea[f]						
			Any	1608	135 (8.4)	(7.1, 9.9)	1598	95 (5.9)	(4.8, 7.2)
			Mild	1608	113 (7.0)	(5.8, 8.4)	1598	71 (4.4)	(3.5, 5.6)
			Moderate	1608	20 (1.2)	(0.8, 1.9)	1598	22 (1.4)	(0.9, 2.1)
			Severe	1608	2 (0.1)	(0.0, 0.4)	1598	2 (0.1)	(0.0, 0.5)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			New or worsened muscle pain[d]						
			Any	1608	461 (28.7)	(26.5, 30.9)	1598	84 (5.3)	(4.2, 6.5)
			Mild	1608	196 (12.2)	(10.6, 13.9)	1598	55 (3.4)	(2.6, 4.5)
			Moderate	1608	250 (15.5)	(13.8, 17.4)	1598	28 (1.8)	(1.2, 2.5)
			Severe	1608	15 (0.9)	(0.5, 1.5)	1598	1 (0.1)	(0.0, 0.3)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			New or worsened joint pain[d]						
			Any	1608	299 (18.6)	(16.7, 20.6)	1598	60 (3.8)	(2.9, 4.8)
			Mild	1608	155 (9.6)	(8.2, 11.2)	1598	34 (2.1)	(1.5, 3.0)
			Moderate	1608	137 (8.5)	(7.2, 10.0)	1598	25 (1.6)	(1.0, 2.3)
			Severe	1608	7 (0.4)	(0.2, 0.9)	1598	1 (0.1)	(0.0, 0.3)
			Grade 4	1608	0	(0.0, 0.2)	1598	0	(0.0, 0.2)
			Any systemic event[g]	1608	1037 (64.5)	(62.1, 66.8)	1598	455 (28.5)	(26.3, 30.8)
			Use of antipyretic or pain medication[h]	1608	605 (37.6)	(35.2, 40.0)	1598	157 (9.8)	(8.4, 11.4)
		Any dose	Fever						
			≥38.0°C	1753	186 (10.6)	(9.2, 12.1)	1742	7 (0.4)	(0.2, 0.8)
			≥38.0°C to 38.4°C	1753	135 (7.7)	(6.5, 9.0)	1742	3 (0.2)	(0.0, 0.5)
			>38.4°C to 38.9°C	1753	44 (2.5)	(1.8, 3.4)	1742	1 (0.1)	(0.0, 0.3)
			>38.9°C to 40.0°C	1753	6 (0.3)	(0.1, 0.7)	1742	3 (0.2)	(0.0, 0.5)
			>40.0°C	1753	1 (0.1)	(0.0, 0.3)	1742	0	(0.0, 0.2)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Fatigue[d]						
			Any	1753	990 (56.5)	(54.1, 58.8)	1742	516 (29.6)	(27.5, 31.8)
			Mild	1753	426 (24.3)	(22.3, 26.4)	1742	292 (16.8)	(15.0, 18.6)
			Moderate	1753	518 (29.5)	(27.4, 31.7)	1742	220 (12.6)	(11.1, 14.3)
			Severe	1753	46 (2.6)	(1.9, 3.5)	1742	4 (0.2)	(0.1, 0.6)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Headache[d]						
			Any	1753	799 (45.6)	(43.2, 47.9)	1742	425 (24.4)	(22.4, 26.5)
			Mild	1753	522 (29.8)	(27.6, 32.0)	1742	300 (17.2)	(15.5, 19.1)
			Moderate	1753	266 (15.2)	(13.5, 16.9)	1742	118 (6.8)	(5.6, 8.1)
			Severe	1753	11 (0.6)	(0.3, 1.1)	1742	7 (0.4)	(0.2, 0.8)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Chills[d]						
			Any	1753	419 (23.9)	(21.9, 26.0)	1742	91 (5.2)	(4.2, 6.4)
			Mild	1753	235 (13.4)	(11.8, 15.1)	1742	65 (3.7)	(2.9, 4.7)
			Moderate	1753	167 (9.5)	(8.2, 11.0)	1742	25 (1.4)	(0.9, 2.1)
			Severe	1753	17 (1.0)	(0.6, 1.5)	1742	1 (0.1)	(0.0, 0.3)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Vomiting[e]						
			Any	1753	19 (1.1)	(0.7, 1.7)	1742	13 (0.7)	(0.4, 1.3)
			Mild	1753	16 (0.9)	(0.5, 1.5)	1742	13 (0.7)	(0.4, 1.3)
			Moderate	1753	2 (0.1)	(0.0, 0.4)	1742	0	(0.0, 0.2)
			Severe	1753	1 (0.1)	(0.0, 0.3)	1742	0	(0.0, 0.2)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Diarrhea[f]						
			Any	1753	229 (13.1)	(11.5, 14.7)	1742	179 (10.3)	(8.9, 11.8)
			Mild	1753	182 (10.4)	(9.0, 11.9)	1742	140 (8.0)	(6.8, 9.4)
			Moderate	1753	42 (2.4)	(1.7, 3.2)	1742	36 (2.1)	(1.5, 2.8)
			Severe	1753	5 (0.3)	(0.1, 0.7)	1742	3 (0.2)	(0.0, 0.5)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			New or worsened muscle pain[d]						
			Any	1753	566 (32.3)	(30.1, 34.5)	1742	191 (11.0)	(9.5, 12.5)
			Mild	1753	260 (14.8)	(13.2, 16.6)	1742	120 (6.9)	(5.7, 8.2)
			Moderate	1753	290 (16.5)	(14.8, 18.4)	1742	67 (3.8)	(3.0, 4.9)

14.375. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status and Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

				Vaccine Group (as Administered)					
				BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
			Severe	1753	16 (0.9)	(0.5, 1.5)	1742	4 (0.2)	(0.1, 0.6)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			New or worsened joint pain[d]						
			Any	1753	364 (20.8)	(18.9, 22.7)	1742	143 (8.2)	(7.0, 9.6)
			Mild	1753	188 (10.7)	(9.3, 12.3)	1742	81 (4.6)	(3.7, 5.7)
			Moderate	1753	168 (9.6)	(8.2, 11.1)	1742	60 (3.4)	(2.6, 4.4)
			Severe	1753	8 (0.5)	(0.2, 0.9)	1742	2 (0.1)	(0.0, 0.4)
			Grade 4	1753	0	(0.0, 0.2)	1742	0	(0.0, 0.2)
			Any systemic event[g]	1753	1242 (70.8)	(68.7, 73.0)	1742	806 (46.3)	(43.9, 48.6)
			Use of antipyretic or pain medication[h]	1753	719 (41.0)	(38.7, 43.4)	1742	290 (16.6)	(14.9, 18.5)

Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (22:35)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_s020_se_bsage_p3_saf

14.376. Onset Days for Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
1	Fever (≥38.0°C)		
	n[a]	111	27
	Mean (SD)	2.5 (1.33)	3.6 (1.92)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Fatigue		
	n[a]	1700	1172
	Mean (SD)	2.1 (1.28)	2.4 (1.62)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Headache		
	n[a]	1413	1100
	Mean (SD)	2.5 (1.56)	2.7 (1.75)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Chills		
	n[a]	434	203
	Mean (SD)	2.3 (1.29)	3.0 (1.75)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Vomiting		
	n[a]	37	37
	Mean (SD)	3.4 (1.83)	3.5 (1.86)
	Median	3.0	4.0
	Min, max	(1, 7)	(1, 7)
	Diarrhea		
	n[a]	402	388
	Mean (SD)	3.4 (1.73)	3.6 (1.73)
	Median	3.0	3.0
	Min, max	(1, 7)	(1, 7)
	New or worsened muscle pain		
	n[a]	738	398
	Mean (SD)	2.4 (1.31)	3.3 (1.80)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	New or worsened joint pain		
	n[a]	406	247

14.376. Onset Days for Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Mean (SD)	2.7 (1.51)	3.6 (1.71)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Any systemic event[b]		
	n[a]	2421	1922
	Mean (SD)	2.1 (1.30)	2.4 (1.61)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		
	n[a]	996	545
	Mean (SD)	2.5 (1.39)	3.3 (1.86)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
2	Fever (≥38.0°C)		
	n[a]	512	14
	Mean (SD)	2.0 (0.48)	4.1 (2.20)
	Median	2.0	4.5
	Min, max	(1, 7)	(1, 7)
	Fatigue		
	n[a]	2086	756
	Mean (SD)	2.0 (0.86)	2.5 (1.65)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Headache		
	n[a]	1732	735
	Mean (SD)	2.2 (1.11)	2.8 (1.79)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Chills		
	n[a]	1114	125
	Mean (SD)	2.0 (0.54)	2.9 (1.68)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Vomiting		
	n[a]	51	30
	Mean (SD)	2.9 (1.69)	3.7 (2.05)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Diarrhea		

14.376. Onset Days for Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
	n[a]	356	276
	Mean (SD)	3.4 (1.71)	3.7 (1.79)
	Median	3.0	3.0
	Min, max	(1, 7)	(1, 7)
	New or worsened muscle pain		
	n[a]	1260	260
	Mean (SD)	2.1 (0.75)	3.1 (1.75)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	New or worsened joint pain		
	n[a]	772	170
	Mean (SD)	2.2 (0.87)	3.4 (1.75)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)
	Any systemic event[b]		
	n[a]	2627	1267
	Mean (SD)	1.9 (0.91)	2.5 (1.66)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		
	n[a]	1570	427
	Mean (SD)	2.1 (0.86)	3.5 (1.87)
	Median	2.0	3.0
	Min, max	(1, 7)	(1, 7)

Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (22:11)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_s060_se_onset_p3_saf

14.377. Onset Days for Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Fever (≥38.0°C)		
		n[a]	85	20
		Mean (SD)	2.6 (1.36)	3.5 (2.01)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Fatigue		
		n[a]	1085	767
		Mean (SD)	2.1 (1.28)	2.3 (1.61)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	959	775
		Mean (SD)	2.5 (1.58)	2.7 (1.77)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	321	146
		Mean (SD)	2.2 (1.20)	3.0 (1.75)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[a]	28	28
		Mean (SD)	3.6 (1.85)	3.5 (1.93)
		Median	3.5	3.5
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[a]	255	270
		Mean (SD)	3.5 (1.70)	3.6 (1.74)
		Median	3.0	3.5
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	487	249
		Mean (SD)	2.3 (1.22)	3.2 (1.79)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[a]	251	138

14.377. Onset Days for Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	2.6 (1.44)	3.5 (1.66)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	1538	1243
		Mean (SD)	2.1 (1.26)	2.3 (1.61)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	638	332
		Mean (SD)	2.4 (1.35)	3.3 (1.83)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
	2	Fever (≥38.0°C)		
		n[a]	331	10
		Mean (SD)	2.0 (0.58)	4.0 (2.21)
		Median	2.0	4.5
		Min, max	(1, 7)	(1, 7)
		Fatigue		
		n[a]	1247	479
		Mean (SD)	1.9 (0.78)	2.4 (1.58)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	1085	506
		Mean (SD)	2.2 (1.07)	2.7 (1.73)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	737	79
		Mean (SD)	2.0 (0.50)	2.6 (1.54)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 7)
		Vomiting		
		n[a]	40	25
		Mean (SD)	2.8 (1.55)	3.6 (2.12)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		

14.377. Onset Days for Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	219	177
		Mean (SD)	3.3 (1.70)	3.8 (1.93)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	783	173
		Mean (SD)	2.0 (0.65)	3.0 (1.77)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[a]	459	109
		Mean (SD)	2.1 (0.78)	3.2 (1.69)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	1557	803
		Mean (SD)	1.9 (0.87)	2.4 (1.61)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	945	266
		Mean (SD)	2.0 (0.79)	3.5 (1.80)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
>55 Years	1	Fever (≥38.0°C)		
		n[a]	26	7
		Mean (SD)	2.5 (1.24)	4.0 (1.73)
		Median	2.0	4.0
		Min, max	(1, 6)	(2, 7)
		Fatigue		
		n[a]	615	405
		Mean (SD)	2.2 (1.28)	2.6 (1.63)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	454	325
		Mean (SD)	2.5 (1.53)	2.7 (1.70)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)

14.377. Onset Days for Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Chills		
		n[a]	113	57
		Mean (SD)	2.5 (1.51)	2.9 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[a]	9	9
		Mean (SD)	2.8 (1.72)	3.7 (1.73)
		Median	2.0	4.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[a]	147	118
		Mean (SD)	3.4 (1.78)	3.6 (1.71)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	251	149
		Mean (SD)	2.6 (1.47)	3.5 (1.81)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[a]	155	109
		Mean (SD)	2.8 (1.61)	3.7 (1.76)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	883	679
		Mean (SD)	2.2 (1.35)	2.6 (1.60)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	358	213
		Mean (SD)	2.5 (1.45)	3.2 (1.90)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
	2	Fever (≥38.0°C)		
		n[a]	181	4
		Mean (SD)	2.0 (0.22)	4.3 (2.50)
		Median	2.0	4.5

14.377. Onset Days for Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 3)	(1, 7)
		Fatigue		
		n[a]	839	277
		Mean (SD)	2.1 (0.96)	2.7 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	647	229
		Mean (SD)	2.2 (1.17)	3.0 (1.90)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	377	46
		Mean (SD)	2.1 (0.60)	3.2 (1.87)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[a]	11	5
		Mean (SD)	3.5 (2.11)	4.2 (1.79)
		Median	2.0	4.0
		Min, max	(2, 7)	(2, 7)
		Diarrhea		
		n[a]	137	99
		Mean (SD)	3.4 (1.72)	3.5 (1.49)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	477	87
		Mean (SD)	2.1 (0.87)	3.2 (1.72)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[a]	313	61
		Mean (SD)	2.2 (0.98)	3.6 (1.85)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	1070	464
		Mean (SD)	2.0 (0.97)	2.7 (1.73)

14.377. Onset Days for Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	625	161
		Mean (SD)	2.1 (0.95)	3.4 (1.98)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)

Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (22:11)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_s060_se_onset_age_p3_saf

14.378. Duration (Days) From First to Last Day of Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
1	Fever (≥38.0°C)		
	n[a]	111	27
	Mean (SD)	1.2 (0.79)	1.9 (1.86)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 8)
	Unknown[b]	1	2
	Fatigue		
	n[a]	1700	1172
	Mean (SD)	2.5 (2.64)	2.9 (3.04)
	Median	1.0	1.0
	Min, max	(1, 34)	(1, 23)
	Unknown[b]	9	7
	Headache		
	n[a]	1413	1100
	Mean (SD)	2.2 (2.18)	2.5 (2.54)
	Median	1.0	1.0
	Min, max	(1, 22)	(1, 22)
	Unknown[b]	5	9
	Chills		
	n[a]	434	203
	Mean (SD)	1.5 (1.22)	1.9 (1.93)
	Median	1.0	1.0
	Min, max	(1, 9)	(1, 15)
	Unknown[b]	3	3
	Vomiting		
	n[a]	37	37
	Mean (SD)	1.5 (1.19)	1.4 (0.91)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 4)
	Unknown[b]	0	1
	Diarrhea		
	n[a]	402	388
	Mean (SD)	1.9 (2.70)	2.0 (2.56)
	Median	1.0	1.0
	Min, max	(1, 39)	(1, 23)
	Unknown[b]	3	1
	New or worsened muscle pain		

14.378. Duration (Days) From First to Last Day of Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	n[a]	738	398
	Mean (SD)	1.6 (1.55)	1.9 (2.25)
	Median	1.0	1.0
	Min, max	(1, 17)	(1, 18)
	Unknown[b]	2	1
	New or worsened joint pain		
	n[a]	406	247
	Mean (SD)	1.8 (2.62)	2.1 (2.43)
	Median	1.0	1.0
	Min, max	(1, 36)	(1, 17)
	Unknown[b]	2	0
	Use of antipyretic or pain medication		
	n[a]	996	545
	Mean (SD)	1.9 (2.09)	2.4 (2.62)
	Median	1.0	1.0
	Min, max	(1, 31)	(1, 22)
	Unknown[b]	8	11
2	Fever (≥38.0°C)		
	n[a]	512	14
	Mean (SD)	1.1 (0.45)	1.8 (1.60)
	Median	1.0	1.0
	Min, max	(1, 8)	(1, 6)
	Unknown[b]	0	2
	Fatigue		
	n[a]	2086	756
	Mean (SD)	2.2 (2.09)	2.7 (3.13)
	Median	1.0	1.0
	Min, max	(1, 35)	(1, 38)
	Unknown[b]	13	21
	Headache		
	n[a]	1732	735
	Mean (SD)	2.0 (1.72)	2.3 (2.63)
	Median	1.0	1.0
	Min, max	(1, 25)	(1, 35)
	Unknown[b]	15	17
	Chills		
	n[a]	1114	125
	Mean (SD)	1.2 (0.70)	2.1 (2.22)
	Median	1.0	1.0

14.378. Duration (Days) From First to Last Day of Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Min, max	(1, 8)	(1, 16)
	Unknown[b]	3	6
	Vomiting		
	n[a]	51	30
	Mean (SD)	2.5 (5.62)	1.5 (1.17)
	Median	1.0	1.0
	Min, max	(1, 37)	(1, 6)
	Unknown[b]	1	2
	Diarrhea		
	n[a]	356	276
	Mean (SD)	1.8 (2.14)	2.1 (3.12)
	Median	1.0	1.0
	Min, max	(1, 31)	(1, 33)
	Unknown[b]	7	7
	New or worsened muscle pain		
	n[a]	1260	260
	Mean (SD)	1.4 (1.21)	2.0 (2.51)
	Median	1.0	1.0
	Min, max	(1, 23)	(1, 27)
	Unknown[b]	5	8
	New or worsened joint pain		
	n[a]	772	170
	Mean (SD)	1.6 (1.96)	2.2 (2.21)
	Median	1.0	1.0
	Min, max	(1, 32)	(1, 16)
	Unknown[b]	7	5
	Use of antipyretic or pain medication		
	n[a]	1570	427
	Mean (SD)	1.9 (1.99)	2.0 (2.01)
	Median	1.0	1.0
	Min, max	(1, 34)	(1, 16)
	Unknown[b]	13	24

14.378. Duration (Days) From First to Last Day of Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

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

Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. For symptoms that are ongoing at the time of next dose, stop date is computed as the next dose date.
Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adcevd Table Generation: 17NOV2020 (22:15)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adce s040 se dur p3 saf

14.379. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Fever (≥38.0°C)		
		n[a]	85	20
		Mean (SD)	1.3 (0.89)	1.8 (1.54)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Unknown[b]	1	2
		Fatigue		
		n[a]	1085	767
		Mean (SD)	2.5 (2.59)	2.8 (2.78)
		Median	1.0	2.0
		Min, max	(1, 23)	(1, 22)
		Unknown[b]	7	4
		Headache		
		n[a]	959	775
		Mean (SD)	2.3 (2.37)	2.6 (2.45)
		Median	1.0	1.0
		Min, max	(1, 22)	(1, 22)
		Unknown[b]	5	4
		Chills		
		n[a]	321	146
		Mean (SD)	1.5 (1.26)	1.8 (1.84)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 15)
		Unknown[b]	2	2
		Vomiting		
		n[a]	28	28
		Mean (SD)	1.4 (1.03)	1.4 (0.88)
		Median	1.0	1.0
		Min, max	(1, 5)	(1, 4)
		Diarrhea		
		n[a]	255	270
		Mean (SD)	2.0 (3.16)	1.8 (2.00)
		Median	1.0	1.0
		Min, max	(1, 39)	(1, 23)
		Unknown[b]	2	0
		New or worsened muscle pain		
		n[a]	487	249

14.379. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	1.7 (1.64)	1.9 (2.10)
		Median	1.0	1.0
		Min, max	(1, 17)	(1, 15)
		Unknown[b]	1	1
		New or worsened joint pain		
		n[a]	251	138
		Mean (SD)	1.7 (1.93)	2.1 (2.47)
		Median	1.0	1.0
		Min, max	(1, 24)	(1, 17)
		Unknown[b]	2	0
		Use of antipyretic or pain medication		
		n[a]	638	332
		Mean (SD)	1.9 (1.83)	2.1 (2.15)
		Median	1.0	1.0
		Min, max	(1, 16)	(1, 20)
		Unknown[b]	2	3
	2	Fever (≥38.0°C)		
		n[a]	331	10
		Mean (SD)	1.1 (0.50)	1.8 (1.75)
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 6)
		Unknown[b]	0	2
		Fatigue		
		n[a]	1247	479
		Mean (SD)	2.2 (2.20)	2.8 (3.15)
		Median	1.0	2.0
		Min, max	(1, 35)	(1, 38)
		Unknown[b]	9	12
		Headache		
		n[a]	1085	506
		Mean (SD)	2.1 (1.87)	2.3 (2.50)
		Median	1.0	1.0
		Min, max	(1, 25)	(1, 35)
		Unknown[b]	11	15
		Chills		
		n[a]	737	79
		Mean (SD)	1.2 (0.73)	2.0 (1.63)
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 7)

14.379. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Unknown[b]	3	3
		Vomiting		
		n[a]	40	25
		Mean (SD)	2.9 (6.32)	1.6 (1.24)
		Median	1.0	1.0
		Min, max	(1, 37)	(1, 6)
		Unknown[b]	1	1
		Diarrhea		
		n[a]	219	177
		Mean (SD)	1.8 (2.46)	2.1 (3.26)
		Median	1.0	1.0
		Min, max	(1, 31)	(1, 33)
		Unknown[b]	4	5
		New or worsened muscle pain		
		n[a]	783	173
		Mean (SD)	1.5 (1.36)	2.2 (2.91)
		Median	1.0	1.0
		Min, max	(1, 23)	(1, 27)
		Unknown[b]	4	5
		New or worsened joint pain		
		n[a]	459	109
		Mean (SD)	1.6 (1.90)	2.3 (2.43)
		Median	1.0	1.0
		Min, max	(1, 28)	(1, 16)
		Unknown[b]	5	5
		Use of antipyretic or pain medication		
		n[a]	945	266
		Mean (SD)	1.9 (2.03)	1.9 (2.01)
		Median	1.0	1.0
		Min, max	(1, 34)	(1, 16)
		Unknown[b]	9	14
>55 Years	1	Fever (≥38.0°C)		
		n[a]	26	7
		Mean (SD)	1.1 (0.33)	2.0 (2.65)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 8)
		Fatigue		
		n[a]	615	405
		Mean (SD)	2.4 (2.73)	2.9 (3.49)

14.379. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Median	1.0	1.0
		Min, max	(1, 34)	(1, 23)
		Unknown[b]	2	3
		Headache		
		n[a]	454	325
		Mean (SD)	2.0 (1.69)	2.3 (2.73)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 20)
		Unknown[b]	0	5
		Chills		
		n[a]	113	57
		Mean (SD)	1.5 (1.08)	2.1 (2.14)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 13)
		Unknown[b]	1	1
		Vomiting		
		n[a]	9	9
		Mean (SD)	1.7 (1.66)	1.5 (1.07)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 4)
		Unknown[b]	0	1
		Diarrhea		
		n[a]	147	118
		Mean (SD)	1.8 (1.60)	2.4 (3.51)
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 22)
		Unknown[b]	1	1
		New or worsened muscle pain		
		n[a]	251	149
		Mean (SD)	1.5 (1.37)	1.8 (2.49)
		Median	1.0	1.0
		Min, max	(1, 14)	(1, 18)
		Unknown[b]	1	0
		New or worsened joint pain		
		n[a]	155	109
		Mean (SD)	2.0 (3.45)	2.0 (2.38)
		Median	1.0	1.0
		Min, max	(1, 36)	(1, 17)
		Use of antipyretic or pain medication		

14.379. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	358	213
		Mean (SD)	2.0 (2.50)	2.7 (3.20)
		Median	1.0	1.0
		Min, max	(1, 31)	(1, 22)
		Unknown[b]	6	8
	2	Fever (≥38.0°C)		
		n[a]	181	4
		Mean (SD)	1.1 (0.36)	1.8 (1.50)
		Median	1.0	1.0
		Min, max	(1, 4)	(1, 4)
		Fatigue		
		n[a]	839	277
		Mean (SD)	2.1 (1.90)	2.6 (3.10)
		Median	1.0	1.0
		Min, max	(1, 20)	(1, 25)
		Unknown[b]	4	9
		Headache		
		n[a]	647	229
		Mean (SD)	1.8 (1.43)	2.4 (2.89)
		Median	1.0	1.0
		Min, max	(1, 12)	(1, 34)
		Unknown[b]	4	2
		Chills		
		n[a]	377	46
		Mean (SD)	1.2 (0.64)	2.4 (3.00)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 16)
		Unknown[b]	0	3
		Vomiting		
		n[a]	11	5
		Mean (SD)	1.2 (0.40)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 1)
		Unknown[b]	0	1
		Diarrhea		
		n[a]	137	99
		Mean (SD)	1.8 (1.49)	2.1 (2.87)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 26)

14.379. Duration (Days) From First to Last Day of Systemic Events, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Unknown[b]	3	2
		New or worsened muscle pain		
		n[a]	477	87
		Mean (SD)	1.4 (0.93)	1.6 (1.34)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 8)
		Unknown[b]	1	3
		New or worsened joint pain		
		n[a]	313	61
		Mean (SD)	1.5 (2.06)	2.1 (1.80)
		Median	1.0	1.0
		Min, max	(1, 32)	(1, 8)
		Unknown[b]	2	0
		Use of antipyretic or pain medication		
		n[a]	625	161
		Mean (SD)	1.8 (1.92)	2.1 (2.01)
		Median	1.0	1.0
		Min, max	(1, 30)	(1, 10)
		Unknown[b]	4	10

Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. For symptoms that are ongoing at the time of next dose, stop date is computed as the next dose date.
Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adcevd Table Generation: 17NOV2020 (22:15)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_s040_se_dur_age_p3_saf

Adverse Events

14.380. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=10841) n[b] (%)	Placebo (N[a]=10851) n[b] (%)
Any event	3177 (29.3)	1427 (13.2)
Related[c]	2551 (23.5)	622 (5.7)
Severe	131 (1.2)	51 (0.5)
Life-threatening	7 (0.1)	9 (0.1)
Any serious adverse event	43 (0.4)	32 (0.3)
Related[c]	2 (0.0)	0
Severe	22 (0.2)	22 (0.2)
Life-threatening	7 (0.1)	8 (0.1)
Any adverse event leading to withdrawal	19 (0.2)	15 (0.1)
Related[c]	8 (0.1)	5 (0.0)
Severe	5 (0.0)	3 (0.0)
Life-threatening	1 (0.0)	2 (0.0)
Death	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 pd2 age p3 saf

14.381. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=7960)	Placebo (N[a]=7934)
Adverse Event	n[b] (%)	n[b] (%)
Any event	1894 (23.8)	929 (11.7)
Related[c]	1364 (17.1)	331 (4.2)
Severe	89 (1.1)	58 (0.7)
Life-threatening	11 (0.1)	11 (0.1)
Any serious adverse event	60 (0.8)	49 (0.6)
Related[c]	1 (0.0)	0
Severe	35 (0.4)	26 (0.3)
Life-threatening	11 (0.1)	11 (0.1)
Any adverse event leading to withdrawal	15 (0.2)	10 (0.1)
Related[c]	6 (0.1)	2 (0.0)
Severe	8 (0.1)	4 (0.1)
Life-threatening	1 (0.0)	2 (0.0)
Death	1 (0.0)	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_age_p3_saf

14.382. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=545) n[b] (%)	Placebo (N[a]=580) n[b] (%)
Any event	120 (22.0)	57 (9.8)
Related[c]	90 (16.5)	26 (4.5)
Severe	8 (1.5)	2 (0.3)
Life-threatening	2 (0.4)	0
Any serious adverse event	4 (0.7)	1 (0.2)
Related[c]	0	0
Severe	2 (0.4)	1 (0.2)
Life-threatening	2 (0.4)	0
Any adverse event leading to withdrawal	2 (0.4)	1 (0.2)
Related[c]	0	0
Severe	0	0
Life-threatening	1 (0.2)	0
Death	1 (0.2)	0

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. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 pd2 bs p3 saf

14.383. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=17841)	Placebo (N[a]=17808)
Adverse Event	n[b] (%)	n[b] (%)
Any event	4837 (27.1)	2253 (12.7)
Related[c]	3742 (21.0)	911 (5.1)
Severe	205 (1.1)	105 (0.6)
Life-threatening	16 (0.1)	20 (0.1)
Any serious adverse event	97 (0.5)	80 (0.4)
Related[c]	3 (0.0)	0
Severe	54 (0.3)	47 (0.3)
Life-threatening	16 (0.1)	19 (0.1)
Any adverse event leading to withdrawal	31 (0.2)	24 (0.1)
Related[c]	13 (0.1)	7 (0.0)
Severe	13 (0.1)	7 (0.0)
Life-threatening	1 (0.0)	4 (0.0)
Death	0	2 (0.0)

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. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_bs_p3_saf

14.384. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=397) n[b] (%)	Placebo (N[a]=429) n[b] (%)
Any event	96 (24.2)	45 (10.5)
Related[c]	73 (18.4)	20 (4.7)
Severe	8 (2.0)	2 (0.5)
Life-threatening	0	0
Any serious adverse event	2 (0.5)	1 (0.2)
Related[c]	0	0
Severe	2 (0.5)	1 (0.2)
Life-threatening	0	0
Any adverse event leading to withdrawal	1 (0.3)	1 (0.2)
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

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. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 pd2 bsage p3 saf

14.385. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: >55 Years

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=148) n[b] (%)	Placebo (N[a]=151) n[b] (%)
Any event	24 (16.2)	12 (7.9)
Related[c]	17 (11.5)	6 (4.0)
Severe	0	0
Life-threatening	2 (1.4)	0
Any serious adverse event	2 (1.4)	0
Related[c]	0	0
Severe	0	0
Life-threatening	2 (1.4)	0
Any adverse event leading to withdrawal	1 (0.7)	0
Related[c]	0	0
Severe	0	0
Life-threatening	1 (0.7)	0
Death	1 (0.7)	0

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. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 pd2 bsage p3 saf

14.386. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=10186) n[b] (%)	Placebo (N[a]=10187) n[b] (%)
Any event	3009 (29.5)	1351 (13.3)
Related[c]	2425 (23.8)	592 (5.8)
Severe	117 (1.1)	48 (0.5)
Life-threatening	7 (0.1)	9 (0.1)
Any serious adverse event	41 (0.4)	31 (0.3)
Related[c]	2 (0.0)	0
Severe	20 (0.2)	21 (0.2)
Life-threatening	7 (0.1)	8 (0.1)
Any adverse event leading to withdrawal	17 (0.2)	14 (0.1)
Related[c]	7 (0.1)	5 (0.0)
Severe	5 (0.0)	3 (0.0)
Life-threatening	1 (0.0)	2 (0.0)
Death	0	1 (0.0)

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. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 pd2 bsage p3 saf

14.387. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=7655)	Placebo (N[a]=7621)
Adverse Event	n[b] (%)	n[b] (%)
Any event	1828 (23.9)	902 (11.8)
Related[c]	1317 (17.2)	319 (4.2)
Severe	88 (1.1)	57 (0.7)
Life-threatening	9 (0.1)	11 (0.1)
Any serious adverse event	56 (0.7)	49 (0.6)
Related[c]	1 (0.0)	0
Severe	34 (0.4)	26 (0.3)
Life-threatening	9 (0.1)	11 (0.1)
Any adverse event leading to withdrawal	14 (0.2)	10 (0.1)
Related[c]	6 (0.1)	2 (0.0)
Severe	8 (0.1)	4 (0.1)
Life-threatening	0	2 (0.0)
Death	0	1 (0.0)

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. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 pd2 bsage p3 saf

14.388. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5253)	Placebo (N[a]=5269)
Adverse Event	n[b] (%)	n[b] (%)
Any event	1429 (27.2)	834 (15.8)
Related[c]	940 (17.9)	278 (5.3)
Severe	71 (1.4)	38 (0.7)
Life-threatening	4 (0.1)	4 (0.1)
Any serious adverse event	27 (0.5)	21 (0.4)
Related[c]	0	0
Severe	13 (0.2)	16 (0.3)
Life-threatening	4 (0.1)	4 (0.1)
Any adverse event leading to withdrawal	9 (0.2)	2 (0.0)
Related[c]	3 (0.1)	0
Severe	4 (0.1)	0
Life-threatening	0	2 (0.0)
Death	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_eth_p3_saf

14.389. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=13436)	Placebo (N[a]=13407)
Adverse Event	n[b] (%)	n[b] (%)
Any event	3621 (26.9)	1511 (11.3)
Related[c]	2959 (22.0)	669 (5.0)
Severe	149 (1.1)	71 (0.5)
Life-threatening	14 (0.1)	16 (0.1)
Any serious adverse event	76 (0.6)	60 (0.4)
Related[c]	3 (0.0)	0
Severe	44 (0.3)	32 (0.2)
Life-threatening	14 (0.1)	15 (0.1)
Any adverse event leading to withdrawal	25 (0.2)	23 (0.2)
Related[c]	11 (0.1)	7 (0.1)
Severe	9 (0.1)	7 (0.1)
Life-threatening	2 (0.0)	2 (0.0)
Death	1 (0.0)	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_eth_p3_saf

14.390. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=112)	Placebo (N[a]=109)
Adverse Event	n[b] (%)	n[b] (%)
Any event	21 (18.8)	11 (10.1)
Related[c]	16 (14.3)	6 (5.5)
Severe	0	0
Life-threatening	0	0
Any serious adverse event	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any 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 = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_eth_p3_saf

14.391. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=15615) n[b] (%)	Placebo (N[a]=15615) n[b] (%)
Any event	4252 (27.2)	1991 (12.8)
Related[c]	3234 (20.7)	748 (4.8)
Severe	185 (1.2)	94 (0.6)
Life-threatening	16 (0.1)	17 (0.1)
Any serious adverse event	81 (0.5)	71 (0.5)
Related[c]	2 (0.0)	0
Severe	44 (0.3)	41 (0.3)
Life-threatening	16 (0.1)	16 (0.1)
Any adverse event leading to withdrawal	29 (0.2)	18 (0.1)
Related[c]	13 (0.1)	4 (0.0)
Severe	13 (0.1)	6 (0.0)
Life-threatening	1 (0.0)	4 (0.0)
Death	1 (0.0)	2 (0.0)

Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 pd2 race p3 saf

14.392. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1694)	Placebo (N[a]=1722)
Adverse Event	n[b] (%)	n[b] (%)
Any event	269 (15.9)	176 (10.2)
Related[c]	194 (11.5)	87 (5.1)
Severe	14 (0.8)	11 (0.6)
Life-threatening	0	3 (0.2)
Any serious adverse event	11 (0.6)	9 (0.5)
Related[c]	0	0
Severe	7 (0.4)	6 (0.3)
Life-threatening	0	3 (0.2)
Any adverse event leading to withdrawal	3 (0.2)	6 (0.3)
Related[c]	1 (0.1)	3 (0.2)
Severe	0	1 (0.1)
Life-threatening	0	0
Death	0	0

Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_race_p3_saf

14.393. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1492)	Placebo (N[a]=1448)
Adverse Event	n[b] (%)	n[b] (%)
Any event	550 (36.9)	189 (13.1)
Related[c]	487 (32.6)	118 (8.1)
Severe	21 (1.4)	4 (0.3)
Life-threatening	2 (0.1)	0
Any serious adverse event	11 (0.7)	1 (0.1)
Related[c]	1 (0.1)	0
Severe	6 (0.4)	1 (0.1)
Life-threatening	2 (0.1)	0
Any adverse event leading to withdrawal	2 (0.1)	1 (0.1)
Related[c]	0	0
Severe	0	0
Life-threatening	1 (0.1)	0
Death	0	0

Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_race_p3_saf

14.394. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9602)	Placebo (N[a]=9399)
Adverse Event	n[b] (%)	n[b] (%)
Any event	2356 (24.5)	1121 (11.9)
Related[c]	1828 (19.0)	459 (4.9)
Severe	94 (1.0)	59 (0.6)
Life-threatening	13 (0.1)	12 (0.1)
Any serious adverse event	57 (0.6)	43 (0.5)
Related[c]	0	0
Severe	33 (0.3)	27 (0.3)
Life-threatening	13 (0.1)	12 (0.1)
Any adverse event leading to withdrawal	9 (0.1)	11 (0.1)
Related[c]	2 (0.0)	3 (0.0)
Severe	4 (0.0)	4 (0.0)
Life-threatening	2 (0.0)	2 (0.0)
Death	1 (0.0)	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_sex_p3_saf

14.395. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9199)	Placebo (N[a]=9386)
Adverse Event	n[b] (%)	n[b] (%)
Any event	2715 (29.5)	1235 (13.2)
Related[c]	2087 (22.7)	494 (5.3)
Severe	126 (1.4)	50 (0.5)
Life-threatening	5 (0.1)	8 (0.1)
Any serious adverse event	46 (0.5)	38 (0.4)
Related[c]	3 (0.0)	0
Severe	24 (0.3)	21 (0.2)
Life-threatening	5 (0.1)	7 (0.1)
Any adverse event leading to withdrawal	25 (0.3)	14 (0.1)
Related[c]	12 (0.1)	4 (0.0)
Severe	9 (0.1)	3 (0.0)
Life-threatening	0	2 (0.0)
Death	0	2 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_pd2_sex_p3_saf

14.396. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
Adverse Event	BNT162b2 (30 µg) (N[a]=5350) n[b] (%)	Placebo (N[a]=5377) n[b] (%)	Total (N[a]=10727) n[b] (%)
Any event	1232 (23.0)	693 (12.9)	1925 (17.9)
Related[c]	807 (15.1)	211 (3.9)	1018 (9.5)
Severe	56 (1.0)	34 (0.6)	90 (0.8)
Life-threatening	5 (0.1)	4 (0.1)	9 (0.1)
Any serious adverse event	24 (0.4)	22 (0.4)	46 (0.4)
Related[c]	2 (0.0)	0	2 (0.0)
Severe	9 (0.2)	16 (0.3)	25 (0.2)
Life-threatening	5 (0.1)	4 (0.1)	9 (0.1)
Any adverse event leading to withdrawal	0	0	0
Related[c]	0	0	0
Severe	0	0	0
Life-threatening	0	0	0
Death	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_2mpd2_age_p23_saf

14.397. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=4181)	Placebo (N[a]=4159)	Total (N[a]=8340)
Adverse Event	n[b] (%)	n[b] (%)	n[b] (%)
Any event	812 (19.4)	504 (12.1)	1316 (15.8)
Related[c]	490 (11.7)	132 (3.2)	622 (7.5)
Severe	49 (1.2)	35 (0.8)	84 (1.0)
Life-threatening	5 (0.1)	7 (0.2)	12 (0.1)
Any serious adverse event	33 (0.8)	31 (0.7)	64 (0.8)
Related[c]	0	0	0
Severe	23 (0.6)	17 (0.4)	40 (0.5)
Life-threatening	5 (0.1)	7 (0.2)	12 (0.1)
Any adverse event leading to withdrawal	1 (0.0)	0	1 (0.0)
Related[c]	0	0	0
Severe	0	0	0
Life-threatening	1 (0.0)	0	1 (0.0)
Death	1 (0.0)	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_2mpd2_age_p23_saf

14.398. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12706)	Placebo (N[a]=12756)
Adverse Event	n[b] (%)	n[b] (%)
Any event	3660 (28.8)	1605 (12.6)
Related[c]	2961 (23.3)	728 (5.7)
Severe	135 (1.1)	67 (0.5)
Life-threatening	7 (0.1)	10 (0.1)
Any serious adverse event	47 (0.4)	45 (0.4)
Related[c]	3 (0.0)	0
Severe	23 (0.2)	30 (0.2)
Life-threatening	7 (0.1)	9 (0.1)
Any adverse event leading to withdrawal	20 (0.2)	18 (0.1)
Related[c]	9 (0.1)	6 (0.0)
Severe	5 (0.0)	4 (0.0)
Life-threatening	1 (0.0)	3 (0.0)
Death	0	2 (0.0)

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s091 all age p23 saf

14.399. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=8915)	Placebo (N[a]=8875)
Adverse Event	n[b] (%)	n[b] (%)
Any event	2110 (23.7)	1033 (11.6)
Related[c]	1523 (17.1)	367 (4.1)
Severe	105 (1.2)	72 (0.8)
Life-threatening	14 (0.2)	14 (0.2)
Any serious adverse event	79 (0.9)	66 (0.7)
Related[c]	1 (0.0)	0
Severe	48 (0.5)	38 (0.4)
Life-threatening	14 (0.2)	14 (0.2)
Any adverse event leading to withdrawal	17 (0.2)	12 (0.1)
Related[c]	7 (0.1)	3 (0.0)
Severe	8 (0.1)	5 (0.1)
Life-threatening	2 (0.0)	3 (0.0)
Death	2 (0.0)	2 (0.0)

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s091_all_age_p23_saf

14.400. Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[e])
GASTROINTESTINAL DISORDERS						
Nausea	214 (1.1)	(1.0, 1.3)	63 (0.3)	(0.3, 0.4)	0.8	(0.6, 1.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
Injection site pain	2108 (11.2)	(10.8, 11.7)	281 (1.5)	(1.3, 1.7)	9.7	(9.2, 10.2)
Pyrexia	1144 (6.1)	(5.7, 6.4)	61 (0.3)	(0.2, 0.4)	5.8	(5.4, 6.1)
Fatigue	1026 (5.5)	(5.1, 5.8)	258 (1.4)	(1.2, 1.6)	4.1	(3.7, 4.5)
Chills	998 (5.3)	(5.0, 5.6)	85 (0.5)	(0.4, 0.6)	4.9	(4.5, 5.2)
Pain	455 (2.4)	(2.2, 2.6)	36 (0.2)	(0.1, 0.3)	2.2	(2.0, 2.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
Myalgia	904 (4.8)	(4.5, 5.1)	126 (0.7)	(0.6, 0.8)	4.1	(3.8, 4.5)
Arthralgia	210 (1.1)	(1.0, 1.3)	76 (0.4)	(0.3, 0.5)	0.7	(0.5, 0.9)
NERVOUS SYSTEM DISORDERS						
Headache	966 (5.1)	(4.8, 5.5)	302 (1.6)	(1.4, 1.8)	3.5	(3.2, 3.9)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Tier 2 events are "common" adverse events with an incidence rate ≥1.0% in any vaccine group (preferred term level). No Tier 1 events were identified at this stage for this program.
Note: The 95% confidence interval quantifies the precision of the risk difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (BNT162b2 [30 µg] - placebo) for subjects ≥16 years.
e. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:56)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_vax_tier2_p3_saf

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3177 (29.3)	(28.4, 30.2)	1427 (13.2)	(12.5, 13.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	64 (0.6)	(0.5, 0.8)	7 (0.1)	(0.0, 0.1)
Lymphadenopathy	54 (0.5)	(0.4, 0.6)	3 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	22 (0.2)	(0.1, 0.3)	20 (0.2)	(0.1, 0.3)
Palpitations	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Tachycardia	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Left ventricular hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tricuspid valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	31 (0.3)	(0.2, 0.4)	16 (0.1)	(0.1, 0.2)
Vertigo	9 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Tinnitus	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ear pain	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo positional	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniere's disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sudden hearing loss	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	29 (0.3)	(0.2, 0.4)	19 (0.2)	(0.1, 0.3)
Eye pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye irritation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dry eye	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Keratitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vitreous detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Conjunctivitis allergic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ocular hyperaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lacrimation increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Corneal irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	328 (3.0)	(2.7, 3.4)	226 (2.1)	(1.8, 2.4)
Diarrhoea	110 (1.0)	(0.8, 1.2)	95 (0.9)	(0.7, 1.1)
Nausea	139 (1.3)	(1.1, 1.5)	41 (0.4)	(0.3, 0.5)
Vomiting	33 (0.3)	(0.2, 0.4)	20 (0.2)	(0.1, 0.3)
Toothache	13 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Abdominal pain upper	15 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Abdominal pain	9 (0.1)	(0.0, 0.2)	13 (0.1)	(0.1, 0.2)
Dyspepsia	7 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Odynophagia	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dental caries	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abdominal distension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dry mouth	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Stomatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Large intestine polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Faeces soft	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swollen tongue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Umbilical hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angular cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastritis erosive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Noninfective gingivitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2288 (21.1)	(20.3, 21.9)	485 (4.5)	(4.1, 4.9)
Injection site pain	1358 (12.5)	(11.9, 13.2)	192 (1.8)	(1.5, 2.0)
Fatigue	690 (6.4)	(5.9, 6.8)	175 (1.6)	(1.4, 1.9)
Pyrexia	819 (7.6)	(7.1, 8.1)	39 (0.4)	(0.3, 0.5)
Chills	693 (6.4)	(5.9, 6.9)	56 (0.5)	(0.4, 0.7)
Pain	307 (2.8)	(2.5, 3.2)	23 (0.2)	(0.1, 0.3)
Injection site erythema	87 (0.8)	(0.6, 1.0)	13 (0.1)	(0.1, 0.2)
Malaise	60 (0.6)	(0.4, 0.7)	8 (0.1)	(0.0, 0.1)
Injection site swelling	52 (0.5)	(0.4, 0.6)	9 (0.1)	(0.0, 0.2)
Asthenia	36 (0.3)	(0.2, 0.5)	18 (0.2)	(0.1, 0.3)
Injection site pruritus	15 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Influenza like illness	12 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Chest pain	9 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Injection site bruising	7 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Vaccination site pain	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Axillary pain	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest discomfort	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site induration	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site oedema	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Peripheral swelling	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling face	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thirst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Application site pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Application site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaccination site induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	21 (0.2)	(0.1, 0.3)	12 (0.1)	(0.1, 0.2)
Seasonal allergy	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Drug hypersensitivity	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Immunisation reaction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	160 (1.5)	(1.3, 1.7)	171 (1.6)	(1.4, 1.8)
Urinary tract infection	25 (0.2)	(0.1, 0.3)	22 (0.2)	(0.1, 0.3)
Tooth infection	10 (0.1)	(0.0, 0.2)	18 (0.2)	(0.1, 0.3)
Sinusitis	8 (0.1)	(0.0, 0.1)	12 (0.1)	(0.1, 0.2)
Herpes zoster	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cellulitis	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Ear infection	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Conjunctivitis	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cystitis	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Hordeolum	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diverticulitis	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingivitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Oral herpes	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth abscess	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Furuncle	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Periodontitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Influenza	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nasopharyngitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paronychia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Folliculitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes simplex	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rash pustular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Trichomoniasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bartholinitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Genital herpes simplex	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Papilloma viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinusitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varicella	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	83 (0.8)	(0.6, 0.9)	101 (0.9)	(0.8, 1.1)
Fall	10 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Ligament sprain	4 (0.0)	(0.0, 0.1)	12 (0.1)	(0.1, 0.2)
Skin laceration	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Contusion	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Muscle strain	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Arthropod bite	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Road traffic accident	5 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.2)
Skin abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Limb injury	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Foot fracture	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Procedural pain	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Animal bite	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint dislocation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint injury	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rib fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Head injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Epicondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foreign body in eye	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb traumatic amputation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penis injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post procedural swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	75 (0.7)	(0.5, 0.9)	17 (0.2)	(0.1, 0.3)
Body temperature increased	56 (0.5)	(0.4, 0.7)	7 (0.1)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Blood glucose increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Heart rate increased	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Weight decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mammogram abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	44 (0.4)	(0.3, 0.5)	30 (0.3)	(0.2, 0.4)
Decreased appetite	22 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperlipidaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypocholesterolaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	900 (8.3)	(7.8, 8.8)	221 (2.0)	(1.8, 2.3)
Myalgia	628 (5.8)	(5.4, 6.2)	76 (0.7)	(0.6, 0.9)
Arthralgia	132 (1.2)	(1.0, 1.4)	37 (0.3)	(0.2, 0.5)
Pain in extremity	92 (0.8)	(0.7, 1.0)	17 (0.2)	(0.1, 0.3)
Back pain	43 (0.4)	(0.3, 0.5)	47 (0.4)	(0.3, 0.6)
Neck pain	14 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Muscle spasms	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Osteoarthritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle contracture	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tendonitis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bursitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flank pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Exostosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Costochondritis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tendon disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Torticollis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Coccydynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periarthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal stenosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Trigger finger	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle tightness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	12 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.2)
Lipoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	750 (6.9)	(6.4, 7.4)	279 (2.6)	(2.3, 2.9)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Headache	649 (6.0)	(5.5, 6.4)	199 (1.8)	(1.6, 2.1)
Dizziness	31 (0.3)	(0.2, 0.4)	25 (0.2)	(0.1, 0.3)
Paraesthesia	11 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Migraine	17 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.1)
Lethargy	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Syncope	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Sciatica	7 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Tension headache	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Presyncope	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tremor	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ageusia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cervical radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depressed level of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	52 (0.5)	(0.4, 0.6)	37 (0.3)	(0.2, 0.5)
Anxiety	14 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Insomnia	16 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Depression	10 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sleep disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bruxism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Substance abuse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RENAL AND URINARY DISORDERS	10 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
Dysuria	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematuria	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	24 (0.2)	(0.1, 0.3)	27 (0.2)	(0.2, 0.4)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ovarian cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mammary duct ectasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Polycystic ovaries	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	91 (0.8)	(0.7, 1.0)	104 (1.0)	(0.8, 1.2)
Oropharyngeal pain	23 (0.2)	(0.1, 0.3)	24 (0.2)	(0.1, 0.3)
Nasal congestion	14 (0.1)	(0.1, 0.2)	23 (0.2)	(0.1, 0.3)
Cough	13 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Rhinorrhoea	9 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Rhinitis allergic	9 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
Asthma	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspnoea	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sinus congestion	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Epistaxis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nasal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Reflux laryngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	102 (0.9)	(0.8, 1.1)	66 (0.6)	(0.5, 0.8)
Rash	26 (0.2)	(0.2, 0.4)	20 (0.2)	(0.1, 0.3)
Pruritus	8 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Hyperhidrosis	14 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.2)
Urticaria	9 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erythema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eczema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin lesion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angioedema	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermal cyst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis allergic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug eruption	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ecchymosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acne	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rash papular	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis acneiform	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic foot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Livedo reticularis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pityriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stress at work	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	13 (0.1)	(0.1, 0.2)	13 (0.1)	(0.1, 0.2)
Tooth extraction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dental implantation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Endodontic procedure	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug titration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Salpingectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	17 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
FATIGUE@@	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MYALGIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	29 (0.3)	(0.2, 0.4)	29 (0.3)	(0.2, 0.4)
Hypertension	11 (0.1)	(0.1, 0.2)	16 (0.1)	(0.1, 0.2)
Hot flush	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Haematoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arteriosclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.401. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Essential hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_age_p3_saf

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1894 (23.8)	(22.9, 24.7)	929 (11.7)	(11.0, 12.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	17 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.2)
Lymphadenopathy	10 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	4 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	23 (0.3)	(0.2, 0.4)	16 (0.2)	(0.1, 0.3)
Palpitations	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tachycardia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	24 (0.3)	(0.2, 0.4)	19 (0.2)	(0.1, 0.4)
Vertigo	13 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Tinnitus	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vertigo positional	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniere's disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	22 (0.3)	(0.2, 0.4)	21 (0.3)	(0.2, 0.4)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vision blurred	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cataract	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Keratitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal detachment	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	219 (2.8)	(2.4, 3.1)	132 (1.7)	(1.4, 2.0)
Diarrhoea	77 (1.0)	(0.8, 1.2)	51 (0.6)	(0.5, 0.8)
Nausea	75 (0.9)	(0.7, 1.2)	22 (0.3)	(0.2, 0.4)
Vomiting	11 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Toothache	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Abdominal pain upper	7 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Abdominal pain	5 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Dyspepsia	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Odynophagia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Constipation	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Dental caries	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Abdominal distension	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stomatitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Large intestine polyp	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Faeces soft	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Food poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Colitis microscopic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiatus hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swollen tongue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1206 (15.2)	(14.4, 16.0)	240 (3.0)	(2.7, 3.4)
Injection site pain	750 (9.4)	(8.8, 10.1)	89 (1.1)	(0.9, 1.4)
Fatigue	336 (4.2)	(3.8, 4.7)	83 (1.0)	(0.8, 1.3)
Pyrexia	325 (4.1)	(3.7, 4.5)	22 (0.3)	(0.2, 0.4)
Chills	305 (3.8)	(3.4, 4.3)	29 (0.4)	(0.2, 0.5)
Pain	148 (1.9)	(1.6, 2.2)	13 (0.2)	(0.1, 0.3)
Injection site erythema	51 (0.6)	(0.5, 0.8)	7 (0.1)	(0.0, 0.2)
Malaise	36 (0.5)	(0.3, 0.6)	7 (0.1)	(0.0, 0.2)
Injection site swelling	41 (0.5)	(0.4, 0.7)	8 (0.1)	(0.0, 0.2)
Asthenia	28 (0.4)	(0.2, 0.5)	7 (0.1)	(0.0, 0.2)
Injection site pruritus	12 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Chest pain	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site bruising	3 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Vaccination site pain	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	4 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cyst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	4 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Immunisation reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	126 (1.6)	(1.3, 1.9)	118 (1.5)	(1.2, 1.8)
Urinary tract infection	19 (0.2)	(0.1, 0.4)	22 (0.3)	(0.2, 0.4)
Tooth infection	13 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Sinusitis	10 (0.1)	(0.1, 0.2)	9 (0.1)	(0.1, 0.2)
Herpes zoster	7 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Cellulitis	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Ear infection	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Conjunctivitis	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cystitis	4 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hordeolum	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Upper respiratory tract infection	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulitis	4 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis externa	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingivitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Oral herpes	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth abscess	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bronchitis	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Furuncle	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Influenza	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasopharyngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis media acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Erysipelas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fungal skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival abscess	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Onychomycosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash pustular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trichomoniasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bone abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cellulitis orbital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fungal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	86 (1.1)	(0.9, 1.3)	103 (1.3)	(1.1, 1.6)
Fall	23 (0.3)	(0.2, 0.4)	27 (0.3)	(0.2, 0.5)
Ligament sprain	9 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.2)
Skin laceration	4 (0.1)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)
Contusion	4 (0.1)	(0.0, 0.1)	9 (0.1)	(0.1, 0.2)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle strain	6 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Arthropod bite	8 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Skin abrasion	4 (0.1)	(0.0, 0.1)	9 (0.1)	(0.1, 0.2)
Limb injury	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Procedural pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Animal bite	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint dislocation	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rib fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vaccination complication	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thermal burn	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chest injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hand fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wound	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Epicondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scapula fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	56 (0.7)	(0.5, 0.9)	16 (0.2)	(0.1, 0.3)
Body temperature increased	33 (0.4)	(0.3, 0.6)	1 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood testosterone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Platelet count increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	30 (0.4)	(0.3, 0.5)	24 (0.3)	(0.2, 0.4)
Decreased appetite	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Type 2 diabetes mellitus	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitamin D deficiency	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hyponatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	473 (5.9)	(5.4, 6.5)	163 (2.1)	(1.8, 2.4)
Myalgia	276 (3.5)	(3.1, 3.9)	50 (0.6)	(0.5, 0.8)
Arthralgia	78 (1.0)	(0.8, 1.2)	39 (0.5)	(0.3, 0.7)
Pain in extremity	71 (0.9)	(0.7, 1.1)	16 (0.2)	(0.1, 0.3)
Back pain	37 (0.5)	(0.3, 0.6)	24 (0.3)	(0.2, 0.4)
Neck pain	7 (0.1)	(0.0, 0.2)	9 (0.1)	(0.1, 0.2)
Muscle spasms	14 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.2)
Musculoskeletal stiffness	9 (0.1)	(0.1, 0.2)	4 (0.1)	(0.0, 0.1)
Osteoarthritis	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Muscle contracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tendonitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscular weakness	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bursitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Exostosis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bone pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigger finger	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	10 (0.1)	(0.1, 0.2)	20 (0.3)	(0.2, 0.4)
Basal cell carcinoma	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Lipoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adenoma benign	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	391 (4.9)	(4.4, 5.4)	163 (2.1)	(1.8, 2.4)
Headache	317 (4.0)	(3.6, 4.4)	103 (1.3)	(1.1, 1.6)
Dizziness	25 (0.3)	(0.2, 0.5)	23 (0.3)	(0.2, 0.4)
Paraesthesia	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Migraine	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lethargy	15 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Sciatica	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tension headache	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Burning sensation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cervical radiculopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Migraine with aura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Balance disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device connection issue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	24 (0.3)	(0.2, 0.4)	17 (0.2)	(0.1, 0.3)
Anxiety	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Insomnia	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sleep disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Libido increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	18 (0.2)	(0.1, 0.4)	12 (0.2)	(0.1, 0.3)
Dysuria	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Haematuria	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Prostatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaginal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostatomegaly	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	72 (0.9)	(0.7, 1.1)	44 (0.6)	(0.4, 0.7)
Oropharyngeal pain	12 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Nasal congestion	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Cough	9 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.2)
Rhinorrhoea	10 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.1)
Rhinitis allergic	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthma	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dyspnoea	4 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchospasm	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	81 (1.0)	(0.8, 1.3)	61 (0.8)	(0.6, 1.0)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rash	18 (0.2)	(0.1, 0.4)	16 (0.2)	(0.1, 0.3)
Pruritus	11 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.1)
Hyperhidrosis	10 (0.1)	(0.1, 0.2)	4 (0.1)	(0.0, 0.1)
Dermatitis contact	6 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Urticaria	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Rash pruritic	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erythema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin lesion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermatitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angioedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermal cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis allergic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rosacea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
SURGICAL AND MEDICAL PROCEDURES	15 (0.2)	(0.1, 0.3)	5 (0.1)	(0.0, 0.1)
Tooth extraction	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dental implantation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	6 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CHILLS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	27 (0.3)	(0.2, 0.5)	34 (0.4)	(0.3, 0.6)
Hypertension	15 (0.2)	(0.1, 0.3)	19 (0.2)	(0.1, 0.4)

14.402. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hot flush	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypotension	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Orthostatic hypotension	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut age p3 saf

14.403. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=545)		Placebo (N[a]=580)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	120 (22.0)	(18.6, 25.7)	57 (9.8)	(7.5, 12.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Lymphadenopathy	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
EAR AND LABYRINTH DISORDERS	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Vertigo	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
EYE DISORDERS	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.6)
Dry eye	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Photophobia	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
GASTROINTESTINAL DISORDERS	10 (1.8)	(0.9, 3.3)	10 (1.7)	(0.8, 3.1)
Diarrhoea	5 (0.9)	(0.3, 2.1)	3 (0.5)	(0.1, 1.5)
Nausea	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.6)
Vomiting	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Toothache	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Abdominal pain	0	(0.0, 0.7)	2 (0.3)	(0.0, 1.2)
Gastritis	0	(0.0, 0.7)	2 (0.3)	(0.0, 1.2)
Paraesthesia oral	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Food poisoning	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Retching	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Colitis microscopic	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Gingival pain	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Hiatus hernia	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Parotid duct obstruction	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	76 (13.9)	(11.1, 17.1)	23 (4.0)	(2.5, 5.9)
Injection site pain	48 (8.8)	(6.6, 11.5)	11 (1.9)	(1.0, 3.4)
Fatigue	23 (4.2)	(2.7, 6.3)	4 (0.7)	(0.2, 1.8)
Pyrexia	24 (4.4)	(2.8, 6.5)	4 (0.7)	(0.2, 1.8)
Chills	17 (3.1)	(1.8, 4.9)	4 (0.7)	(0.2, 1.8)
Pain	4 (0.7)	(0.2, 1.9)	0	(0.0, 0.6)
Injection site erythema	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Malaise	2 (0.4)	(0.0, 1.3)	1 (0.2)	(0.0, 1.0)
Injection site swelling	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Asthenia	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)

14.403. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=545)		Placebo (N[a]=580)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site pruritus	2 (0.4)	(0.0, 1.3)	1 (0.2)	(0.0, 1.0)
Chest pain	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Injection site bruising	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Vaccination site pain	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Injection site discomfort	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Injection site haematoma	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
IMMUNE SYSTEM DISORDERS	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Drug hypersensitivity	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Hypersensitivity	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
INFECTIONS AND INFESTATIONS	7 (1.3)	(0.5, 2.6)	4 (0.7)	(0.2, 1.8)
Ear infection	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.6)
Upper respiratory tract infection	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Vulvovaginal mycotic infection	0	(0.0, 0.7)	2 (0.3)	(0.0, 1.2)
Appendicitis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Oral herpes	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Pyelonephritis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Folliculitis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Escherichia urinary tract infection	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Parotitis	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	7 (1.3)	(0.5, 2.6)	4 (0.7)	(0.2, 1.8)
Fall	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Contusion	3 (0.6)	(0.1, 1.6)	0	(0.0, 0.6)
Muscle strain	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Road traffic accident	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Exposure during pregnancy	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Limb injury	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Rib fracture	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Chest injury	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Muscle injury	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Overdose	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
INVESTIGATIONS	2 (0.4)	(0.0, 1.3)	1 (0.2)	(0.0, 1.0)
Body temperature increased	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.6)
Colonoscopy	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)

14.403. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=545)		Placebo (N[a]=580)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
METABOLISM AND NUTRITION DISORDERS	1 (0.2)	(0.0, 1.0)	2 (0.3)	(0.0, 1.2)
Hypokalaemia	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Glucose tolerance impaired	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Hypomagnesaemia	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	33 (6.1)	(4.2, 8.4)	10 (1.7)	(0.8, 3.1)
Myalgia	16 (2.9)	(1.7, 4.7)	4 (0.7)	(0.2, 1.8)
Arthralgia	5 (0.9)	(0.3, 2.1)	1 (0.2)	(0.0, 1.0)
Pain in extremity	3 (0.6)	(0.1, 1.6)	3 (0.5)	(0.1, 1.5)
Back pain	4 (0.7)	(0.2, 1.9)	2 (0.3)	(0.0, 1.2)
Muscle spasms	3 (0.6)	(0.1, 1.6)	0	(0.0, 0.6)
Musculoskeletal stiffness	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Muscle contracture	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Musculoskeletal chest pain	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Musculoskeletal discomfort	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Joint effusion	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.7)	2 (0.3)	(0.0, 1.2)
Acrochordon	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Colon adenoma	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
NERVOUS SYSTEM DISORDERS	23 (4.2)	(2.7, 6.3)	9 (1.6)	(0.7, 2.9)
Headache	18 (3.3)	(2.0, 5.2)	8 (1.4)	(0.6, 2.7)
Dizziness	3 (0.6)	(0.1, 1.6)	0	(0.0, 0.6)
Tension headache	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Presyncope	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Carpal tunnel syndrome	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Abortion spontaneous incomplete	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
PSYCHIATRIC DISORDERS	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Insomnia	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Depression	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.2)	(0.0, 1.0)	1 (0.2)	(0.0, 1.0)
Ovarian cyst	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Vaginal haemorrhage	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)

14.403. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=545)		Placebo (N[a]=580)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4 (0.7)	(0.2, 1.9)	5 (0.9)	(0.3, 2.0)
Oropharyngeal pain	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Cough	3 (0.6)	(0.1, 1.6)	0	(0.0, 0.6)
Rhinorrhoea	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Rhinitis allergic	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Pulmonary embolism	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Nasal turbinate hypertrophy	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Haemoptysis	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.7)	2 (0.3)	(0.0, 1.2)
Pruritus	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Psoriasis	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Polypectomy	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
UNCODED TERM	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
VASCULAR DISORDERS	2 (0.4)	(0.0, 1.3)	1 (0.2)	(0.0, 1.0)
Hypertension	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Deep vein thrombosis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Arteriosclerosis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut bs p3 saf

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4837 (27.1)	(26.5, 27.8)	2253 (12.7)	(12.2, 13.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	75 (0.4)	(0.3, 0.5)	12 (0.1)	(0.0, 0.1)
Lymphadenopathy	60 (0.3)	(0.3, 0.4)	6 (0.0)	(0.0, 0.1)
Anaemia	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	45 (0.3)	(0.2, 0.3)	36 (0.2)	(0.1, 0.3)
Palpitations	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Tachycardia	11 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	52 (0.3)	(0.2, 0.4)	34 (0.2)	(0.1, 0.3)
Vertigo	20 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Tinnitus	9 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Ear pain	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vertigo positional	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
ENDOCRINE DISORDERS	11 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypothyroidism	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hypogonadism	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thyroid mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	47 (0.3)	(0.2, 0.4)	39 (0.2)	(0.2, 0.3)
Vision blurred	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cataract	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Eye pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Eye irritation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vitreous detachment	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	526 (2.9)	(2.7, 3.2)	343 (1.9)	(1.7, 2.1)
Diarrhoea	179 (1.0)	(0.9, 1.2)	142 (0.8)	(0.7, 0.9)
Nausea	207 (1.2)	(1.0, 1.3)	62 (0.3)	(0.3, 0.4)
Vomiting	44 (0.2)	(0.2, 0.3)	27 (0.2)	(0.1, 0.2)
Toothache	20 (0.1)	(0.1, 0.2)	18 (0.1)	(0.1, 0.2)
Abdominal pain upper	21 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Abdominal pain	13 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Dyspepsia	12 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Gastrooesophageal reflux disease	6 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Odynophagia	12 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Constipation	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Dental caries	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Gastritis	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Abdominal distension	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Flatulence	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Stomatitis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rectal haemorrhage	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis microscopic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3342 (18.7)	(18.2, 19.3)	687 (3.9)	(3.6, 4.2)
Injection site pain	2014 (11.3)	(10.8, 11.8)	266 (1.5)	(1.3, 1.7)
Fatigue	982 (5.5)	(5.2, 5.8)	248 (1.4)	(1.2, 1.6)
Pyrexia	1093 (6.1)	(5.8, 6.5)	55 (0.3)	(0.2, 0.4)
Chills	965 (5.4)	(5.1, 5.8)	80 (0.4)	(0.4, 0.6)
Pain	442 (2.5)	(2.3, 2.7)	34 (0.2)	(0.1, 0.3)
Injection site erythema	137 (0.8)	(0.6, 0.9)	20 (0.1)	(0.1, 0.2)
Malaise	93 (0.5)	(0.4, 0.6)	13 (0.1)	(0.0, 0.1)
Injection site swelling	90 (0.5)	(0.4, 0.6)	16 (0.1)	(0.1, 0.1)
Asthenia	57 (0.3)	(0.2, 0.4)	24 (0.1)	(0.1, 0.2)
Injection site pruritus	24 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Influenza like illness	20 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Chest pain	13 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Injection site bruising	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Vaccination site pain	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	11 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Axillary pain	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest discomfort	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site oedema	8 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Peripheral swelling	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site discomfort	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oedema peripheral	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Reactogenicity event	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	11 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Cholelithiasis	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	23 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.2)
Seasonal allergy	8 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	271 (1.5)	(1.3, 1.7)	280 (1.6)	(1.4, 1.8)
Urinary tract infection	44 (0.2)	(0.2, 0.3)	43 (0.2)	(0.2, 0.3)
Tooth infection	21 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Sinusitis	18 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.2)
Herpes zoster	11 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Cellulitis	9 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ear infection	6 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Conjunctivitis	8 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Cystitis	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Gastroenteritis	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Diverticulitis	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis media	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Gingivitis	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Oral herpes	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Tooth abscess	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Periodontitis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Furuncle	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Influenza	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Otitis media acute	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin infection	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Folliculitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Herpes simplex	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pustular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	161 (0.9)	(0.8, 1.1)	197 (1.1)	(1.0, 1.3)
Fall	32 (0.2)	(0.1, 0.3)	34 (0.2)	(0.1, 0.3)
Ligament sprain	13 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)
Skin laceration	11 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)
Contusion	8 (0.0)	(0.0, 0.1)	16 (0.1)	(0.1, 0.1)
Muscle strain	11 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Road traffic accident	4 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Skin abrasion	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Arthropod bite	9 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Exposure during pregnancy	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Limb injury	4 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth fracture	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Procedural pain	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Meniscus injury	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Facial bones fracture	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Joint dislocation	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint injury	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Rib fracture	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Ankle fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Vaccination complication	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Thermal burn	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Chest injury	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Concussion	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand fracture	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Radius fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Head injury	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Muscle injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal compression fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bone contusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	127 (0.7)	(0.6, 0.8)	31 (0.2)	(0.1, 0.2)
Body temperature increased	86 (0.5)	(0.4, 0.6)	8 (0.0)	(0.0, 0.1)
Blood pressure increased	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood cholesterol increased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	72 (0.4)	(0.3, 0.5)	49 (0.3)	(0.2, 0.4)
Decreased appetite	29 (0.2)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dyslipidaemia	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Hypokalaemia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gout	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Hyperlipidaemia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Vitamin D deficiency	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dehydration	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hyperglycaemia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Insulin resistance	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1317 (7.4)	(7.0, 7.8)	365 (2.0)	(1.8, 2.3)
Myalgia	873 (4.9)	(4.6, 5.2)	119 (0.7)	(0.6, 0.8)
Arthralgia	199 (1.1)	(1.0, 1.3)	74 (0.4)	(0.3, 0.5)
Pain in extremity	159 (0.9)	(0.8, 1.0)	30 (0.2)	(0.1, 0.2)
Back pain	74 (0.4)	(0.3, 0.5)	66 (0.4)	(0.3, 0.5)
Neck pain	21 (0.1)	(0.1, 0.2)	24 (0.1)	(0.1, 0.2)
Muscle spasms	20 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Osteoarthritis	7 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tendonitis	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle contracture	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Muscular weakness	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Bursitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Arthritis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Flank pain	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Plantar fasciitis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Exostosis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Joint stiffness	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Costochondritis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Synovial cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	22 (0.1)	(0.1, 0.2)	28 (0.2)	(0.1, 0.2)
Basal cell carcinoma	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Lipoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1093 (6.1)	(5.8, 6.5)	421 (2.4)	(2.1, 2.6)
Headache	926 (5.2)	(4.9, 5.5)	284 (1.6)	(1.4, 1.8)
Dizziness	53 (0.3)	(0.2, 0.4)	47 (0.3)	(0.2, 0.4)
Paraesthesia	15 (0.1)	(0.0, 0.1)	17 (0.1)	(0.1, 0.2)
Lethargy	21 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Migraine	16 (0.1)	(0.1, 0.1)	9 (0.1)	(0.0, 0.1)
Syncope	8 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Sciatica	9 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Dysgeusia	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Somnolence	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tension headache	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Presyncope	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tremor	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Burning sensation	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Parosmia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nerve compression	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paralysis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Transient ischaemic attack	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=17841) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=17808) n[b] (%)	 (95% CI[c])
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	74 (0.4)	(0.3, 0.5)	53 (0.3)	(0.2, 0.4)
Anxiety	18 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Insomnia	21 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Depression	10 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Irritability	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety disorder	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sleep disorder	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disorientation	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	26 (0.1)	(0.1, 0.2)	22 (0.1)	(0.1, 0.2)
Dysuria	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Nephrolithiasis	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pollakiuria	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Acute kidney injury	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	32 (0.2)	(0.1, 0.3)	34 (0.2)	(0.1, 0.3)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ovarian cyst	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	157 (0.9)	(0.7, 1.0)	141 (0.8)	(0.7, 0.9)
Oropharyngeal pain	34 (0.2)	(0.1, 0.3)	30 (0.2)	(0.1, 0.2)
Nasal congestion	21 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Cough	19 (0.1)	(0.1, 0.2)	17 (0.1)	(0.1, 0.2)
Rhinorrhoea	18 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Rhinitis allergic	10 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Asthma	9 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dyspnoea	7 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Sinus congestion	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bronchospasm	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	177 (1.0)	(0.9, 1.1)	124 (0.7)	(0.6, 0.8)
Rash	42 (0.2)	(0.2, 0.3)	36 (0.2)	(0.1, 0.3)
Hyperhidrosis	24 (0.1)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Pruritus	18 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Dermatitis contact	13 (0.1)	(0.0, 0.1)	17 (0.1)	(0.1, 0.2)
Urticaria	12 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Night sweats	14 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Rash pruritic	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Erythema	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eczema	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rash maculo-papular	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Skin lesion	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Alopecia	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dermatitis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Angioedema	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dermal cyst	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	26 (0.1)	(0.1, 0.2)	16 (0.1)	(0.1, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Tooth extraction	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Endodontic procedure	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salpingectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	23 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
FATIGUE@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	52 (0.3)	(0.2, 0.4)	60 (0.3)	(0.3, 0.4)
Hypertension	24 (0.1)	(0.1, 0.2)	33 (0.2)	(0.1, 0.3)
Hot flush	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)

14.404. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Flushing	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Haematoma	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_bs_p3_saf

14.405. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=397)		Placebo (N[a]=429)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	96 (24.2)	(20.0, 28.7)	45 (10.5)	(7.8, 13.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Lymphadenopathy	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
EAR AND LABYRINTH DISORDERS	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
Vertigo	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
EYE DISORDERS	2 (0.5)	(0.1, 1.8)	0	(0.0, 0.9)
Dry eye	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Photophobia	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
GASTROINTESTINAL DISORDERS	8 (2.0)	(0.9, 3.9)	8 (1.9)	(0.8, 3.6)
Diarrhoea	4 (1.0)	(0.3, 2.6)	2 (0.5)	(0.1, 1.7)
Nausea	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Vomiting	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Toothache	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Abdominal pain	0	(0.0, 0.9)	2 (0.5)	(0.1, 1.7)
Gastritis	0	(0.0, 0.9)	2 (0.5)	(0.1, 1.7)
Paraesthesia oral	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Food poisoning	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Retching	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Gingival pain	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Hiatus hernia	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	63 (15.9)	(12.4, 19.8)	20 (4.7)	(2.9, 7.1)
Injection site pain	41 (10.3)	(7.5, 13.7)	10 (2.3)	(1.1, 4.2)
Fatigue	22 (5.5)	(3.5, 8.3)	4 (0.9)	(0.3, 2.4)
Pyrexia	22 (5.5)	(3.5, 8.3)	3 (0.7)	(0.1, 2.0)
Chills	12 (3.0)	(1.6, 5.2)	4 (0.9)	(0.3, 2.4)
Pain	3 (0.8)	(0.2, 2.2)	0	(0.0, 0.9)
Injection site erythema	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Malaise	2 (0.5)	(0.1, 1.8)	1 (0.2)	(0.0, 1.3)
Injection site swelling	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Asthenia	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Injection site pruritus	2 (0.5)	(0.1, 1.8)	1 (0.2)	(0.0, 1.3)
Chest pain	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)

14.405. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=397)		Placebo (N[a]=429)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site bruising	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Vaccination site pain	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
IMMUNE SYSTEM DISORDERS	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
Drug hypersensitivity	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Hypersensitivity	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
INFECTIONS AND INFESTATIONS	7 (1.8)	(0.7, 3.6)	3 (0.7)	(0.1, 2.0)
Ear infection	2 (0.5)	(0.1, 1.8)	0	(0.0, 0.9)
Upper respiratory tract infection	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Vulvovaginal mycotic infection	0	(0.0, 0.9)	2 (0.5)	(0.1, 1.7)
Appendicitis	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Oral herpes	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Pyelonephritis	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Folliculitis	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Escherichia urinary tract infection	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (1.3)	(0.4, 2.9)	3 (0.7)	(0.1, 2.0)
Fall	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Contusion	2 (0.5)	(0.1, 1.8)	0	(0.0, 0.9)
Muscle strain	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Road traffic accident	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
Exposure during pregnancy	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
Limb injury	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Chest injury	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
INVESTIGATIONS	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
Body temperature increased	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Colonoscopy	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Glucose tolerance impaired	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	26 (6.5)	(4.3, 9.4)	6 (1.4)	(0.5, 3.0)
Myalgia	13 (3.3)	(1.8, 5.5)	2 (0.5)	(0.1, 1.7)
Arthralgia	4 (1.0)	(0.3, 2.6)	1 (0.2)	(0.0, 1.3)
Pain in extremity	2 (0.5)	(0.1, 1.8)	2 (0.5)	(0.1, 1.7)
Back pain	3 (0.8)	(0.2, 2.2)	1 (0.2)	(0.0, 1.3)

14.405. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=397)		Placebo (N[a]=429)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle spasms	3 (0.8)	(0.2, 2.2)	0	(0.0, 0.9)
Musculoskeletal stiffness	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Muscle contracture	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Musculoskeletal chest pain	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Musculoskeletal discomfort	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.9)	2 (0.5)	(0.1, 1.7)
Acrochordon	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Colon adenoma	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
NERVOUS SYSTEM DISORDERS	20 (5.0)	(3.1, 7.7)	7 (1.6)	(0.7, 3.3)
Headache	17 (4.3)	(2.5, 6.8)	6 (1.4)	(0.5, 3.0)
Dizziness	2 (0.5)	(0.1, 1.8)	0	(0.0, 0.9)
Tension headache	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Presyncope	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Abortion spontaneous incomplete	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
PSYCHIATRIC DISORDERS	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
Insomnia	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Depression	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.3)	(0.0, 1.4)	1 (0.2)	(0.0, 1.3)
Ovarian cyst	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Vaginal haemorrhage	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.8)	(0.2, 2.2)	5 (1.2)	(0.4, 2.7)
Oropharyngeal pain	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Cough	2 (0.5)	(0.1, 1.8)	0	(0.0, 0.9)
Rhinorrhoea	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Rhinitis allergic	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Pulmonary embolism	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Nasal turbinate hypertrophy	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Haemoptysis	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Pruritus	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)

14.405. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=397)		Placebo (N[a]=429)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Polypectomy	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
UNCODED TERM	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
VASCULAR DISORDERS	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Deep vein thrombosis	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut bsage p3 saf

14.406. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=148)		Placebo (N[a]=151)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	24 (16.2)	(10.7, 23.2)	12 (7.9)	(4.2, 13.5)
GASTROINTESTINAL DISORDERS	2 (1.4)	(0.2, 4.8)	2 (1.3)	(0.2, 4.7)
Diarrhoea	1 (0.7)	(0.0, 3.7)	1 (0.7)	(0.0, 3.6)
Nausea	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Colitis microscopic	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Parotid duct obstruction	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	13 (8.8)	(4.8, 14.6)	3 (2.0)	(0.4, 5.7)
Injection site pain	7 (4.7)	(1.9, 9.5)	1 (0.7)	(0.0, 3.6)
Fatigue	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Pyrexia	2 (1.4)	(0.2, 4.8)	1 (0.7)	(0.0, 3.6)
Chills	5 (3.4)	(1.1, 7.7)	0	(0.0, 2.4)
Pain	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Injection site discomfort	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
Injection site haematoma	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
INFECTIONS AND INFESTATIONS	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
Parotitis	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (1.4)	(0.2, 4.8)	1 (0.7)	(0.0, 3.6)
Fall	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
Contusion	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Rib fracture	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
Muscle injury	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Overdose	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
INVESTIGATIONS	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Body temperature increased	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
METABOLISM AND NUTRITION DISORDERS	1 (0.7)	(0.0, 3.7)	1 (0.7)	(0.0, 3.6)
Hypokalaemia	1 (0.7)	(0.0, 3.7)	1 (0.7)	(0.0, 3.6)
Hypomagnesaemia	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (4.7)	(1.9, 9.5)	4 (2.6)	(0.7, 6.6)
Myalgia	3 (2.0)	(0.4, 5.8)	2 (1.3)	(0.2, 4.7)
Arthralgia	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Pain in extremity	1 (0.7)	(0.0, 3.7)	1 (0.7)	(0.0, 3.6)

14.406. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=148)		Placebo (N[a]=151)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Back pain	1 (0.7)	(0.0, 3.7)	1 (0.7)	(0.0, 3.6)
Joint effusion	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
NERVOUS SYSTEM DISORDERS	3 (2.0)	(0.4, 5.8)	2 (1.3)	(0.2, 4.7)
Headache	1 (0.7)	(0.0, 3.7)	2 (1.3)	(0.2, 4.7)
Dizziness	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Carpal tunnel syndrome	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Cough	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
Psoriasis	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
VASCULAR DISORDERS	1 (0.7)	(0.0, 3.7)	1 (0.7)	(0.0, 3.6)
Hypertension	0	(0.0, 2.5)	1 (0.7)	(0.0, 3.6)
Arteriosclerosis	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut bsage p3 saf

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3009 (29.5)	(28.7, 30.4)	1351 (13.3)	(12.6, 13.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	60 (0.6)	(0.4, 0.8)	7 (0.1)	(0.0, 0.1)
Lymphadenopathy	51 (0.5)	(0.4, 0.7)	3 (0.0)	(0.0, 0.1)
Anaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	22 (0.2)	(0.1, 0.3)	20 (0.2)	(0.1, 0.3)
Palpitations	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Tachycardia	8 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Left ventricular hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tricuspid valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	28 (0.3)	(0.2, 0.4)	15 (0.1)	(0.1, 0.2)
Vertigo	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Tinnitus	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ear pain	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo positional	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniere's disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sudden hearing loss	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	25 (0.2)	(0.2, 0.4)	19 (0.2)	(0.1, 0.3)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye irritation	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Keratitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vitreous detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Conjunctivitis allergic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ocular hyperaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Photophobia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lacrimation increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Corneal irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	313 (3.1)	(2.7, 3.4)	214 (2.1)	(1.8, 2.4)
Diarrhoea	103 (1.0)	(0.8, 1.2)	92 (0.9)	(0.7, 1.1)
Nausea	136 (1.3)	(1.1, 1.6)	41 (0.4)	(0.3, 0.5)
Vomiting	33 (0.3)	(0.2, 0.5)	19 (0.2)	(0.1, 0.3)
Toothache	12 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Abdominal pain upper	14 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Abdominal pain	8 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Dyspepsia	7 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Odynophagia	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dental caries	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abdominal distension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Stomatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Large intestine polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Faeces soft	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tooth impacted	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Umbilical hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angular cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Noninfective gingivitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swollen tongue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2178 (21.4)	(20.6, 22.2)	455 (4.5)	(4.1, 4.9)
Injection site pain	1292 (12.7)	(12.0, 13.3)	178 (1.7)	(1.5, 2.0)
Fatigue	657 (6.5)	(6.0, 6.9)	167 (1.6)	(1.4, 1.9)
Pyrexia	776 (7.6)	(7.1, 8.2)	34 (0.3)	(0.2, 0.5)
Chills	668 (6.6)	(6.1, 7.1)	51 (0.5)	(0.4, 0.7)
Pain	297 (2.9)	(2.6, 3.3)	22 (0.2)	(0.1, 0.3)
Injection site erythema	86 (0.8)	(0.7, 1.0)	13 (0.1)	(0.1, 0.2)
Malaise	57 (0.6)	(0.4, 0.7)	6 (0.1)	(0.0, 0.1)
Injection site swelling	50 (0.5)	(0.4, 0.6)	9 (0.1)	(0.0, 0.2)
Asthenia	31 (0.3)	(0.2, 0.4)	17 (0.2)	(0.1, 0.3)
Injection site pruritus	13 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Influenza like illness	12 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Chest pain	9 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Injection site bruising	5 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Vaccination site pain	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Axillary pain	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest discomfort	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site oedema	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site induration	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Peripheral swelling	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling face	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thirst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Application site pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Application site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Medical device pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaccination site induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	19 (0.2)	(0.1, 0.3)	11 (0.1)	(0.1, 0.2)
Seasonal allergy	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Immunisation reaction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	149 (1.5)	(1.2, 1.7)	165 (1.6)	(1.4, 1.9)
Urinary tract infection	25 (0.2)	(0.2, 0.4)	22 (0.2)	(0.1, 0.3)
Tooth infection	9 (0.1)	(0.0, 0.2)	18 (0.2)	(0.1, 0.3)
Sinusitis	8 (0.1)	(0.0, 0.2)	12 (0.1)	(0.1, 0.2)
Herpes zoster	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cellulitis	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Ear infection	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Conjunctivitis	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cystitis	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hordeolum	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Upper respiratory tract infection	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Appendicitis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingivitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Oral herpes	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tooth abscess	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periodontitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Furuncle	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Influenza	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nasopharyngitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paronychia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis streptococcal	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pyelonephritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Folliculitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes simplex	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Escherichia urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Trichomoniasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bartholinitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Genital herpes simplex	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Papilloma viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinusitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Varicella	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	78 (0.8)	(0.6, 1.0)	95 (0.9)	(0.8, 1.1)
Fall	9 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Ligament sprain	4 (0.0)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)
Skin laceration	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Contusion	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Muscle strain	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Road traffic accident	4 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Skin abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arthropod bite	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Exposure during pregnancy	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Limb injury	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Foot fracture	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Procedural pain	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Animal bite	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint dislocation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint injury	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rib fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Head injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Epicondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foreign body in eye	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb traumatic amputation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penis injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post procedural swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INVESTIGATIONS	73 (0.7)	(0.6, 0.9)	15 (0.1)	(0.1, 0.2)
Body temperature increased	55 (0.5)	(0.4, 0.7)	7 (0.1)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Blood glucose increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Heart rate increased	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Weight decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Weight increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	43 (0.4)	(0.3, 0.6)	27 (0.3)	(0.2, 0.4)
Decreased appetite	22 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Type 2 diabetes mellitus	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperlipidaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypocalcaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	859 (8.4)	(7.9, 9.0)	210 (2.1)	(1.8, 2.4)
Myalgia	604 (5.9)	(5.5, 6.4)	73 (0.7)	(0.6, 0.9)
Arthralgia	123 (1.2)	(1.0, 1.4)	35 (0.3)	(0.2, 0.5)
Pain in extremity	90 (0.9)	(0.7, 1.1)	15 (0.1)	(0.1, 0.2)
Back pain	39 (0.4)	(0.3, 0.5)	45 (0.4)	(0.3, 0.6)
Neck pain	14 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Muscle spasms	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Osteoarthritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tendonitis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscle contracture	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bursitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flank pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Exostosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Costochondritis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tendon disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Coccydynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periarthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal stenosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Trigger finger	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle tightness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	12 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Lipoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	711 (7.0)	(6.5, 7.5)	265 (2.6)	(2.3, 2.9)
Headache	616 (6.0)	(5.6, 6.5)	188 (1.8)	(1.6, 2.1)
Dizziness	29 (0.3)	(0.2, 0.4)	25 (0.2)	(0.2, 0.4)
Paraesthesia	10 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Lethargy	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Migraine	15 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Syncope	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Sciatica	7 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Tension headache	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Presyncope	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tremor	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cervical radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depressed level of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	50 (0.5)	(0.4, 0.6)	36 (0.4)	(0.2, 0.5)
Anxiety	14 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Insomnia	14 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Depression	10 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sleep disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bruxism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Substance abuse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RENAL AND URINARY DISORDERS	9 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
Dysuria	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Haematuria	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	22 (0.2)	(0.1, 0.3)	26 (0.3)	(0.2, 0.4)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ovarian cyst	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Menstruation irregular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Polycystic ovaries	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	87 (0.9)	(0.7, 1.1)	98 (1.0)	(0.8, 1.2)
Oropharyngeal pain	23 (0.2)	(0.1, 0.3)	22 (0.2)	(0.1, 0.3)
Nasal congestion	14 (0.1)	(0.1, 0.2)	23 (0.2)	(0.1, 0.3)
Cough	11 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Rhinorrhoea	8 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Rhinitis allergic	9 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Asthma	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspnoea	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sinus congestion	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Epistaxis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Reflux laryngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	97 (1.0)	(0.8, 1.2)	64 (0.6)	(0.5, 0.8)
Rash	24 (0.2)	(0.2, 0.4)	20 (0.2)	(0.1, 0.3)
Hyperhidrosis	14 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Pruritus	8 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.2)
Urticaria	8 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erythema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eczema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin lesion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Alopecia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angioedema	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermal cyst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis allergic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug eruption	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ecchymosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acne	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash papular	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis acneiform	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic foot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Livedo reticularis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pityriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	11 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Dental implantation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth extraction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Endodontic procedure	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug titration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Salpingectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	17 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.1)
FATIGUE@@	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MYALGIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	26 (0.3)	(0.2, 0.4)	28 (0.3)	(0.2, 0.4)
Hypertension	9 (0.1)	(0.0, 0.2)	16 (0.2)	(0.1, 0.3)
Hot flush	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arteriosclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Essential hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.407. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut bsage p3 saf

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=7655) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=7621) n[b] (%)	 (95% CI[c])
Any event	1828 (23.9)	(22.9, 24.9)	902 (11.8)	(11.1, 12.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	15 (0.2)	(0.1, 0.3)	5 (0.1)	(0.0, 0.2)
Lymphadenopathy	9 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	4 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	23 (0.3)	(0.2, 0.5)	16 (0.2)	(0.1, 0.3)
Palpitations	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tachycardia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	5 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	24 (0.3)	(0.2, 0.5)	19 (0.2)	(0.2, 0.4)
Vertigo	13 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Tinnitus	5 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vertigo positional	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniere's disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	22 (0.3)	(0.2, 0.4)	20 (0.3)	(0.2, 0.4)
Vision blurred	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cataract	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chalazion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Keratitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	213 (2.8)	(2.4, 3.2)	129 (1.7)	(1.4, 2.0)
Diarrhoea	76 (1.0)	(0.8, 1.2)	50 (0.7)	(0.5, 0.9)
Nausea	71 (0.9)	(0.7, 1.2)	21 (0.3)	(0.2, 0.4)
Vomiting	11 (0.1)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Toothache	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Abdominal pain upper	7 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Abdominal pain	5 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.1)
Dyspepsia	5 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Odynophagia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Constipation	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Dental caries	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Abdominal distension	5 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stomatitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Large intestine polyp	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Faeces soft	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Food poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis microscopic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiatus hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1164 (15.2)	(14.4, 16.0)	232 (3.0)	(2.7, 3.5)
Injection site pain	722 (9.4)	(8.8, 10.1)	88 (1.2)	(0.9, 1.4)
Fatigue	325 (4.2)	(3.8, 4.7)	81 (1.1)	(0.8, 1.3)
Pyrexia	317 (4.1)	(3.7, 4.6)	21 (0.3)	(0.2, 0.4)
Chills	297 (3.9)	(3.5, 4.3)	29 (0.4)	(0.3, 0.5)
Pain	145 (1.9)	(1.6, 2.2)	12 (0.2)	(0.1, 0.3)
Injection site erythema	51 (0.7)	(0.5, 0.9)	7 (0.1)	(0.0, 0.2)
Malaise	36 (0.5)	(0.3, 0.7)	7 (0.1)	(0.0, 0.2)
Injection site swelling	40 (0.5)	(0.4, 0.7)	7 (0.1)	(0.0, 0.2)
Asthenia	26 (0.3)	(0.2, 0.5)	7 (0.1)	(0.0, 0.2)
Injection site pruritus	11 (0.1)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Chest pain	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site bruising	3 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Vaccination site pain	5 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Injection site warmth	4 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cyst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	5 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	4 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Immunisation reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	122 (1.6)	(1.3, 1.9)	115 (1.5)	(1.2, 1.8)
Urinary tract infection	19 (0.2)	(0.1, 0.4)	21 (0.3)	(0.2, 0.4)
Tooth infection	12 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Sinusitis	10 (0.1)	(0.1, 0.2)	9 (0.1)	(0.1, 0.2)
Herpes zoster	6 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cellulitis	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Ear infection	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Conjunctivitis	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cystitis	4 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Hordeolum	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Upper respiratory tract infection	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulitis	4 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis externa	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingivitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Acute sinusitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Oral herpes	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth abscess	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bronchitis	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Furuncle	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Influenza	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasopharyngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis media acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Erysipelas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fungal skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival abscess	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trichomoniasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cellulitis orbital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fungal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rash pustular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	83 (1.1)	(0.9, 1.3)	102 (1.3)	(1.1, 1.6)
Fall	23 (0.3)	(0.2, 0.5)	26 (0.3)	(0.2, 0.5)
Ligament sprain	9 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.2)
Skin laceration	4 (0.1)	(0.0, 0.1)	11 (0.1)	(0.1, 0.3)
Contusion	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.1, 0.2)
Muscle strain	6 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Road traffic accident	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Skin abrasion	4 (0.1)	(0.0, 0.1)	9 (0.1)	(0.1, 0.2)
Arthropod bite	7 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)
Limb injury	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Procedural pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Animal bite	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.2)
Arthropod sting	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint dislocation	5 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Joint injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rib fracture	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vaccination complication	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thermal burn	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chest injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hand fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Wound	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Epicondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scapula fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	54 (0.7)	(0.5, 0.9)	16 (0.2)	(0.1, 0.3)
Body temperature increased	31 (0.4)	(0.3, 0.6)	1 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood testosterone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Platelet count increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	29 (0.4)	(0.3, 0.5)	22 (0.3)	(0.2, 0.4)
Decreased appetite	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitamin D deficiency	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diabetes mellitus inadequate control	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	458 (6.0)	(5.5, 6.5)	155 (2.0)	(1.7, 2.4)
Myalgia	269 (3.5)	(3.1, 4.0)	46 (0.6)	(0.4, 0.8)
Arthralgia	76 (1.0)	(0.8, 1.2)	39 (0.5)	(0.4, 0.7)
Pain in extremity	69 (0.9)	(0.7, 1.1)	15 (0.2)	(0.1, 0.3)
Back pain	35 (0.5)	(0.3, 0.6)	21 (0.3)	(0.2, 0.4)
Neck pain	7 (0.1)	(0.0, 0.2)	9 (0.1)	(0.1, 0.2)
Muscle spasms	14 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.2)
Musculoskeletal stiffness	9 (0.1)	(0.1, 0.2)	4 (0.1)	(0.0, 0.1)
Osteoarthritis	5 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Tendonitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle contracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscular weakness	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bursitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Exostosis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Joint swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bone pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigger finger	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	10 (0.1)	(0.1, 0.2)	20 (0.3)	(0.2, 0.4)
Basal cell carcinoma	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Lipoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adenoma benign	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	382 (5.0)	(4.5, 5.5)	156 (2.0)	(1.7, 2.4)
Headache	310 (4.0)	(3.6, 4.5)	96 (1.3)	(1.0, 1.5)
Dizziness	24 (0.3)	(0.2, 0.5)	22 (0.3)	(0.2, 0.4)
Paraesthesia	5 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Lethargy	15 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Migraine	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Sciatica	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Presyncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Burning sensation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cervical radiculopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Migraine with aura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Balance disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device connection issue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	24 (0.3)	(0.2, 0.5)	17 (0.2)	(0.1, 0.4)
Anxiety	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Insomnia	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.2)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sleep disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Mental status changes	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Libido increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	17 (0.2)	(0.1, 0.4)	12 (0.2)	(0.1, 0.3)
Dysuria	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Prostatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaginal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostatomegaly	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	70 (0.9)	(0.7, 1.2)	43 (0.6)	(0.4, 0.8)
Oropharyngeal pain	11 (0.1)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Nasal congestion	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Cough	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Rhinorrhoea	10 (0.1)	(0.1, 0.2)	4 (0.1)	(0.0, 0.1)
Rhinitis allergic	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthma	5 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Dyspnoea	4 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchospasm	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hiccups	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	80 (1.0)	(0.8, 1.3)	60 (0.8)	(0.6, 1.0)
Rash	18 (0.2)	(0.1, 0.4)	16 (0.2)	(0.1, 0.3)
Hyperhidrosis	10 (0.1)	(0.1, 0.2)	4 (0.1)	(0.0, 0.1)
Pruritus	10 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.2)
Dermatitis contact	6 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Urticaria	4 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Rash pruritic	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erythema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin lesion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermatitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angioedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermal cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis allergic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	15 (0.2)	(0.1, 0.3)	4 (0.1)	(0.0, 0.1)
Dental implantation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth extraction	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Apicectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	6 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CHILLS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	26 (0.3)	(0.2, 0.5)	32 (0.4)	(0.3, 0.6)
Hypertension	15 (0.2)	(0.1, 0.3)	17 (0.2)	(0.1, 0.4)
Hot flush	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypotension	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Orthostatic hypotension	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.408. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut bsage p3 saf

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1429 (27.2)	(26.0, 28.4)	834 (15.8)	(14.9, 16.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	36 (0.7)	(0.5, 0.9)	4 (0.1)	(0.0, 0.2)
Lymphadenopathy	29 (0.6)	(0.4, 0.8)	2 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Anaemia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lymph node pain	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
CARDIAC DISORDERS	13 (0.2)	(0.1, 0.4)	15 (0.3)	(0.2, 0.5)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Palpitations	4 (0.1)	(0.0, 0.2)	8 (0.2)	(0.1, 0.3)
Tachycardia	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Sinus tachycardia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tricuspid valve incompetence	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Aortic valve incompetence	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Bundle branch block right	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Cardiac disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Myocarditis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	22 (0.4)	(0.3, 0.6)	13 (0.2)	(0.1, 0.4)
Vertigo	8 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.2)
Tinnitus	5 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Ear pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Vertigo positional	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Meniere's disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergic otitis media	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Sudden hearing loss	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Tympanic membrane perforation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	6 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Hypothyroidism	4 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Thyroid mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
EYE DISORDERS	15 (0.3)	(0.2, 0.5)	19 (0.4)	(0.2, 0.6)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cataract	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry eye	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Keratitis	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ocular hyperaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lacrimation increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Blepharospasm	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Dacryostenosis acquired	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Episcleritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Eye allergy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eyelid haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eyelid oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Eyelid pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Eyelids pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Iritis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ocular discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ulcerative keratitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	153 (2.9)	(2.5, 3.4)	127 (2.4)	(2.0, 2.9)
Diarrhoea	55 (1.0)	(0.8, 1.4)	43 (0.8)	(0.6, 1.1)
Nausea	36 (0.7)	(0.5, 0.9)	12 (0.2)	(0.1, 0.4)
Vomiting	9 (0.2)	(0.1, 0.3)	10 (0.2)	(0.1, 0.3)
Toothache	8 (0.2)	(0.1, 0.3)	11 (0.2)	(0.1, 0.4)
Abdominal pain upper	13 (0.2)	(0.1, 0.4)	5 (0.1)	(0.0, 0.2)
Abdominal pain	7 (0.1)	(0.1, 0.3)	10 (0.2)	(0.1, 0.3)
Dyspepsia	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Gastrooesophageal reflux disease	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)
Odynophagia	10 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.2)
Constipation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental caries	5 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Haemorrhoids	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Abdominal distension	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry mouth	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flatulence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Irritable bowel syndrome	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Stomatitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Large intestine polyp	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Faeces soft	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Inguinal hernia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Parotid duct obstruction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Umbilical hernia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal hernia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute abdomen	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anal pruritus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angular cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Gastritis erosive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Gingival bleeding	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lip oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Loose tooth	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oesophageal food impaction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Oral mucosa haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Palatal disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Salivary gland mucocoele	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tongue discolouration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tooth disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	814 (15.5)	(14.5, 16.5)	193 (3.7)	(3.2, 4.2)
Injection site pain	451 (8.6)	(7.8, 9.4)	65 (1.2)	(1.0, 1.6)
Fatigue	193 (3.7)	(3.2, 4.2)	71 (1.3)	(1.1, 1.7)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pyrexia	292 (5.6)	(5.0, 6.2)	13 (0.2)	(0.1, 0.4)
Chills	168 (3.2)	(2.7, 3.7)	26 (0.5)	(0.3, 0.7)
Pain	65 (1.2)	(1.0, 1.6)	8 (0.2)	(0.1, 0.3)
Injection site erythema	34 (0.6)	(0.4, 0.9)	4 (0.1)	(0.0, 0.2)
Malaise	21 (0.4)	(0.2, 0.6)	0	(0.0, 0.1)
Injection site swelling	15 (0.3)	(0.2, 0.5)	4 (0.1)	(0.0, 0.2)
Asthenia	41 (0.8)	(0.6, 1.1)	20 (0.4)	(0.2, 0.6)
Injection site pruritus	4 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Influenza like illness	6 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Chest pain	5 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Injection site bruising	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaccination site pain	5 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Injection site warmth	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary pain	4 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Feeling hot	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Injection site oedema	8 (0.2)	(0.1, 0.3)	0	(0.0, 0.1)
Injection site discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oedema peripheral	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Swelling face	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Swelling	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Face oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Nodule	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thirst	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaccination site oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Vessel puncture site haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Application site pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Application site rash	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Application site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Capsular contracture associated with breast implant	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Illness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Medical device site granuloma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Biliary colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hepatic cirrhosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hypersensitivity	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	100 (1.9)	(1.6, 2.3)	104 (2.0)	(1.6, 2.4)
Urinary tract infection	12 (0.2)	(0.1, 0.4)	10 (0.2)	(0.1, 0.3)
Tooth infection	17 (0.3)	(0.2, 0.5)	20 (0.4)	(0.2, 0.6)
Sinusitis	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Herpes zoster	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Cellulitis	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Ear infection	2 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Gastroenteritis	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Conjunctivitis	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Cystitis	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Hordeolum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Upper respiratory tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)
Diverticulitis	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Otitis externa	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Otitis media	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Appendicitis	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Gingivitis	5 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oral herpes	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth abscess	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Furuncle	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Periodontitis	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Influenza	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Otitis media acute	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paronychia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pyelonephritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Folliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Genital herpes	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Herpes simplex	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Erysipelas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Laryngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Onychomycosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngitis	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Rash pustular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Vulvovaginitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess limb	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acarodermatitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anal fistula infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bartholinitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Bone abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Dental fistula	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Endocarditis bacterial	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Genital herpes simplex	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ophthalmic herpes zoster	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Papilloma viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pilonidal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Sialoadenitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinusitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Soft tissue infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Urosepsis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Viral upper respiratory tract infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	42 (0.8)	(0.6, 1.1)	66 (1.3)	(1.0, 1.6)
Fall	6 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Ligament sprain	2 (0.0)	(0.0, 0.1)	9 (0.2)	(0.1, 0.3)
Skin laceration	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Contusion	3 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)
Muscle strain	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Arthropod bite	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Road traffic accident	3 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)
Skin abrasion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Exposure during pregnancy	3 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)
Limb injury	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Procedural pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint dislocation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Joint injury	0	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Ankle fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Thermal burn	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hand fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ligament rupture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Wound	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Epicondylitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Procedural dizziness	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Dental restoration failure	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ligament injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Penis injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Post procedural discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Post procedural haemorrhage	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Postoperative ileus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Tendon injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	29 (0.6)	(0.4, 0.8)	7 (0.1)	(0.1, 0.3)
Body temperature increased	24 (0.5)	(0.3, 0.7)	5 (0.1)	(0.0, 0.2)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Weight decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
C-reactive protein	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Colonoscopy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Endoscopy upper gastrointestinal tract	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lumbar puncture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	23 (0.4)	(0.3, 0.7)	24 (0.5)	(0.3, 0.7)
Decreased appetite	7 (0.1)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Type 2 diabetes mellitus	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Gout	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hyperlipidaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Insulin resistance	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	393 (7.5)	(6.8, 8.2)	164 (3.1)	(2.7, 3.6)
Myalgia	239 (4.5)	(4.0, 5.1)	61 (1.2)	(0.9, 1.5)
Arthralgia	60 (1.1)	(0.9, 1.5)	29 (0.6)	(0.4, 0.8)
Pain in extremity	40 (0.8)	(0.5, 1.0)	10 (0.2)	(0.1, 0.3)
Back pain	44 (0.8)	(0.6, 1.1)	39 (0.7)	(0.5, 1.0)
Neck pain	11 (0.2)	(0.1, 0.4)	12 (0.2)	(0.1, 0.4)
Muscle spasms	5 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Osteoarthritis	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle contracture	5 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Tendonitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bursitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flank pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Musculoskeletal discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Exostosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Costochondritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Temporomandibular joint syndrome	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Tendon disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Torticollis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Coccydynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Osteitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Spondylitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Synovial cyst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Trigger finger	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Bone swelling	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	9 (0.2)	(0.1, 0.3)	3 (0.1)	(0.0, 0.2)
Lipoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Acrochordon	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Benign breast neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Chondroma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	296 (5.6)	(5.0, 6.3)	182 (3.5)	(3.0, 4.0)
Headache	243 (4.6)	(4.1, 5.2)	132 (2.5)	(2.1, 3.0)
Dizziness	14 (0.3)	(0.1, 0.4)	10 (0.2)	(0.1, 0.3)
Paraesthesia	8 (0.2)	(0.1, 0.3)	8 (0.2)	(0.1, 0.3)
Migraine	4 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Syncope	5 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Sciatica	6 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)
Tension headache	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Dysgeusia	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Somnolence	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Presyncope	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Burning sensation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Neuropathy peripheral	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cervical radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Migraine with aura	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Trigeminal neuralgia	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Facial paresis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Head discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Intention tremor	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myoclonus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PRODUCT ISSUES	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Device breakage	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	19 (0.4)	(0.2, 0.6)	23 (0.4)	(0.3, 0.7)
Anxiety	5 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Insomnia	4 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Depression	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Irritability	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Panic attack	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Sleep disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Bruxism	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Confusional state	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Panic disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Panic reaction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Schizophrenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Stress	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	9 (0.2)	(0.1, 0.3)	7 (0.1)	(0.1, 0.3)
Dysuria	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary retention	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Costovertebral angle tenderness	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Urethral discharge	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary bladder polyp	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	18 (0.3)	(0.2, 0.5)	18 (0.3)	(0.2, 0.5)
Dysmenorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ovarian cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pelvic pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Erectile dysfunction	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast cyst	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Genital erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Menorrhagia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pruritus genital	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast calcifications	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cervical dysplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Haematospermia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Haemorrhagic ovarian cyst	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mammary duct ectasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Menstruation irregular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Penile vein thrombosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Premenstrual syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Testicular pain	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Vaginal discharge	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	47 (0.9)	(0.7, 1.2)	38 (0.7)	(0.5, 1.0)
Oropharyngeal pain	9 (0.2)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)
Nasal congestion	5 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Cough	5 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Rhinorrhoea	5 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Rhinitis allergic	6 (0.1)	(0.0, 0.2)	8 (0.2)	(0.1, 0.3)
Asthma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyspnoea	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Throat irritation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Epistaxis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Productive cough	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bronchospasm	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Dyspnoea exertional	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Dysphonia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nasal turbinate hypertrophy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngeal swelling	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pulmonary mass	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Snoring	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	49 (0.9)	(0.7, 1.2)	44 (0.8)	(0.6, 1.1)
Rash	12 (0.2)	(0.1, 0.4)	17 (0.3)	(0.2, 0.5)
Pruritus	11 (0.2)	(0.1, 0.4)	4 (0.1)	(0.0, 0.2)
Hyperhidrosis	4 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Dermatitis contact	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Urticaria	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Night sweats	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)
Erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eczema	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin lesion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermal cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Dermatitis allergic	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Acne	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pain of skin	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pruritus allergic	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash papular	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rosacea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Dermatitis bullous	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Mechanical urticaria	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pityriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pityriasis rosea	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urticaria chronic	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urticaria contact	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
High risk sexual behaviour	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Stress at work	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	13 (0.2)	(0.1, 0.4)	15 (0.3)	(0.2, 0.5)
Tooth extraction	4 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)
Dental implantation	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Endodontic procedure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Wisdom teeth removal	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Cataract operation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug titration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lens extraction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Medical device implantation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Polypectomy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinoplasty	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vasectomy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	4 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)
FATIGUE@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
MYALGIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
VOMITING@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	18 (0.3)	(0.2, 0.5)	25 (0.5)	(0.3, 0.7)
Hypertension	9 (0.2)	(0.1, 0.3)	17 (0.3)	(0.2, 0.5)
Hot flush	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

14.409. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Orthostatic hypotension	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Varicose vein	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Arteriosclerosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diastolic hypertension	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertensive crisis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intermittent claudication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Raynaud's phenomenon	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subgaleal haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_eth_p3_saf

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13436) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=13407) n[b] (%)	 (95% CI[c])
Any event	3621 (26.9)	(26.2, 27.7)	1511 (11.3)	(10.7, 11.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	45 (0.3)	(0.2, 0.4)	8 (0.1)	(0.0, 0.1)
Lymphadenopathy	35 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymph node pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	32 (0.2)	(0.2, 0.3)	21 (0.2)	(0.1, 0.2)
Palpitations	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tachycardia	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Atrial fibrillation	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	33 (0.2)	(0.2, 0.3)	22 (0.2)	(0.1, 0.2)
Vertigo	14 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.1)
Tinnitus	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ear pain	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vertigo positional	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypothyroidism	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hypogonadism	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	36 (0.3)	(0.2, 0.4)	21 (0.2)	(0.1, 0.2)
Eye pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vision blurred	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cataract	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye irritation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chalazion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	394 (2.9)	(2.7, 3.2)	227 (1.7)	(1.5, 1.9)
Diarrhoea	132 (1.0)	(0.8, 1.2)	102 (0.8)	(0.6, 0.9)
Nausea	178 (1.3)	(1.1, 1.5)	50 (0.4)	(0.3, 0.5)
Vomiting	35 (0.3)	(0.2, 0.4)	18 (0.1)	(0.1, 0.2)
Toothache	13 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.1)
Abdominal pain upper	9 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Abdominal pain	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Dyspepsia	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Odynophagia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Constipation	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Dental caries	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dry mouth	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Flatulence	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stomatitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Faeces soft	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis microscopic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Haematochezia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Lip swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Swollen tongue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2667 (19.8)	(19.2, 20.5)	529 (3.9)	(3.6, 4.3)
Injection site pain	1649 (12.3)	(11.7, 12.8)	216 (1.6)	(1.4, 1.8)
Fatigue	829 (6.2)	(5.8, 6.6)	185 (1.4)	(1.2, 1.6)
Pyrexia	847 (6.3)	(5.9, 6.7)	48 (0.4)	(0.3, 0.5)
Chills	825 (6.1)	(5.7, 6.6)	59 (0.4)	(0.3, 0.6)
Pain	386 (2.9)	(2.6, 3.2)	26 (0.2)	(0.1, 0.3)
Injection site erythema	104 (0.8)	(0.6, 0.9)	16 (0.1)	(0.1, 0.2)
Malaise	75 (0.6)	(0.4, 0.7)	15 (0.1)	(0.1, 0.2)
Injection site swelling	78 (0.6)	(0.5, 0.7)	13 (0.1)	(0.1, 0.2)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Asthenia	23 (0.2)	(0.1, 0.3)	5 (0.0)	(0.0, 0.1)
Injection site pruritus	23 (0.2)	(0.1, 0.3)	3 (0.0)	(0.0, 0.1)
Influenza like illness	13 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Chest pain	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Injection site bruising	8 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Vaccination site pain	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site warmth	10 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Axillary pain	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Peripheral swelling	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Oedema peripheral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Face oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vessel puncture site bruise	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	23 (0.2)	(0.1, 0.3)	14 (0.1)	(0.1, 0.2)
Seasonal allergy	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Drug hypersensitivity	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	185 (1.4)	(1.2, 1.6)	185 (1.4)	(1.2, 1.6)
Urinary tract infection	32 (0.2)	(0.2, 0.3)	34 (0.3)	(0.2, 0.4)
Tooth infection	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinusitis	16 (0.1)	(0.1, 0.2)	17 (0.1)	(0.1, 0.2)
Herpes zoster	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Cellulitis	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Ear infection	6 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Gastroenteritis	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Conjunctivitis	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cystitis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hordeolum	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Diverticulitis	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis media	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Appendicitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Oral herpes	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal candidiasis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bronchitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Furuncle	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Influenza	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nasopharyngitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Otitis media acute	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paronychia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Folliculitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Infected bite	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Laryngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	126 (0.9)	(0.8, 1.1)	136 (1.0)	(0.9, 1.2)
Fall	27 (0.2)	(0.1, 0.3)	31 (0.2)	(0.2, 0.3)
Ligament sprain	11 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Skin laceration	9 (0.1)	(0.0, 0.1)	14 (0.1)	(0.1, 0.2)
Contusion	8 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Muscle strain	10 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Arthropod bite	10 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Road traffic accident	2 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Skin abrasion	5 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Exposure during pregnancy	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Limb injury	2 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Foot fracture	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth fracture	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Procedural pain	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Meniscus injury	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Facial bones fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint dislocation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint injury	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rib fracture	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest injury	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fibula fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hand fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bone contusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	101 (0.8)	(0.6, 0.9)	26 (0.2)	(0.1, 0.3)
Body temperature increased	64 (0.5)	(0.4, 0.6)	3 (0.0)	(0.0, 0.1)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood pressure increased	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Blood glucose increased	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Weight decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	50 (0.4)	(0.3, 0.5)	30 (0.2)	(0.2, 0.3)
Decreased appetite	22 (0.2)	(0.1, 0.2)	7 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitamin D deficiency	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dehydration	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	973 (7.2)	(6.8, 7.7)	217 (1.6)	(1.4, 1.8)
Myalgia	661 (4.9)	(4.6, 5.3)	65 (0.5)	(0.4, 0.6)
Arthralgia	150 (1.1)	(0.9, 1.3)	45 (0.3)	(0.2, 0.4)
Pain in extremity	122 (0.9)	(0.8, 1.1)	23 (0.2)	(0.1, 0.3)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Back pain	36 (0.3)	(0.2, 0.4)	32 (0.2)	(0.2, 0.3)
Neck pain	10 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Muscle spasms	17 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Osteoarthritis	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tendonitis	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bursitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Arthritis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flank pain	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Exostosis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint stiffness	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Costochondritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bone pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pain in jaw	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coccydynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigger finger	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13 (0.1)	(0.1, 0.2)	27 (0.2)	(0.1, 0.3)
Basal cell carcinoma	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Lipoma	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Uterine leiomyoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	841 (6.3)	(5.9, 6.7)	260 (1.9)	(1.7, 2.2)
Headache	720 (5.4)	(5.0, 5.8)	170 (1.3)	(1.1, 1.5)
Dizziness	42 (0.3)	(0.2, 0.4)	38 (0.3)	(0.2, 0.4)
Paraesthesia	8 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Migraine	13 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Lethargy	21 (0.2)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Syncope	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Sciatica	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tension headache	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Somnolence	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Presyncope	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tremor	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Parosmia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus headache	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical radiculopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	57 (0.4)	(0.3, 0.5)	31 (0.2)	(0.2, 0.3)
Anxiety	13 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Insomnia	19 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Depression	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Irritability	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sleep disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Disorientation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Bruxism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	19 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Dysuria	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	16 (0.1)	(0.1, 0.2)	17 (0.1)	(0.1, 0.2)
Dysmenorrhoea	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ovarian cyst	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Menorrhagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	116 (0.9)	(0.7, 1.0)	110 (0.8)	(0.7, 1.0)
Oropharyngeal pain	26 (0.2)	(0.1, 0.3)	30 (0.2)	(0.2, 0.3)
Nasal congestion	16 (0.1)	(0.1, 0.2)	23 (0.2)	(0.1, 0.3)
Cough	17 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Rhinorrhoea	14 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Rhinitis allergic	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Asthma	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dyspnoea	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sinus congestion	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Epistaxis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	133 (1.0)	(0.8, 1.2)	82 (0.6)	(0.5, 0.8)
Rash	31 (0.2)	(0.2, 0.3)	19 (0.1)	(0.1, 0.2)
Pruritus	8 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Hyperhidrosis	20 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Dermatitis contact	11 (0.1)	(0.0, 0.1)	13 (0.1)	(0.1, 0.2)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urticaria	10 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Night sweats	14 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Rash pruritic	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Dermatitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angioedema	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermal cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blister	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Drug eruption	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rosacea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	15 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Dental implantation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salpingectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	19 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)
FATIGUE@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	37 (0.3)	(0.2, 0.4)	37 (0.3)	(0.2, 0.4)
Hypertension	16 (0.1)	(0.1, 0.2)	18 (0.1)	(0.1, 0.2)
Hot flush	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Haematoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flushing	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicose vein	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.410. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut eth p3 saf

14.411. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=112)		Placebo (N[a]=109)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	21 (18.8)	(12.0, 27.2)	11 (10.1)	(5.1, 17.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
Anaemia	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 3.2)	4 (3.7)	(1.0, 9.1)
Diarrhoea	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
Nausea	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
Large intestine polyp	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
Diverticulum	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
Gingival discomfort	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	13 (11.6)	(6.3, 19.0)	3 (2.8)	(0.6, 7.8)
Injection site pain	8 (7.1)	(3.1, 13.6)	0	(0.0, 3.3)
Fatigue	4 (3.6)	(1.0, 8.9)	2 (1.8)	(0.2, 6.5)
Pyrexia	5 (4.5)	(1.5, 10.1)	0	(0.0, 3.3)
Chills	5 (4.5)	(1.5, 10.1)	0	(0.0, 3.3)
Pain	4 (3.6)	(1.0, 8.9)	2 (1.8)	(0.2, 6.5)
Influenza like illness	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
INFECTIONS AND INFESTATIONS	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Tooth infection	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.9)	(0.0, 4.9)	2 (1.8)	(0.2, 6.5)
Fall	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
Tooth fracture	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Muscle rupture	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
INVESTIGATIONS	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Body temperature increased	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
METABOLISM AND NUTRITION DISORDERS	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Hypercholesterolaemia	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (6.3)	(2.5, 12.5)	3 (2.8)	(0.6, 7.8)
Myalgia	4 (3.6)	(1.0, 8.9)	0	(0.0, 3.3)
Arthralgia	0	(0.0, 3.2)	2 (1.8)	(0.2, 6.5)
Pain in extremity	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Muscle spasms	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Musculoskeletal stiffness	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)

14.411. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=112)		Placebo (N[a]=109)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Arthritis	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
NERVOUS SYSTEM DISORDERS	4 (3.6)	(1.0, 8.9)	0	(0.0, 3.3)
Headache	3 (2.7)	(0.6, 7.6)	0	(0.0, 3.3)
Migraine	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.9)	(0.0, 4.9)	1 (0.9)	(0.0, 5.0)
Rash	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Skin induration	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)
VASCULAR DISORDERS	1 (0.9)	(0.0, 4.9)	1 (0.9)	(0.0, 5.0)
Hypertension	1 (0.9)	(0.0, 4.9)	0	(0.0, 3.3)
Hypotension	0	(0.0, 3.2)	1 (0.9)	(0.0, 5.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut eth p3 saf

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4252 (27.2)	(26.5, 27.9)	1991 (12.8)	(12.2, 13.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	69 (0.4)	(0.3, 0.6)	12 (0.1)	(0.0, 0.1)
Lymphadenopathy	55 (0.4)	(0.3, 0.5)	6 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaemia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	40 (0.3)	(0.2, 0.3)	33 (0.2)	(0.1, 0.3)
Palpitations	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Tachycardia	11 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	50 (0.3)	(0.2, 0.4)	32 (0.2)	(0.1, 0.3)
Vertigo	19 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Tinnitus	9 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Ear pain	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vertigo positional	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	10 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypothyroidism	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypogonadism	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thyroid mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	46 (0.3)	(0.2, 0.4)	37 (0.2)	(0.2, 0.3)
Eye pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vision blurred	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cataract	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Eye irritation	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Keratitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	463 (3.0)	(2.7, 3.2)	295 (1.9)	(1.7, 2.1)
Diarrhoea	150 (1.0)	(0.8, 1.1)	124 (0.8)	(0.7, 0.9)
Nausea	186 (1.2)	(1.0, 1.4)	50 (0.3)	(0.2, 0.4)
Vomiting	36 (0.2)	(0.2, 0.3)	19 (0.1)	(0.1, 0.2)
Toothache	18 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.2)
Abdominal pain upper	17 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)
Abdominal pain	14 (0.1)	(0.0, 0.2)	13 (0.1)	(0.0, 0.1)
Dyspepsia	10 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Gastrooesophageal reflux disease	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Odynophagia	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Constipation	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Dental caries	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gastritis	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Abdominal distension	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Flatulence	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Stomatitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rectal haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis microscopic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diverticulum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swollen tongue	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Umbilical hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2892 (18.5)	(17.9, 19.1)	564 (3.6)	(3.3, 3.9)
Injection site pain	1736 (11.1)	(10.6, 11.6)	211 (1.4)	(1.2, 1.5)
Fatigue	846 (5.4)	(5.1, 5.8)	205 (1.3)	(1.1, 1.5)
Pyrexia	936 (6.0)	(5.6, 6.4)	45 (0.3)	(0.2, 0.4)
Chills	835 (5.3)	(5.0, 5.7)	67 (0.4)	(0.3, 0.5)
Pain	387 (2.5)	(2.2, 2.7)	28 (0.2)	(0.1, 0.3)
Injection site erythema	120 (0.8)	(0.6, 0.9)	19 (0.1)	(0.1, 0.2)
Malaise	85 (0.5)	(0.4, 0.7)	14 (0.1)	(0.0, 0.2)
Injection site swelling	73 (0.5)	(0.4, 0.6)	11 (0.1)	(0.0, 0.1)
Asthenia	52 (0.3)	(0.2, 0.4)	23 (0.1)	(0.1, 0.2)
Injection site pruritus	22 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Influenza like illness	19 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.0)
Chest pain	13 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Injection site bruising	10 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Vaccination site pain	10 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site warmth	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Axillary pain	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Feeling hot	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest discomfort	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site oedema	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Peripheral swelling	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oedema peripheral	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cholelithiasis	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	20 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Seasonal allergy	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Drug hypersensitivity	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Immunisation reaction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15615) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=15615) n[b] (%)	 (95% CI[c])
Hypersensitivity	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	245 (1.6)	(1.4, 1.8)	258 (1.7)	(1.5, 1.9)
Urinary tract infection	38 (0.2)	(0.2, 0.3)	40 (0.3)	(0.2, 0.3)
Tooth infection	21 (0.1)	(0.1, 0.2)	24 (0.2)	(0.1, 0.2)
Sinusitis	16 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.2)
Herpes zoster	11 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Cellulitis	9 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Ear infection	5 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Gastroenteritis	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Conjunctivitis	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Cystitis	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rhinitis	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Diverticulitis	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Appendicitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Gingivitis	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Oral herpes	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Tooth abscess	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Furuncle	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Periodontitis	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Skin infection	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Influenza	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15615) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=15615) n[b] (%)	 (95% CI[c])
Nasopharyngitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Otitis media acute	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pyelonephritis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Folliculitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Herpes simplex	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash pustular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	149 (1.0)	(0.8, 1.1)	181 (1.2)	(1.0, 1.3)
Fall	30 (0.2)	(0.1, 0.3)	33 (0.2)	(0.1, 0.3)
Ligament sprain	13 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)
Skin laceration	10 (0.1)	(0.0, 0.1)	17 (0.1)	(0.1, 0.2)
Contusion	10 (0.1)	(0.0, 0.1)	16 (0.1)	(0.1, 0.2)
Muscle strain	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Arthropod bite	9 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Road traffic accident	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Skin abrasion	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Exposure during pregnancy	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Limb injury	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth fracture	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Procedural pain	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Meniscus injury	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Joint dislocation	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint injury	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rib fracture	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Thermal burn	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Chest injury	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radius fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Head injury	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal compression fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bone contusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Epicondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	113 (0.7)	(0.6, 0.9)	28 (0.2)	(0.1, 0.3)
Body temperature increased	78 (0.5)	(0.4, 0.6)	6 (0.0)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Blood glucose increased	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	63 (0.4)	(0.3, 0.5)	48 (0.3)	(0.2, 0.4)
Decreased appetite	25 (0.2)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dyslipidaemia	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Hypokalaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Hyperlipidaemia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Vitamin D deficiency	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hyperglycaemia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Insulin resistance	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1171 (7.5)	(7.1, 7.9)	332 (2.1)	(1.9, 2.4)
Myalgia	754 (4.8)	(4.5, 5.2)	103 (0.7)	(0.5, 0.8)
Arthralgia	185 (1.2)	(1.0, 1.4)	62 (0.4)	(0.3, 0.5)
Pain in extremity	148 (0.9)	(0.8, 1.1)	30 (0.2)	(0.1, 0.3)
Back pain	67 (0.4)	(0.3, 0.5)	65 (0.4)	(0.3, 0.5)
Neck pain	20 (0.1)	(0.1, 0.2)	23 (0.1)	(0.1, 0.2)
Muscle spasms	21 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Osteoarthritis	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Muscle contracture	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tendonitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscular weakness	8 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bursitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Plantar fasciitis	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Arthritis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Flank pain	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Exostosis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Joint stiffness	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Joint swelling	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Costochondritis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bone pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tendon disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coccydynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint effusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	22 (0.1)	(0.1, 0.2)	26 (0.2)	(0.1, 0.2)
Basal cell carcinoma	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Lipoma	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	957 (6.1)	(5.8, 6.5)	358 (2.3)	(2.1, 2.5)
Headache	803 (5.1)	(4.8, 5.5)	247 (1.6)	(1.4, 1.8)
Dizziness	46 (0.3)	(0.2, 0.4)	38 (0.2)	(0.2, 0.3)
Paraesthesia	13 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.2)
Migraine	15 (0.1)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lethargy	18 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Syncope	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Sciatica	9 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tension headache	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Presyncope	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tremor	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Parosmia	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dizziness postural	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15615) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=15615) n[b] (%)	 (95% CI[c])
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	66 (0.4)	(0.3, 0.5)	51 (0.3)	(0.2, 0.4)
Anxiety	13 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.2)
Insomnia	20 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Depression	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Irritability	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety disorder	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Sleep disorder	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disorientation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	27 (0.2)	(0.1, 0.3)	21 (0.1)	(0.1, 0.2)
Dysuria	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Haematuria	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pollakiuria	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	28 (0.2)	(0.1, 0.3)	30 (0.2)	(0.1, 0.3)
Dysmenorrhoea	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pelvic pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Breast pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	136 (0.9)	(0.7, 1.0)	124 (0.8)	(0.7, 0.9)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oropharyngeal pain	31 (0.2)	(0.1, 0.3)	30 (0.2)	(0.1, 0.3)
Nasal congestion	15 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.2)
Cough	18 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.2)
Rhinorrhoea	17 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)
Rhinitis allergic	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Asthma	8 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Dyspnoea	7 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Sinus congestion	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bronchospasm	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep apnoea syndrome	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	161 (1.0)	(0.9, 1.2)	109 (0.7)	(0.6, 0.8)
Rash	40 (0.3)	(0.2, 0.3)	32 (0.2)	(0.1, 0.3)
Pruritus	18 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Hyperhidrosis	20 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Dermatitis contact	13 (0.1)	(0.0, 0.1)	16 (0.1)	(0.1, 0.2)
Urticaria	11 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Night sweats	11 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rash pruritic	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Erythema	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Eczema	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Dermatitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angioedema	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dermal cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress at work	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	25 (0.2)	(0.1, 0.2)	17 (0.1)	(0.1, 0.2)
Tooth extraction	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Endodontic procedure	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	17 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
FATIGUE@@	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	50 (0.3)	(0.2, 0.4)	59 (0.4)	(0.3, 0.5)
Hypertension	23 (0.1)	(0.1, 0.2)	34 (0.2)	(0.2, 0.3)
Hot flush	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Haematoma	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Flushing	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.412. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut race p3 saf

14.413. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1694) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1722) n[b] (%)	 (95% CI[c])
Any event	269 (15.9)	(14.2, 17.7)	176 (10.2)	(8.8, 11.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	5 (0.3)	(0.1, 0.7)	1 (0.1)	(0.0, 0.3)
Lymphadenopathy	4 (0.2)	(0.1, 0.6)	0	(0.0, 0.2)
Iron deficiency anaemia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Anaemia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Neutropenia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
CARDIAC DISORDERS	2 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.3)
Coronary artery disease	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Myocardial infarction	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Sinus arrhythmia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	3 (0.2)	(0.0, 0.5)	3 (0.2)	(0.0, 0.5)
Vertigo	3 (0.2)	(0.0, 0.5)	1 (0.1)	(0.0, 0.3)
Tinnitus	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Ear pruritus	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
EYE DISORDERS	3 (0.2)	(0.0, 0.5)	1 (0.1)	(0.0, 0.3)
Vision blurred	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Cataract	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Photophobia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Amaurosis fugax	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	28 (1.7)	(1.1, 2.4)	30 (1.7)	(1.2, 2.5)
Diarrhoea	14 (0.8)	(0.5, 1.4)	9 (0.5)	(0.2, 1.0)
Nausea	7 (0.4)	(0.2, 0.8)	6 (0.3)	(0.1, 0.8)
Vomiting	3 (0.2)	(0.0, 0.5)	5 (0.3)	(0.1, 0.7)
Toothache	2 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Abdominal pain upper	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Abdominal pain	0	(0.0, 0.2)	4 (0.2)	(0.1, 0.6)
Dyspepsia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Gastrooesophageal reflux disease	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Odynophagia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Constipation	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Gastritis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Dry mouth	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Gastrointestinal disorder	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Large intestine polyp	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Rectal haemorrhage	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)

14.413. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1694) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1722) n[b] (%)	 (95% CI[c])
Inguinal hernia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Retching	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Cheilitis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Hypoaesthesia oral	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Salivary gland calculus	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Tooth impacted	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Obstructive pancreatitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	167 (9.9)	(8.5, 11.4)	67 (3.9)	(3.0, 4.9)
Injection site pain	97 (5.7)	(4.7, 6.9)	28 (1.6)	(1.1, 2.3)
Fatigue	43 (2.5)	(1.8, 3.4)	16 (0.9)	(0.5, 1.5)
Pyrexia	53 (3.1)	(2.4, 4.1)	10 (0.6)	(0.3, 1.1)
Chills	44 (2.6)	(1.9, 3.5)	12 (0.7)	(0.4, 1.2)
Pain	13 (0.8)	(0.4, 1.3)	3 (0.2)	(0.0, 0.5)
Injection site erythema	3 (0.2)	(0.0, 0.5)	1 (0.1)	(0.0, 0.3)
Malaise	4 (0.2)	(0.1, 0.6)	1 (0.1)	(0.0, 0.3)
Injection site swelling	7 (0.4)	(0.2, 0.8)	2 (0.1)	(0.0, 0.4)
Asthenia	5 (0.3)	(0.1, 0.7)	1 (0.1)	(0.0, 0.3)
Injection site pruritus	3 (0.2)	(0.0, 0.5)	0	(0.0, 0.2)
Influenza like illness	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Chest pain	0	(0.0, 0.2)	3 (0.2)	(0.0, 0.5)
Chest discomfort	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Non-cardiac chest pain	1 (0.1)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Peripheral swelling	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Sensation of foreign body	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Bile duct stone	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	3 (0.2)	(0.0, 0.5)	3 (0.2)	(0.0, 0.5)
Seasonal allergy	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Drug hypersensitivity	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Food allergy	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Hypersensitivity	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Allergy to vaccine	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	18 (1.1)	(0.6, 1.7)	18 (1.0)	(0.6, 1.6)
Urinary tract infection	2 (0.1)	(0.0, 0.4)	3 (0.2)	(0.0, 0.5)
Tooth infection	2 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)

14.413. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1694) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1722) n[b] (%)	 (95% CI[c])
Ear infection	2 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.3)
Gastroenteritis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Conjunctivitis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Upper respiratory tract infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Rhinitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Otitis externa	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Otitis media	3 (0.2)	(0.0, 0.5)	1 (0.1)	(0.0, 0.3)
Vulvovaginal mycotic infection	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Appendicitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Pneumonia	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Bronchitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Pharyngitis streptococcal	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Vaginal infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Folliculitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Trichomoniasis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Dermatitis infected	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Fungal infection	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Orchitis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pelvic inflammatory disease	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Sinusitis bacterial	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Skin bacterial infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Varicella	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Wound infection	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	7 (0.4)	(0.2, 0.8)	15 (0.9)	(0.5, 1.4)
Fall	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Skin laceration	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Arthropod bite	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Road traffic accident	1 (0.1)	(0.0, 0.3)	3 (0.2)	(0.0, 0.5)
Exposure during pregnancy	2 (0.1)	(0.0, 0.4)	4 (0.2)	(0.1, 0.6)
Foot fracture	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Meniscus injury	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Ankle fracture	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Thermal burn	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Head injury	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Post procedural discomfort	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Sunburn	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Toxicity to various agents	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)

14.413. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1694) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1722) n[b] (%)	 (95% CI[c])
INVESTIGATIONS	4 (0.2)	(0.1, 0.6)	4 (0.2)	(0.1, 0.6)
Body temperature increased	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Blood pressure increased	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Blood glucose increased	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Blood cholesterol increased	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Blood creatinine decreased	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Blood potassium decreased	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Cardiac stress test abnormal	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	7 (0.4)	(0.2, 0.8)	6 (0.3)	(0.1, 0.8)
Decreased appetite	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Hypercholesterolaemia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Type 2 diabetes mellitus	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Gout	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Vitamin D deficiency	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Dehydration	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Hyperglycaemia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Hypoglycaemia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Hypertriglyceridaemia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Diabetes mellitus	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Increased appetite	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Vitamin B12 deficiency	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	60 (3.5)	(2.7, 4.5)	23 (1.3)	(0.8, 2.0)
Myalgia	38 (2.2)	(1.6, 3.1)	9 (0.5)	(0.2, 1.0)
Arthralgia	8 (0.5)	(0.2, 0.9)	8 (0.5)	(0.2, 0.9)
Pain in extremity	5 (0.3)	(0.1, 0.7)	1 (0.1)	(0.0, 0.3)
Back pain	6 (0.4)	(0.1, 0.8)	3 (0.2)	(0.0, 0.5)
Neck pain	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Muscle spasms	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Musculoskeletal stiffness	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Osteoarthritis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Tendonitis	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Muscular weakness	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Exostosis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Joint range of motion decreased	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Tendon disorder	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)

14.413. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1694) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1722) n[b] (%)	 (95% CI[c])
Coccydynia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Muscle discomfort	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Synovitis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Lipoma	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Uterine leiomyoma	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	54 (3.2)	(2.4, 4.1)	37 (2.1)	(1.5, 2.9)
Headache	45 (2.7)	(1.9, 3.5)	20 (1.2)	(0.7, 1.8)
Dizziness	2 (0.1)	(0.0, 0.4)	5 (0.3)	(0.1, 0.7)
Paraesthesia	2 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.4)
Migraine	3 (0.2)	(0.0, 0.5)	1 (0.1)	(0.0, 0.3)
Syncope	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Tension headache	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Dysgeusia	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Somnolence	1 (0.1)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Hypoaesthesia	0	(0.0, 0.2)	4 (0.2)	(0.1, 0.6)
Burning sensation	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Parosmia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Cerebrovascular accident	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Nerve compression	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Dizziness postural	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Abortion spontaneous incomplete	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	4 (0.2)	(0.1, 0.6)	3 (0.2)	(0.0, 0.5)
Anxiety	2 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.3)
Depression	1 (0.1)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Dysphemia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Libido increased	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Suicide attempt	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
RENAL AND URINARY DISORDERS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Renal colic	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.2)	(0.0, 0.5)	3 (0.2)	(0.0, 0.5)
Dysmenorrhoea	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Vaginal haemorrhage	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Dysfunctional uterine bleeding	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)

14.413. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1694)		Placebo (N[a]=1722)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostatomegaly	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Vaginal discharge	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	12 (0.7)	(0.4, 1.2)	17 (1.0)	(0.6, 1.6)
Oropharyngeal pain	2 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.4)
Nasal congestion	5 (0.3)	(0.1, 0.7)	5 (0.3)	(0.1, 0.7)
Cough	0	(0.0, 0.2)	3 (0.2)	(0.0, 0.5)
Rhinorrhoea	1 (0.1)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Rhinitis allergic	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Asthma	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Throat irritation	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Sinus congestion	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Productive cough	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pulmonary embolism	2 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Nasal turbinate hypertrophy	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pharyngeal swelling	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pneumonia aspiration	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Wheezing	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Haemoptysis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Hypoxia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Paranasal sinus hypersecretion	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6 (0.4)	(0.1, 0.8)	6 (0.3)	(0.1, 0.8)
Rash	1 (0.1)	(0.0, 0.3)	3 (0.2)	(0.0, 0.5)
Pruritus	1 (0.1)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Hyperhidrosis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Urticaria	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Night sweats	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Eczema	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Rash maculo-papular	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Alopecia areata	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Dental implantation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Inguinal hernia repair	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
UNCODED TERM	3 (0.2)	(0.0, 0.5)	0	(0.0, 0.2)
FATIGUE@@	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
FEVER@@	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
BOTH UNDERARM LYMPH NODE@@	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)

14.413. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1694)		Placebo (N[a]=1722)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
MUSCLE ACHES@@	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
VASCULAR DISORDERS	6 (0.4)	(0.1, 0.8)	3 (0.2)	(0.0, 0.5)
Hypertension	3 (0.2)	(0.0, 0.5)	1 (0.1)	(0.0, 0.3)
Hot flush	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Flushing	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Deep vein thrombosis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Essential hypertension	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Hypertensive urgency	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_race_p3_saf

14.414. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1492)		Placebo (N[a]=1448)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	550 (36.9)	(34.4, 39.4)	189 (13.1)	(11.4, 14.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.5)	(0.2, 1.0)	0	(0.0, 0.3)
Lymphadenopathy	5 (0.3)	(0.1, 0.8)	0	(0.0, 0.3)
Iron deficiency anaemia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Hypochromic anaemia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
CARDIAC DISORDERS	3 (0.2)	(0.0, 0.6)	2 (0.1)	(0.0, 0.5)
Palpitations	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Atrial fibrillation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Acute myocardial infarction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Angina pectoris	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Coronary artery disease	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Heart disease congenital	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
EAR AND LABYRINTH DISORDERS	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Vertigo positional	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Cerumen impaction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
ENDOCRINE DISORDERS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Basedow's disease	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
EYE DISORDERS	2 (0.1)	(0.0, 0.5)	2 (0.1)	(0.0, 0.5)
Eye pain	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Eye irritation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Ocular hyperaemia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Conjunctival oedema	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Corneal irritation	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Diabetic retinopathy	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
GASTROINTESTINAL DISORDERS	56 (3.8)	(2.8, 4.8)	33 (2.3)	(1.6, 3.2)
Diarrhoea	23 (1.5)	(1.0, 2.3)	13 (0.9)	(0.5, 1.5)
Nausea	21 (1.4)	(0.9, 2.1)	7 (0.5)	(0.2, 1.0)
Vomiting	5 (0.3)	(0.1, 0.8)	4 (0.3)	(0.1, 0.7)
Toothache	1 (0.1)	(0.0, 0.4)	4 (0.3)	(0.1, 0.7)
Abdominal pain upper	4 (0.3)	(0.1, 0.7)	1 (0.1)	(0.0, 0.4)
Dyspepsia	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Gastrooesophageal reflux disease	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Odynophagia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)

14.414. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1492) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1448) n[b] (%)	 (95% CI[c])
Constipation	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Dental caries	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Aphthous ulcer	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Abdominal distension	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Abdominal discomfort	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Flatulence	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Stomatitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Gastrointestinal disorder	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Abdominal pain lower	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Dysphagia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Faeces soft	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Umbilical hernia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Eructation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Gingival bleeding	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Gingival discomfort	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Loose tooth	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Noninfective gingivitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	435 (29.2)	(26.9, 31.5)	94 (6.5)	(5.3, 7.9)
Injection site pain	275 (18.4)	(16.5, 20.5)	42 (2.9)	(2.1, 3.9)
Fatigue	137 (9.2)	(7.8, 10.8)	37 (2.6)	(1.8, 3.5)
Pyrexia	155 (10.4)	(8.9, 12.0)	6 (0.4)	(0.2, 0.9)
Chills	119 (8.0)	(6.7, 9.5)	6 (0.4)	(0.2, 0.9)
Pain	55 (3.7)	(2.8, 4.8)	5 (0.3)	(0.1, 0.8)
Injection site erythema	15 (1.0)	(0.6, 1.7)	0	(0.0, 0.3)
Malaise	7 (0.5)	(0.2, 1.0)	0	(0.0, 0.3)
Injection site swelling	13 (0.9)	(0.5, 1.5)	4 (0.3)	(0.1, 0.7)
Asthenia	7 (0.5)	(0.2, 1.0)	1 (0.1)	(0.0, 0.4)
Injection site pruritus	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Influenza like illness	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Chest pain	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Vaccination site pain	3 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.4)
Axillary pain	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Feeling hot	3 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Chest discomfort	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Injection site induration	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Injection site oedema	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)

14.414. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1492) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1448) n[b] (%)	 (95% CI[c])
Non-cardiac chest pain	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Peripheral swelling	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Injection site haematoma	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Swelling face	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.5)
Injection site papule	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Injection site rash	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Injection site reaction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Application site reaction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Injection site macule	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Shoulder injury related to vaccine administration	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
HEPATOBILIARY DISORDERS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Cholelithiasis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
IMMUNE SYSTEM DISORDERS	2 (0.1)	(0.0, 0.5)	2 (0.1)	(0.0, 0.5)
Seasonal allergy	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Drug hypersensitivity	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Immunisation reaction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Food allergy	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
INFECTIONS AND INFESTATIONS	23 (1.5)	(1.0, 2.3)	13 (0.9)	(0.5, 1.5)
Urinary tract infection	4 (0.3)	(0.1, 0.7)	1 (0.1)	(0.0, 0.4)
Tooth infection	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.5)
Sinusitis	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Herpes zoster	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Ear infection	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Conjunctivitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Upper respiratory tract infection	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Rhinitis	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.5)
Appendicitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Gingivitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Oral herpes	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Vulvovaginal candidiasis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Vaginal infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Influenza	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Otitis media acute	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Tonsillitis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Herpes simplex	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Appendicitis perforated	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)

14.414. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1492) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1448) n[b] (%)	 (95% CI[c])
Chronic sinusitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Escherichia urinary tract infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Gastroenteritis viral	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Oral candidiasis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Tinea infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Dental fistula	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Injection site abscess	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Pyelonephritis acute	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Subcutaneous abscess	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Tinea cruris	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Tinea versicolour	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	13 (0.9)	(0.5, 1.5)	8 (0.6)	(0.2, 1.1)
Fall	3 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.4)
Ligament sprain	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Skin laceration	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Contusion	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Muscle strain	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.5)
Arthropod bite	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Road traffic accident	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Exposure during pregnancy	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Tooth fracture	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Arthropod sting	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Facial bones fracture	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Joint dislocation	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Vaccination complication	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Concussion	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Hand fracture	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Spinal compression fracture	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Epicondylitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Administration related reaction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
INVESTIGATIONS	14 (0.9)	(0.5, 1.6)	1 (0.1)	(0.0, 0.4)
Body temperature increased	10 (0.7)	(0.3, 1.2)	1 (0.1)	(0.0, 0.4)
Blood pressure increased	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Blood glucose increased	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Blood cholesterol increased	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Low density lipoprotein increased	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)

14.414. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1492) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1448) n[b] (%)	 (95% CI[c])
METABOLISM AND NUTRITION DISORDERS	4 (0.3)	(0.1, 0.7)	0	(0.0, 0.3)
Decreased appetite	3 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Dehydration	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	142 (9.5)	(8.1, 11.1)	29 (2.0)	(1.3, 2.9)
Myalgia	112 (7.5)	(6.2, 9.0)	14 (1.0)	(0.5, 1.6)
Arthralgia	17 (1.1)	(0.7, 1.8)	6 (0.4)	(0.2, 0.9)
Pain in extremity	10 (0.7)	(0.3, 1.2)	2 (0.1)	(0.0, 0.5)
Back pain	7 (0.5)	(0.2, 1.0)	3 (0.2)	(0.0, 0.6)
Neck pain	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Muscle spasms	1 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.5)
Musculoskeletal chest pain	2 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.4)
Arthritis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Flank pain	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Spinal osteoarthritis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Joint range of motion decreased	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Musculoskeletal pain	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Tenosynovitis stenosans	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Intervertebral disc degeneration	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Osteopenia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.5)
Basal cell carcinoma	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Malignant melanoma	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
NERVOUS SYSTEM DISORDERS	130 (8.7)	(7.3, 10.3)	47 (3.2)	(2.4, 4.3)
Headache	118 (7.9)	(6.6, 9.4)	35 (2.4)	(1.7, 3.3)
Dizziness	8 (0.5)	(0.2, 1.1)	5 (0.3)	(0.1, 0.8)
Paraesthesia	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Migraine	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Lethargy	3 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Syncope	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Tension headache	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Dysgeusia	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.5)
Somnolence	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Presyncope	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Tremor	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Subarachnoid haemorrhage	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)

14.414. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1492)		Placebo (N[a]=1448)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hyperaesthesia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Dystonia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Parkinsonism	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Taste disorder	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
PSYCHIATRIC DISORDERS	6 (0.4)	(0.1, 0.9)	0	(0.0, 0.3)
Anxiety	3 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Insomnia	3 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Depression	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Schizophrenia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
RENAL AND URINARY DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Nephrolithiasis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.2)	(0.0, 0.6)	2 (0.1)	(0.0, 0.5)
Dysmenorrhoea	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Ovarian cyst	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Pelvic pain	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Breast hyperplasia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	15 (1.0)	(0.6, 1.7)	7 (0.5)	(0.2, 1.0)
Oropharyngeal pain	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Nasal congestion	1 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.5)
Cough	4 (0.3)	(0.1, 0.7)	0	(0.0, 0.3)
Rhinorrhoea	1 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.4)
Rhinitis allergic	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Dyspnoea	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.5)
Throat irritation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Upper-airway cough syndrome	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Paranasal sinus discomfort	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Productive cough	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Pulmonary embolism	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Dyspnoea exertional	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Nasal obstruction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Pleurisy	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Rhinalgia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Sinus disorder	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	16 (1.1)	(0.6, 1.7)	12 (0.8)	(0.4, 1.4)
Rash	3 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.4)
Pruritus	0	(0.0, 0.2)	4 (0.3)	(0.1, 0.7)

14.414. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1492) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=1448) n[b] (%)	 (95% CI[c])
Hyperhidrosis	3 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Dermatitis contact	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Urticaria	1 (0.1)	(0.0, 0.4)	3 (0.2)	(0.0, 0.6)
Night sweats	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Erythema	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Alopecia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Rash maculo-papular	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Skin lesion	2 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.4)
Dermatitis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Dermatitis allergic	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Ecchymosis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Cold sweat	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Pruritus allergic	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Skin irritation	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
SURGICAL AND MEDICAL PROCEDURES	2 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Gingival operation	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Salpingectomy	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
UNCODED TERM	3 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.4)
FEVER@@	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
CORONARY ARTERY DISEASE@@	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
INJECTION SITE PAIN@@	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
VOMITING@@	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
VASCULAR DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Aortic aneurysm	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_race_p3_saf

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2356 (24.5)	(23.7, 25.4)	1121 (11.9)	(11.3, 12.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	33 (0.3)	(0.2, 0.5)	6 (0.1)	(0.0, 0.1)
Lymphadenopathy	26 (0.3)	(0.2, 0.4)	3 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymph node pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	20 (0.2)	(0.1, 0.3)	19 (0.2)	(0.1, 0.3)
Palpitations	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Tachycardia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mitral valve incompetence	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Mitral valve prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	23 (0.2)	(0.2, 0.4)	19 (0.2)	(0.1, 0.3)
Vertigo	10 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Tinnitus	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo positional	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ear discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniere's disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypothyroidism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypogonadism	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	17 (0.2)	(0.1, 0.3)	21 (0.2)	(0.1, 0.3)
Eye pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cataract	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blepharitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dry eye	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Keratitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vitreous detachment	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ocular hyperaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Photophobia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal detachment	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Episcleritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glaucoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	233 (2.4)	(2.1, 2.8)	175 (1.9)	(1.6, 2.2)
Diarrhoea	97 (1.0)	(0.8, 1.2)	74 (0.8)	(0.6, 1.0)
Nausea	69 (0.7)	(0.6, 0.9)	30 (0.3)	(0.2, 0.5)
Vomiting	12 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Toothache	11 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)
Abdominal pain upper	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Abdominal pain	4 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Dyspepsia	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Odynophagia	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Constipation	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental caries	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.1)
Abdominal distension	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritable bowel syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Stomatitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Large intestine polyp	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Food poisoning	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swollen tongue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angular cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1612 (16.8)	(16.0, 17.6)	336 (3.6)	(3.2, 4.0)
Injection site pain	961 (10.0)	(9.4, 10.6)	135 (1.4)	(1.2, 1.7)
Fatigue	502 (5.2)	(4.8, 5.7)	117 (1.2)	(1.0, 1.5)
Pyrexia	519 (5.4)	(5.0, 5.9)	30 (0.3)	(0.2, 0.5)
Chills	461 (4.8)	(4.4, 5.2)	36 (0.4)	(0.3, 0.5)
Pain	186 (1.9)	(1.7, 2.2)	16 (0.2)	(0.1, 0.3)
Injection site erythema	41 (0.4)	(0.3, 0.6)	7 (0.1)	(0.0, 0.2)
Malaise	49 (0.5)	(0.4, 0.7)	8 (0.1)	(0.0, 0.2)
Injection site swelling	31 (0.3)	(0.2, 0.5)	8 (0.1)	(0.0, 0.2)
Asthenia	37 (0.4)	(0.3, 0.5)	12 (0.1)	(0.1, 0.2)
Injection site pruritus	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Influenza like illness	10 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Chest pain	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Injection site bruising	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaccination site pain	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site warmth	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Feeling hot	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Peripheral swelling	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Face oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Illness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	8 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Seasonal allergy	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypersensitivity	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	112 (1.2)	(1.0, 1.4)	115 (1.2)	(1.0, 1.5)
Urinary tract infection	4 (0.0)	(0.0, 0.1)	10 (0.1)	(0.1, 0.2)
Tooth infection	14 (0.1)	(0.1, 0.2)	15 (0.2)	(0.1, 0.3)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sinusitis	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Herpes zoster	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cellulitis	7 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Ear infection	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Conjunctivitis	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hordeolum	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rhinitis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Appendicitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gingivitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Oral herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tooth abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Furuncle	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Periodontitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Influenza	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasopharyngitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paronychia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Eye infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Folliculitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Herpes simplex	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Localised infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Escherichia urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Infected bite	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pustule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trichomoniasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bone abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinusitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	80 (0.8)	(0.7, 1.0)	108 (1.1)	(0.9, 1.4)
Fall	14 (0.1)	(0.1, 0.2)	16 (0.2)	(0.1, 0.3)
Ligament sprain	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Skin laceration	3 (0.0)	(0.0, 0.1)	15 (0.2)	(0.1, 0.3)
Contusion	7 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Muscle strain	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Arthropod bite	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Road traffic accident	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Skin abrasion	4 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Exposure during pregnancy	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb injury	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tooth fracture	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Procedural pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Arthropod sting	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint dislocation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint injury	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rib fracture	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ankle fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hand fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Head injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wound	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Wrist fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bone contusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin injury	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tendon rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foreign body in eye	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb traumatic amputation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Scapula fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	59 (0.6)	(0.5, 0.8)	22 (0.2)	(0.1, 0.4)
Body temperature increased	40 (0.4)	(0.3, 0.6)	4 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Blood glucose increased	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Weight decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
High density lipoprotein increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	32 (0.3)	(0.2, 0.5)	26 (0.3)	(0.2, 0.4)
Decreased appetite	12 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Type 2 diabetes mellitus	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperlipidaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dehydration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	650 (6.8)	(6.3, 7.3)	187 (2.0)	(1.7, 2.3)
Myalgia	413 (4.3)	(3.9, 4.7)	60 (0.6)	(0.5, 0.8)
Arthralgia	103 (1.1)	(0.9, 1.3)	36 (0.4)	(0.3, 0.5)
Pain in extremity	78 (0.8)	(0.6, 1.0)	14 (0.1)	(0.1, 0.2)
Back pain	45 (0.5)	(0.3, 0.6)	36 (0.4)	(0.3, 0.5)
Neck pain	6 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Muscle spasms	11 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.2)
Musculoskeletal stiffness	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Osteoarthritis	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Muscle contracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tendonitis	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bursitis	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Flank pain	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Costochondritis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bone pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tendon disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Torticollis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coccydynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteoporosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal stenosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle tightness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	9 (0.1)	(0.0, 0.2)	15 (0.2)	(0.1, 0.3)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Basal cell carcinoma	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Lipoma	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Benign breast neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	488 (5.1)	(4.7, 5.5)	183 (1.9)	(1.7, 2.2)
Headache	400 (4.2)	(3.8, 4.6)	116 (1.2)	(1.0, 1.5)
Dizziness	24 (0.2)	(0.2, 0.4)	26 (0.3)	(0.2, 0.4)
Paraesthesia	12 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.2)
Migraine	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lethargy	12 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Syncope	4 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Sciatica	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tension headache	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysgeusia	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Presyncope	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parosmia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus headache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aphasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical radiculopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Disturbance in attention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Balance disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Loss of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PRODUCT ISSUES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	35 (0.4)	(0.3, 0.5)	22 (0.2)	(0.1, 0.4)
Anxiety	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Insomnia	15 (0.2)	(0.1, 0.3)	4 (0.0)	(0.0, 0.1)
Depression	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Irritability	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Libido increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	16 (0.2)	(0.1, 0.3)	15 (0.2)	(0.1, 0.3)
Dysuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nephrolithiasis	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Urinary retention	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hydronephrosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	7 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Erectile dysfunction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Prostatitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Genital erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haematospermia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostatomegaly	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	81 (0.8)	(0.7, 1.0)	65 (0.7)	(0.5, 0.9)
Oropharyngeal pain	13 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Nasal congestion	18 (0.2)	(0.1, 0.3)	15 (0.2)	(0.1, 0.3)
Cough	12 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)
Rhinorrhoea	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Rhinitis allergic	5 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Asthma	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyspnoea	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Throat irritation	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Productive cough	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchospasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngeal swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atelectasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Reflux laryngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Snoring	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	77 (0.8)	(0.6, 1.0)	53 (0.6)	(0.4, 0.7)
Rash	21 (0.2)	(0.1, 0.3)	13 (0.1)	(0.1, 0.2)
Pruritus	10 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Hyperhidrosis	10 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Dermatitis contact	8 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Urticaria	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Night sweats	10 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Rash pruritic	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin lesion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angioedema	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermal cyst	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Actinic keratosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acne	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rosacea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	11 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Tooth extraction	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental implantation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endodontic procedure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin neoplasm excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	12 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
FATIGUE@@	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.415. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	23 (0.2)	(0.2, 0.4)	37 (0.4)	(0.3, 0.5)
Hypertension	11 (0.1)	(0.1, 0.2)	24 (0.3)	(0.2, 0.4)
Hot flush	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematoma	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_sex_p3_saf

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2715 (29.5)	(28.6, 30.5)	1235 (13.2)	(12.5, 13.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	48 (0.5)	(0.4, 0.7)	7 (0.1)	(0.0, 0.2)
Lymphadenopathy	38 (0.4)	(0.3, 0.6)	3 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lymph node pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	25 (0.3)	(0.2, 0.4)	17 (0.2)	(0.1, 0.3)
Palpitations	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Tachycardia	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	32 (0.3)	(0.2, 0.5)	16 (0.2)	(0.1, 0.3)
Vertigo	12 (0.1)	(0.1, 0.2)	10 (0.1)	(0.1, 0.2)
Tinnitus	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ear pain	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Vertigo positional	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Ear discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Meniere's disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyperacusis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sudden hearing loss	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
ENDOCRINE DISORDERS	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	34 (0.4)	(0.3, 0.5)	19 (0.2)	(0.1, 0.3)
Eye pain	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vision blurred	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cataract	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye irritation	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Keratitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitreous detachment	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retinal detachment	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Corneal irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulcerative keratitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	314 (3.4)	(3.1, 3.8)	183 (1.9)	(1.7, 2.3)
Diarrhoea	90 (1.0)	(0.8, 1.2)	72 (0.8)	(0.6, 1.0)
Nausea	145 (1.6)	(1.3, 1.9)	33 (0.4)	(0.2, 0.5)
Vomiting	32 (0.3)	(0.2, 0.5)	16 (0.2)	(0.1, 0.3)
Toothache	10 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)
Abdominal pain upper	16 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Abdominal pain	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Dyspepsia	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Odynophagia	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Dental caries	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Flatulence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Large intestine polyp	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Faeces soft	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Food poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Colitis microscopic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hiatus hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Swollen tongue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Umbilical hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1882 (20.5)	(19.6, 21.3)	389 (4.1)	(3.8, 4.6)
Injection site pain	1147 (12.5)	(11.8, 13.2)	146 (1.6)	(1.3, 1.8)
Fatigue	524 (5.7)	(5.2, 6.2)	141 (1.5)	(1.3, 1.8)
Pyrexia	625 (6.8)	(6.3, 7.3)	31 (0.3)	(0.2, 0.5)
Chills	537 (5.8)	(5.4, 6.3)	49 (0.5)	(0.4, 0.7)
Pain	269 (2.9)	(2.6, 3.3)	20 (0.2)	(0.1, 0.3)
Injection site erythema	97 (1.1)	(0.9, 1.3)	13 (0.1)	(0.1, 0.2)
Malaise	47 (0.5)	(0.4, 0.7)	7 (0.1)	(0.0, 0.2)
Injection site swelling	62 (0.7)	(0.5, 0.9)	9 (0.1)	(0.0, 0.2)
Asthenia	27 (0.3)	(0.2, 0.4)	13 (0.1)	(0.1, 0.2)
Injection site pruritus	21 (0.2)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)
Influenza like illness	10 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Chest pain	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Injection site bruising	9 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Vaccination site pain	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Injection site warmth	11 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Axillary pain	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Feeling hot	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Face oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thirst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Medical device pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaccination site induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	17 (0.2)	(0.1, 0.3)	13 (0.1)	(0.1, 0.2)
Seasonal allergy	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Immunisation reaction	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	174 (1.9)	(1.6, 2.2)	174 (1.9)	(1.6, 2.1)
Urinary tract infection	40 (0.4)	(0.3, 0.6)	34 (0.4)	(0.3, 0.5)
Tooth infection	9 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Sinusitis	12 (0.1)	(0.1, 0.2)	16 (0.2)	(0.1, 0.3)
Herpes zoster	8 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Cellulitis	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ear infection	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Conjunctivitis	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cystitis	6 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Hordeolum	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Upper respiratory tract infection	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rhinitis	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Diverticulitis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Otitis externa	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Appendicitis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Gingivitis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pneumonia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oral herpes	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth abscess	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bronchitis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Furuncle	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Periodontitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	6 (0.1)	(0.0, 0.1)
Influenza	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nasopharyngitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis media acute	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paronychia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pyelonephritis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Folliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes simplex	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Localised infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingival abscess	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pustular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Trichomoniasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess neck	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bartholinitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carbuncle	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Cellulitis orbital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Papilloma viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	89 (1.0)	(0.8, 1.2)	96 (1.0)	(0.8, 1.2)
Fall	19 (0.2)	(0.1, 0.3)	19 (0.2)	(0.1, 0.3)
Ligament sprain	7 (0.1)	(0.0, 0.2)	13 (0.1)	(0.1, 0.2)
Skin laceration	8 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Contusion	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Muscle strain	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Arthropod bite	8 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Skin abrasion	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Exposure during pregnancy	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Limb injury	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Foot fracture	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Arthropod sting	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Joint dislocation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rib fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ankle fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thermal burn	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chest injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Fibula fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wound	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Epicondylitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	72 (0.8)	(0.6, 1.0)	11 (0.1)	(0.1, 0.2)
Body temperature increased	49 (0.5)	(0.4, 0.7)	4 (0.0)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Heart rate increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Weight decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
High density lipoprotein increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood creatinine decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood testosterone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mammogram abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Weight increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	42 (0.5)	(0.3, 0.6)	28 (0.3)	(0.2, 0.4)
Decreased appetite	17 (0.2)	(0.1, 0.3)	5 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Type 2 diabetes mellitus	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gout	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitamin D deficiency	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dehydration	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obesity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	723 (7.9)	(7.3, 8.4)	197 (2.1)	(1.8, 2.4)
Myalgia	491 (5.3)	(4.9, 5.8)	66 (0.7)	(0.5, 0.9)
Arthralgia	107 (1.2)	(1.0, 1.4)	40 (0.4)	(0.3, 0.6)
Pain in extremity	85 (0.9)	(0.7, 1.1)	19 (0.2)	(0.1, 0.3)
Back pain	35 (0.4)	(0.3, 0.5)	35 (0.4)	(0.3, 0.5)
Neck pain	15 (0.2)	(0.1, 0.3)	16 (0.2)	(0.1, 0.3)
Muscle spasms	12 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Osteoarthritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle contracture	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tendonitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bursitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Arthritis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flank pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Exostosis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint swelling	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tendon disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Coccydynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periarthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Synovial cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13 (0.1)	(0.1, 0.2)	15 (0.2)	(0.1, 0.3)
Basal cell carcinoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lipoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=9386) n[b] (%)	 (95% CI[c])
Acrochordon	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	653 (7.1)	(6.6, 7.6)	259 (2.8)	(2.4, 3.1)
Headache	566 (6.2)	(5.7, 6.7)	186 (2.0)	(1.7, 2.3)
Dizziness	32 (0.3)	(0.2, 0.5)	22 (0.2)	(0.1, 0.4)
Paraesthesia	4 (0.0)	(0.0, 0.1)	10 (0.1)	(0.1, 0.2)
Migraine	14 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Lethargy	9 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Syncope	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sciatica	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tension headache	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Dysgeusia	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Presyncope	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Burning sensation	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Parosmia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nerve compression	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dizziness postural	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervical radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depressed level of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Motor dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	41 (0.4)	(0.3, 0.6)	32 (0.3)	(0.2, 0.5)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Anxiety	12 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Insomnia	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Depression	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anxiety disorder	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Panic attack	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Sleep disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bruxism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	12 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.2)
Dysuria	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	27 (0.3)	(0.2, 0.4)	24 (0.3)	(0.2, 0.4)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ovarian cyst	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic pain	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amenorrhoea	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Menorrhagia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mammary duct ectasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Polycystic ovaries	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	82 (0.9)	(0.7, 1.1)	83 (0.9)	(0.7, 1.1)
Oropharyngeal pain	22 (0.2)	(0.1, 0.4)	20 (0.2)	(0.1, 0.3)
Nasal congestion	3 (0.0)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)
Cough	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Rhinorrhoea	10 (0.1)	(0.1, 0.2)	10 (0.1)	(0.1, 0.2)
Rhinitis allergic	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Asthma	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Dyspnoea	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Throat irritation	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=9386) n[b] (%)	 (95% CI[c])
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Epistaxis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry throat	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pharyngeal swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nasal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	106 (1.2)	(0.9, 1.4)	74 (0.8)	(0.6, 1.0)
Rash	23 (0.3)	(0.2, 0.4)	23 (0.2)	(0.2, 0.4)
Pruritus	9 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Hyperhidrosis	14 (0.2)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)
Dermatitis contact	5 (0.1)	(0.0, 0.1)	10 (0.1)	(0.1, 0.2)
Urticaria	12 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.1)
Night sweats	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rash pruritic	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Erythema	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Alopecia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eczema	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin lesion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermatitis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Angioedema	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis allergic	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Drug eruption	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ecchymosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acne	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Psoriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rosacea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis acneiform	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pseudofolliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9199) n[b] (%)	(95% CI[c])	Placebo (N[a]=9386) n[b] (%)	(95% CI[c])
Stress at work	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	17 (0.2)	(0.1, 0.3)	10 (0.1)	(0.1, 0.2)
Tooth extraction	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental implantation	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Endodontic procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Apicectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug titration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Salpingectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	11 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	33 (0.4)	(0.2, 0.5)	26 (0.3)	(0.2, 0.4)
Hypertension	15 (0.2)	(0.1, 0.3)	11 (0.1)	(0.1, 0.2)
Hot flush	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Haematoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flushing	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Essential hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intermittent claudication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.416. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:00)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_sex_p3_saf

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2044 (21.4)	(20.6, 22.3)	1197 (12.6)	(11.9, 13.2)	3241 (17.0)	(16.5, 17.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	45 (0.5)	(0.3, 0.6)	8 (0.1)	(0.0, 0.2)	53 (0.3)	(0.2, 0.4)
Lymphadenopathy	38 (0.4)	(0.3, 0.5)	3 (0.0)	(0.0, 0.1)	41 (0.2)	(0.2, 0.3)
Anaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Lymph node pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	30 (0.3)	(0.2, 0.4)	15 (0.2)	(0.1, 0.3)	45 (0.2)	(0.2, 0.3)
Palpitations	7 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Tachycardia	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Angina pectoris	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tricuspid valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	31 (0.3)	(0.2, 0.5)	23 (0.2)	(0.2, 0.4)	54 (0.3)	(0.2, 0.4)
Vertigo	12 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)	20 (0.1)	(0.1, 0.2)
Ear pain	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Tinnitus	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vertigo positional	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Ear discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Meniere's disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Thyroid mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	26 (0.3)	(0.2, 0.4)	25 (0.3)	(0.2, 0.4)	51 (0.3)	(0.2, 0.4)
Cataract	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Chalazion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Eye irritation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Keratitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	247 (2.6)	(2.3, 2.9)	168 (1.8)	(1.5, 2.0)	415 (2.2)	(2.0, 2.4)
Diarrhoea	83 (0.9)	(0.7, 1.1)	57 (0.6)	(0.5, 0.8)	140 (0.7)	(0.6, 0.9)
Nausea	79 (0.8)	(0.7, 1.0)	21 (0.2)	(0.1, 0.3)	100 (0.5)	(0.4, 0.6)
Vomiting	17 (0.2)	(0.1, 0.3)	16 (0.2)	(0.1, 0.3)	33 (0.2)	(0.1, 0.2)
Toothache	14 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Abdominal pain	12 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)	21 (0.1)	(0.1, 0.2)
Dyspepsia	9 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)	16 (0.1)	(0.0, 0.1)
Gastrooesophageal reflux disease	5 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)	14 (0.1)	(0.0, 0.1)
Odynophagia	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Abdominal pain upper	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Constipation	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dental caries	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Flatulence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hiatus hernia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1137 (11.9)	(11.3, 12.6)	274 (2.9)	(2.5, 3.2)	1411 (7.4)	(7.0, 7.8)
Injection site pain	621 (6.5)	(6.0, 7.0)	95 (1.0)	(0.8, 1.2)	716 (3.8)	(3.5, 4.0)
Fatigue	331 (3.5)	(3.1, 3.9)	83 (0.9)	(0.7, 1.1)	414 (2.2)	(2.0, 2.4)
Pyrexia	362 (3.8)	(3.4, 4.2)	26 (0.3)	(0.2, 0.4)	388 (2.0)	(1.8, 2.2)
Chills	314 (3.3)	(2.9, 3.7)	25 (0.3)	(0.2, 0.4)	339 (1.8)	(1.6, 2.0)
Pain	142 (1.5)	(1.3, 1.8)	15 (0.2)	(0.1, 0.3)	157 (0.8)	(0.7, 1.0)
Injection site erythema	54 (0.6)	(0.4, 0.7)	9 (0.1)	(0.0, 0.2)	63 (0.3)	(0.3, 0.4)
Injection site swelling	37 (0.4)	(0.3, 0.5)	9 (0.1)	(0.0, 0.2)	46 (0.2)	(0.2, 0.3)
Malaise	29 (0.3)	(0.2, 0.4)	6 (0.1)	(0.0, 0.1)	35 (0.2)	(0.1, 0.3)
Asthenia	16 (0.2)	(0.1, 0.3)	15 (0.2)	(0.1, 0.3)	31 (0.2)	(0.1, 0.2)
Injection site pruritus	10 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Chest pain	7 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Injection site bruising	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)	12 (0.1)	(0.0, 0.1)
Axillary pain	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vaccination site pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Influenza like illness	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Injection site warmth	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oedema peripheral	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Chest discomfort	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Peripheral swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site haematoma	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site induration	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	8 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Cholelithiasis	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gallbladder disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	11 (0.1)	(0.1, 0.2)	17 (0.2)	(0.1, 0.3)	28 (0.1)	(0.1, 0.2)
Seasonal allergy	4 (0.0)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Allergy to arthropod bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	182 (1.9)	(1.6, 2.2)	156 (1.6)	(1.4, 1.9)	338 (1.8)	(1.6, 2.0)
Urinary tract infection	28 (0.3)	(0.2, 0.4)	25 (0.3)	(0.2, 0.4)	53 (0.3)	(0.2, 0.4)
Tooth infection	13 (0.1)	(0.1, 0.2)	14 (0.1)	(0.1, 0.2)	27 (0.1)	(0.1, 0.2)
Sinusitis	12 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)	23 (0.1)	(0.1, 0.2)
Herpes zoster	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)	13 (0.1)	(0.0, 0.1)
Cellulitis	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)	12 (0.1)	(0.0, 0.1)
Gastroenteritis	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)	12 (0.1)	(0.0, 0.1)
Diverticulitis	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Ear infection	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Cystitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tooth abscess	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Folliculitis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Hordeolum	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Conjunctivitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Nasopharyngitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Oral herpes	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis externa	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis media acute	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Periodontitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Gingivitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Pyelonephritis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chronic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Herpes virus infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Herpes zoster cutaneous disseminated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash pustular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syphilis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trichomoniasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vulval abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	82 (0.9)	(0.7, 1.1)	116 (1.2)	(1.0, 1.5)	198 (1.0)	(0.9, 1.2)
Fall	17 (0.2)	(0.1, 0.3)	23 (0.2)	(0.2, 0.4)	40 (0.2)	(0.1, 0.3)
Muscle strain	11 (0.1)	(0.1, 0.2)	10 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.2)
Contusion	7 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)	17 (0.1)	(0.1, 0.1)
Ligament sprain	5 (0.1)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)	16 (0.1)	(0.0, 0.1)
Skin laceration	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)	12 (0.1)	(0.0, 0.1)
Arthropod bite	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Skin abrasion	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Limb injury	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Joint dislocation	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Joint injury	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Meniscus injury	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth fracture	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Chest injury	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Procedural pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hand fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rib fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Thermal burn	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Bone fissure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heat stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tibia fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	45 (0.5)	(0.3, 0.6)	18 (0.2)	(0.1, 0.3)	63 (0.3)	(0.3, 0.4)
Body temperature increased	24 (0.3)	(0.2, 0.4)	5 (0.1)	(0.0, 0.1)	29 (0.2)	(0.1, 0.2)
Blood glucose increased	7 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Blood cholesterol increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Heart rate increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood urea increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Mean cell haemoglobin decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Mean cell volume increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostatic specific antigen increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	34 (0.4)	(0.2, 0.5)	30 (0.3)	(0.2, 0.4)	64 (0.3)	(0.3, 0.4)
Decreased appetite	9 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Vitamin D deficiency	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dehydration	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperlipidaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	525 (5.5)	(5.1, 6.0)	196 (2.1)	(1.8, 2.4)	721 (3.8)	(3.5, 4.1)
Myalgia	304 (3.2)	(2.8, 3.6)	48 (0.5)	(0.4, 0.7)	352 (1.8)	(1.7, 2.0)
Arthralgia	92 (1.0)	(0.8, 1.2)	43 (0.5)	(0.3, 0.6)	135 (0.7)	(0.6, 0.8)
Pain in extremity	67 (0.7)	(0.5, 0.9)	15 (0.2)	(0.1, 0.3)	82 (0.4)	(0.3, 0.5)
Back pain	38 (0.4)	(0.3, 0.5)	38 (0.4)	(0.3, 0.5)	76 (0.4)	(0.3, 0.5)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neck pain	12 (0.1)	(0.1, 0.2)	14 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Muscle spasms	13 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)	17 (0.1)	(0.1, 0.1)
Osteoarthritis	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Muscle contracture	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Tendonitis	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Arthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Bursitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Flank pain	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscular weakness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Costochondritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Joint swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Coccydynia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Exostosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Spinal deformity	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tenosynovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	12 (0.1)	(0.1, 0.2)	14 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Lipoma	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	402 (4.2)	(3.8, 4.6)	201 (2.1)	(1.8, 2.4)	603 (3.2)	(2.9, 3.4)
Headache	320 (3.4)	(3.0, 3.7)	131 (1.4)	(1.1, 1.6)	451 (2.4)	(2.2, 2.6)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dizziness	21 (0.2)	(0.1, 0.3)	19 (0.2)	(0.1, 0.3)	40 (0.2)	(0.1, 0.3)
Paraesthesia	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)	18 (0.1)	(0.1, 0.1)
Migraine	8 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Tension headache	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Lethargy	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Syncope	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Sciatica	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Presyncope	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tremor	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Migraine with aura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	39 (0.4)	(0.3, 0.6)	34 (0.4)	(0.2, 0.5)	73 (0.4)	(0.3, 0.5)
Anxiety	10 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)	19 (0.1)	(0.1, 0.2)
Depression	5 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)	14 (0.1)	(0.0, 0.1)
Insomnia	11 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Irritability	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sleep disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RENAL AND URINARY DISORDERS	20 (0.2)	(0.1, 0.3)	14 (0.1)	(0.1, 0.2)	34 (0.2)	(0.1, 0.2)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Dysuria	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Haematuria	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Pollakiuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	21 (0.2)	(0.1, 0.3)	16 (0.2)	(0.1, 0.3)	37 (0.2)	(0.1, 0.3)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Ovarian cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Menstruation irregular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metrorrhagia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	88 (0.9)	(0.7, 1.1)	76 (0.8)	(0.6, 1.0)	164 (0.9)	(0.7, 1.0)
Oropharyngeal pain	13 (0.1)	(0.1, 0.2)	18 (0.2)	(0.1, 0.3)	31 (0.2)	(0.1, 0.2)
Cough	14 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)	23 (0.1)	(0.1, 0.2)
Nasal congestion	8 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)	18 (0.1)	(0.1, 0.1)
Rhinorrhoea	9 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)	17 (0.1)	(0.1, 0.1)
Rhinitis allergic	6 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)	15 (0.1)	(0.0, 0.1)
Dyspnoea	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Asthma	6 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Throat irritation	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dysphonia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sinus pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	89 (0.9)	(0.8, 1.1)	69 (0.7)	(0.6, 0.9)	158 (0.8)	(0.7, 1.0)
Rash	20 (0.2)	(0.1, 0.3)	21 (0.2)	(0.1, 0.3)	41 (0.2)	(0.2, 0.3)
Pruritus	12 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)	16 (0.1)	(0.0, 0.1)
Hyperhidrosis	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Rash pruritic	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Urticaria	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Erythema	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Rash maculo-papular	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dermal cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dermatitis allergic	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acne	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Night sweats	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erythema nodosum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	20 (0.2)	(0.1, 0.3)	13 (0.1)	(0.1, 0.2)	33 (0.2)	(0.1, 0.2)
Dental implantation	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tooth extraction	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Endodontic procedure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardioversion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	7 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)	14 (0.1)	(0.0, 0.1)
ANEMIC SYNDROME@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BROWNISH EJACULATION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
FEVER@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HYPERTENSION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIB INJURY FROM FALL@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	26 (0.3)	(0.2, 0.4)	38 (0.4)	(0.3, 0.5)	64 (0.3)	(0.3, 0.4)
Hypertension	11 (0.1)	(0.1, 0.2)	20 (0.2)	(0.1, 0.3)	31 (0.2)	(0.1, 0.2)
Haematoma	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Hot flush	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Flushing	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

14.417. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypotension	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Varicose vein	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Phlebitis superficial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:33)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_soc_2mpd2_p23_saf

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1232 (23.0)	(21.9, 24.2)	693 (12.9)	(12.0, 13.8)	1925 (17.9)	(17.2, 18.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	35 (0.7)	(0.5, 0.9)	5 (0.1)	(0.0, 0.2)	40 (0.4)	(0.3, 0.5)
Lymphadenopathy	31 (0.6)	(0.4, 0.8)	2 (0.0)	(0.0, 0.1)	33 (0.3)	(0.2, 0.4)
Anaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Leukocytosis	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lymph node pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Leukopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thrombocytosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	15 (0.3)	(0.2, 0.5)	8 (0.1)	(0.1, 0.3)	23 (0.2)	(0.1, 0.3)
Palpitations	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Tachycardia	5 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrioventricular block second degree	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bundle branch block right	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocarditis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tricuspid valve incompetence	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	18 (0.3)	(0.2, 0.5)	11 (0.2)	(0.1, 0.4)	29 (0.3)	(0.2, 0.4)
Vertigo	6 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Ear pain	4 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tinnitus	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Vertigo positional	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ear discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ear disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergic otitis media	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerumen impaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperacusis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoacusis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sudden hearing loss	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tympanic membrane perforation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	4 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypothyroidism	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	15 (0.3)	(0.2, 0.5)	13 (0.2)	(0.1, 0.4)	28 (0.3)	(0.2, 0.4)
Vision blurred	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Eye pain	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitreous detachment	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Keratitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Photophobia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blepharospasm	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Conjunctival oedema	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Corneal irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry eye	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Episcleritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye allergy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eyelid oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eyelid pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eyelids pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lacrimation increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ocular hyperaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	144 (2.7)	(2.3, 3.2)	103 (1.9)	(1.6, 2.3)	247 (2.3)	(2.0, 2.6)
Diarrhoea	41 (0.8)	(0.6, 1.0)	35 (0.7)	(0.5, 0.9)	76 (0.7)	(0.6, 0.9)
Nausea	52 (1.0)	(0.7, 1.3)	15 (0.3)	(0.2, 0.5)	67 (0.6)	(0.5, 0.8)
Vomiting	14 (0.3)	(0.1, 0.4)	12 (0.2)	(0.1, 0.4)	26 (0.2)	(0.2, 0.4)
Toothache	9 (0.2)	(0.1, 0.3)	8 (0.1)	(0.1, 0.3)	17 (0.2)	(0.1, 0.3)
Abdominal pain	8 (0.1)	(0.1, 0.3)	8 (0.1)	(0.1, 0.3)	16 (0.1)	(0.1, 0.2)
Dyspepsia	7 (0.1)	(0.1, 0.3)	5 (0.1)	(0.0, 0.2)	12 (0.1)	(0.1, 0.2)
Gastrooesophageal reflux disease	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Odynophagia	6 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Abdominal pain upper	4 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Constipation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental caries	4 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Large intestine polyp	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulum	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Faeces soft	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hiatus hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Inguinal hernia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Stomatitis	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute abdomen	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angular cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cheilitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Colitis ulcerative	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Food poisoning	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastritis erosive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gingival swelling	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lip oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Noninfective gingivitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oral mucosa haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retching	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Salivary gland calculus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Salivary gland mucocoele	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tongue discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	702 (13.1)	(12.2, 14.1)	173 (3.2)	(2.8, 3.7)	875 (8.2)	(7.6, 8.7)
Injection site pain	373 (7.0)	(6.3, 7.7)	63 (1.2)	(0.9, 1.5)	436 (4.1)	(3.7, 4.5)
Fatigue	209 (3.9)	(3.4, 4.5)	54 (1.0)	(0.8, 1.3)	263 (2.5)	(2.2, 2.8)
Pyrexia	256 (4.8)	(4.2, 5.4)	12 (0.2)	(0.1, 0.4)	268 (2.5)	(2.2, 2.8)
Chills	211 (3.9)	(3.4, 4.5)	13 (0.2)	(0.1, 0.4)	224 (2.1)	(1.8, 2.4)
Pain	96 (1.8)	(1.5, 2.2)	9 (0.2)	(0.1, 0.3)	105 (1.0)	(0.8, 1.2)
Injection site erythema	29 (0.5)	(0.4, 0.8)	4 (0.1)	(0.0, 0.2)	33 (0.3)	(0.2, 0.4)
Injection site swelling	17 (0.3)	(0.2, 0.5)	4 (0.1)	(0.0, 0.2)	21 (0.2)	(0.1, 0.3)
Malaise	20 (0.4)	(0.2, 0.6)	3 (0.1)	(0.0, 0.2)	23 (0.2)	(0.1, 0.3)
Asthenia	8 (0.1)	(0.1, 0.3)	12 (0.2)	(0.1, 0.4)	20 (0.2)	(0.1, 0.3)
Injection site pruritus	5 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Chest pain	6 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
Injection site bruising	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Axillary pain	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vaccination site pain	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Influenza like illness	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site warmth	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Oedema peripheral	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Chest discomfort	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site induration	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling face	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Feeling hot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injury associated with device	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Application site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Illness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Inflammation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site paraesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Medical device pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaccination site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vessel puncture site haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vessel puncture site induration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	9 (0.2)	(0.1, 0.3)	10 (0.2)	(0.1, 0.3)	19 (0.2)	(0.1, 0.3)
Seasonal allergy	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Food allergy	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Milk allergy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	104 (1.9)	(1.6, 2.4)	91 (1.7)	(1.4, 2.1)	195 (1.8)	(1.6, 2.1)
Urinary tract infection	14 (0.3)	(0.1, 0.4)	11 (0.2)	(0.1, 0.4)	25 (0.2)	(0.2, 0.3)
Tooth infection	6 (0.1)	(0.0, 0.2)	10 (0.2)	(0.1, 0.3)	16 (0.1)	(0.1, 0.2)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sinusitis	5 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
Herpes zoster	3 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Gastroenteritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Upper respiratory tract infection	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Ear infection	4 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Cystitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Tooth abscess	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Appendicitis	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Folliculitis	5 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hordeolum	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Conjunctivitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nasopharyngitis	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Oral herpes	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis externa	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingivitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pyelonephritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Influenza	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Kidney infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paronychia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tinea infection	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal abscess	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess neck	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anal fistula infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bartholinitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis infected	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Furuncle	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastroenteritis viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Genital herpes simplex	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Herpes simplex	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Herpes zoster cutaneous disseminated	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oral fungal infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Orchitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Papilloma viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pilonidal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pustular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinusitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subcutaneous abscess	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syphilis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urosepsis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Varicella	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Viral infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Viral upper respiratory tract infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulval abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	40 (0.7)	(0.5, 1.0)	58 (1.1)	(0.8, 1.4)	98 (0.9)	(0.7, 1.1)
Fall	5 (0.1)	(0.0, 0.2)	8 (0.1)	(0.1, 0.3)	13 (0.1)	(0.1, 0.2)
Muscle strain	5 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Contusion	4 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Ligament sprain	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.1, 0.3)	10 (0.1)	(0.0, 0.2)
Skin laceration	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Arthropod bite	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin abrasion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Foot fracture	2 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Limb injury	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Joint dislocation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint injury	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Meniscus injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest injury	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural pain	4 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fibula fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural dizziness	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rib fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thermal burn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bone contusion	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bone fissure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye contusion	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Heat stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ligament injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lumbar vertebral fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Penis injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Post procedural discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Post procedural haemorrhage	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	22 (0.4)	(0.3, 0.6)	10 (0.2)	(0.1, 0.3)	32 (0.3)	(0.2, 0.4)
Body temperature increased	14 (0.3)	(0.1, 0.4)	4 (0.1)	(0.0, 0.2)	18 (0.2)	(0.1, 0.3)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Heart rate increased	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood creatinine decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
C-reactive protein	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Weight decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	17 (0.3)	(0.2, 0.5)	14 (0.3)	(0.1, 0.4)	31 (0.3)	(0.2, 0.4)
Decreased appetite	6 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gout	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Insulin resistance	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Food intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Obesity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	322 (6.0)	(5.4, 6.7)	110 (2.0)	(1.7, 2.5)	432 (4.0)	(3.7, 4.4)
Myalgia	192 (3.6)	(3.1, 4.1)	27 (0.5)	(0.3, 0.7)	219 (2.0)	(1.8, 2.3)
Arthralgia	52 (1.0)	(0.7, 1.3)	20 (0.4)	(0.2, 0.6)	72 (0.7)	(0.5, 0.8)
Pain in extremity	40 (0.7)	(0.5, 1.0)	11 (0.2)	(0.1, 0.4)	51 (0.5)	(0.4, 0.6)
Back pain	22 (0.4)	(0.3, 0.6)	22 (0.4)	(0.3, 0.6)	44 (0.4)	(0.3, 0.6)
Neck pain	6 (0.1)	(0.0, 0.2)	11 (0.2)	(0.1, 0.4)	17 (0.2)	(0.1, 0.3)
Muscle spasms	6 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle contracture	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tendonitis	4 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bursitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flank pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Groin pain	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint swelling	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spondylitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Synovial cyst	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Temporomandibular joint syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Torticollis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Trigger finger	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bone swelling	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Coccydynia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Periarthritis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhabdomyolysis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Scoliosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal deformity	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Synovitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tenosynovitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
Lipoma	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Benign breast neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chondroma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fibroadenoma of breast	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	257 (4.8)	(4.2, 5.4)	123 (2.3)	(1.9, 2.7)	380 (3.5)	(3.2, 3.9)
Headache	206 (3.9)	(3.4, 4.4)	84 (1.6)	(1.2, 1.9)	290 (2.7)	(2.4, 3.0)
Dizziness	12 (0.2)	(0.1, 0.4)	9 (0.2)	(0.1, 0.3)	21 (0.2)	(0.1, 0.3)
Paraesthesia	8 (0.1)	(0.1, 0.3)	5 (0.1)	(0.0, 0.2)	13 (0.1)	(0.1, 0.2)
Migraine	7 (0.1)	(0.1, 0.3)	4 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Tension headache	5 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Lethargy	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Syncope	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Sciatica	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Dysgeusia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Presyncope	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Somnolence	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Neuropathy peripheral	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ageusia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Depressed level of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplegia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dystonia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Head discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Radiculopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Seizure	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Trigeminal neuralgia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	24 (0.4)	(0.3, 0.7)	25 (0.5)	(0.3, 0.7)	49 (0.5)	(0.3, 0.6)
Anxiety	8 (0.1)	(0.1, 0.3)	8 (0.1)	(0.1, 0.3)	16 (0.1)	(0.1, 0.2)
Depression	5 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Insomnia	7 (0.1)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bruxism	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Depressed mood	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Panic reaction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Stress	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	9 (0.2)	(0.1, 0.3)	7 (0.1)	(0.1, 0.3)	16 (0.1)	(0.1, 0.2)
Nephrolithiasis	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysuria	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Haematuria	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pollakiuria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hydronephrosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary bladder polyp	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	18 (0.3)	(0.2, 0.5)	14 (0.3)	(0.1, 0.4)	32 (0.3)	(0.2, 0.4)
Dysmenorrhoea	4 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Menorrhagia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pruritus genital	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cervical dysplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erectile dysfunction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematospermia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mammary duct ectasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Menstruation irregular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Metrorrhagia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Penile vein thrombosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Polycystic ovaries	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	51 (1.0)	(0.7, 1.3)	51 (0.9)	(0.7, 1.2)	102 (1.0)	(0.8, 1.2)
Oropharyngeal pain	8 (0.1)	(0.1, 0.3)	12 (0.2)	(0.1, 0.4)	20 (0.2)	(0.1, 0.3)
Cough	8 (0.1)	(0.1, 0.3)	6 (0.1)	(0.0, 0.2)	14 (0.1)	(0.1, 0.2)
Nasal congestion	7 (0.1)	(0.1, 0.3)	9 (0.2)	(0.1, 0.3)	16 (0.1)	(0.1, 0.2)
Rhinorrhoea	3 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Rhinitis allergic	6 (0.1)	(0.0, 0.2)	9 (0.2)	(0.1, 0.3)	15 (0.1)	(0.1, 0.2)
Dyspnoea	3 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Epistaxis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysphonia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergic respiratory disease	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemoptysis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pleuritic pain	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Reflux laryngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Snoring	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	47 (0.9)	(0.6, 1.2)	33 (0.6)	(0.4, 0.9)	80 (0.7)	(0.6, 0.9)
Rash	14 (0.3)	(0.1, 0.4)	11 (0.2)	(0.1, 0.4)	25 (0.2)	(0.2, 0.3)
Pruritus	4 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Dermatitis contact	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Hyperhidrosis	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Rash pruritic	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Urticaria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dermal cyst	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis allergic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acne	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Night sweats	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ecchymosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Macule	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain of skin	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash papular	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis atopic	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis bullous	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erythema nodosum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hangnail	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ingrowing nail	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pityriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pityriasis rosea	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pruritus allergic	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	8 (0.1)	(0.1, 0.3)	7 (0.1)	(0.1, 0.3)	15 (0.1)	(0.1, 0.2)
Dental implantation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth extraction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dental care	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Endodontic procedure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cataract operation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dental operation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug titration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingival operation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Medical device implantation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sclerotherapy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wisdom teeth removal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	7 (0.1)	(0.1, 0.3)	3 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
ANEMIC SYNDROME@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
FEVER@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HYPERTENSION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	16 (0.3)	(0.2, 0.5)	16 (0.3)	(0.2, 0.5)	32 (0.3)	(0.2, 0.4)
Hypertension	5 (0.1)	(0.0, 0.2)	8 (0.1)	(0.1, 0.3)	13 (0.1)	(0.1, 0.2)
Haematoma	2 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Hot flush	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Varicose vein	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Essential hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.418. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intermittent claudication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymphoedema	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Phlebitis superficial	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subgaleal haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc 2mpd2 age p23 saf

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	812 (19.4)	(18.2, 20.7)	504 (12.1)	(11.1, 13.1)	1316 (15.8)	(15.0, 16.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	10 (0.2)	(0.1, 0.4)	3 (0.1)	(0.0, 0.2)	13 (0.2)	(0.1, 0.3)
Lymphadenopathy	7 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Anaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	15 (0.4)	(0.2, 0.6)	7 (0.2)	(0.1, 0.3)	22 (0.3)	(0.2, 0.4)
Palpitations	4 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Tachycardia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pericardial effusion	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	13 (0.3)	(0.2, 0.5)	12 (0.3)	(0.1, 0.5)	25 (0.3)	(0.2, 0.4)
Vertigo	6 (0.1)	(0.1, 0.3)	3 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Ear pain	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Tinnitus	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vertigo positional	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Ear discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear pruritus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniere's disease	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hypothyroidism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Thyroid mass	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	11 (0.3)	(0.1, 0.5)	12 (0.3)	(0.1, 0.5)	23 (0.3)	(0.2, 0.4)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cataract	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Vision blurred	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Keratitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retinal detachment	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Conjunctival hyperaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dacryostenosis acquired	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetic retinopathy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eyelid haematoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Iritis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	103 (2.5)	(2.0, 3.0)	65 (1.6)	(1.2, 2.0)	168 (2.0)	(1.7, 2.3)
Diarrhoea	42 (1.0)	(0.7, 1.4)	22 (0.5)	(0.3, 0.8)	64 (0.8)	(0.6, 1.0)
Nausea	27 (0.6)	(0.4, 0.9)	6 (0.1)	(0.1, 0.3)	33 (0.4)	(0.3, 0.6)
Vomiting	3 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Toothache	5 (0.1)	(0.0, 0.3)	4 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Abdominal pain	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Dyspepsia	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	2 (0.0)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Odynophagia	2 (0.0)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Abdominal pain upper	2 (0.0)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.2)	5 (0.1)	(0.0, 0.3)	7 (0.1)	(0.0, 0.2)
Dental caries	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Large intestine polyp	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry mouth	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Faeces soft	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hiatus hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anal pruritus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingival discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mouth ulceration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	435 (10.4)	(9.5, 11.4)	101 (2.4)	(2.0, 2.9)	536 (6.4)	(5.9, 7.0)
Injection site pain	248 (5.9)	(5.2, 6.7)	32 (0.8)	(0.5, 1.1)	280 (3.4)	(3.0, 3.8)
Fatigue	122 (2.9)	(2.4, 3.5)	29 (0.7)	(0.5, 1.0)	151 (1.8)	(1.5, 2.1)
Pyrexia	106 (2.5)	(2.1, 3.1)	14 (0.3)	(0.2, 0.6)	120 (1.4)	(1.2, 1.7)
Chills	103 (2.5)	(2.0, 3.0)	12 (0.3)	(0.1, 0.5)	115 (1.4)	(1.1, 1.7)
Pain	46 (1.1)	(0.8, 1.5)	6 (0.1)	(0.1, 0.3)	52 (0.6)	(0.5, 0.8)
Injection site erythema	25 (0.6)	(0.4, 0.9)	5 (0.1)	(0.0, 0.3)	30 (0.4)	(0.2, 0.5)
Injection site swelling	20 (0.5)	(0.3, 0.7)	5 (0.1)	(0.0, 0.3)	25 (0.3)	(0.2, 0.4)
Malaise	9 (0.2)	(0.1, 0.4)	3 (0.1)	(0.0, 0.2)	12 (0.1)	(0.1, 0.3)
Asthenia	8 (0.2)	(0.1, 0.4)	3 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Injection site pruritus	5 (0.1)	(0.0, 0.3)	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site bruising	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Axillary pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vaccination site pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Influenza like illness	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site warmth	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oedema peripheral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Swelling face	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Face oedema	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Feeling hot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Induration	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site discolouration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site plaque	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mass	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	5 (0.1)	(0.0, 0.3)	2 (0.0)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Cholelithiasis	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gallbladder disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.2)	7 (0.2)	(0.1, 0.3)	9 (0.1)	(0.0, 0.2)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Food allergy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	78 (1.9)	(1.5, 2.3)	65 (1.6)	(1.2, 2.0)	143 (1.7)	(1.4, 2.0)
Urinary tract infection	14 (0.3)	(0.2, 0.6)	14 (0.3)	(0.2, 0.6)	28 (0.3)	(0.2, 0.5)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tooth infection	7 (0.2)	(0.1, 0.3)	4 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Sinusitis	7 (0.2)	(0.1, 0.3)	6 (0.1)	(0.1, 0.3)	13 (0.2)	(0.1, 0.3)
Herpes zoster	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Cellulitis	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Gastroenteritis	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.3)	8 (0.1)	(0.0, 0.2)
Diverticulitis	4 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ear infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cystitis	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis media	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Tooth abscess	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Hordeolum	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Conjunctivitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nasopharyngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis externa	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fungal skin infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Influenza	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Kidney infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paronychia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Appendicitis perforated	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bone abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dental fistula	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fungal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Herpes virus infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Onychomycosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sialoadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin bacterial infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Trichomoniasis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Viral pharyngitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	42 (1.0)	(0.7, 1.4)	58 (1.4)	(1.1, 1.8)	100 (1.2)	(1.0, 1.5)
Fall	12 (0.3)	(0.1, 0.5)	15 (0.4)	(0.2, 0.6)	27 (0.3)	(0.2, 0.5)
Muscle strain	6 (0.1)	(0.1, 0.3)	4 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Contusion	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.3)	8 (0.1)	(0.0, 0.2)
Ligament sprain	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Skin laceration	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Arthropod bite	4 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Skin abrasion	2 (0.0)	(0.0, 0.2)	6 (0.1)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Foot fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Limb injury	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Joint dislocation	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Joint injury	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Tooth fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Chest injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Facial bones fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fibula fracture	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rib fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thermal burn	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Burn oral cavity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Corneal abrasion	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dental restoration failure	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear canal abrasion	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Respiratory fume inhalation disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sunburn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tendon rupture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tibia fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	23 (0.6)	(0.3, 0.8)	8 (0.2)	(0.1, 0.4)	31 (0.4)	(0.3, 0.5)
Body temperature increased	10 (0.2)	(0.1, 0.4)	1 (0.0)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)
Blood glucose increased	7 (0.2)	(0.1, 0.3)	0	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Blood pressure increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood urea increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Body temperature decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lumbar puncture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mean cell haemoglobin decreased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mean cell volume increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Monocyte count increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Prostatic specific antigen increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
White blood cell count increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	17 (0.4)	(0.2, 0.7)	16 (0.4)	(0.2, 0.6)	33 (0.4)	(0.3, 0.6)
Decreased appetite	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.3)	6 (0.1)	(0.0, 0.2)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Vitamin D deficiency	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyslipidaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperkalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperlipidaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Iron deficiency	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	203 (4.9)	(4.2, 5.6)	86 (2.1)	(1.7, 2.5)	289 (3.5)	(3.1, 3.9)
Myalgia	112 (2.7)	(2.2, 3.2)	21 (0.5)	(0.3, 0.8)	133 (1.6)	(1.3, 1.9)
Arthralgia	40 (1.0)	(0.7, 1.3)	23 (0.6)	(0.4, 0.8)	63 (0.8)	(0.6, 1.0)
Pain in extremity	27 (0.6)	(0.4, 0.9)	4 (0.1)	(0.0, 0.2)	31 (0.4)	(0.3, 0.5)
Back pain	16 (0.4)	(0.2, 0.6)	16 (0.4)	(0.2, 0.6)	32 (0.4)	(0.3, 0.5)
Neck pain	6 (0.1)	(0.1, 0.3)	3 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Muscle spasms	7 (0.2)	(0.1, 0.3)	3 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Osteoarthritis	4 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle contracture	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Tendonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Bursitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscular weakness	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint swelling	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Temporomandibular joint syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Trigger finger	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary mass	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dupuytren's contracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Exostosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mobility decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Scleroderma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal stenosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	8 (0.2)	(0.1, 0.4)	8 (0.2)	(0.1, 0.4)	16 (0.2)	(0.1, 0.3)
Lipoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glomus tumour	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma of skin	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	145 (3.5)	(2.9, 4.1)	78 (1.9)	(1.5, 2.3)	223 (2.7)	(2.3, 3.0)
Headache	114 (2.7)	(2.3, 3.3)	47 (1.1)	(0.8, 1.5)	161 (1.9)	(1.6, 2.2)
Dizziness	9 (0.2)	(0.1, 0.4)	10 (0.2)	(0.1, 0.4)	19 (0.2)	(0.1, 0.4)
Paraesthesia	2 (0.0)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Migraine	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tension headache	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Lethargy	6 (0.1)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Syncope	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Sciatica	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysgeusia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Presyncope	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Burning sensation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neuropathy peripheral	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphasia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Encephalopathy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial paresis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Migraine with aura	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myoclonus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neuralgia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Device breakage	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Device connection issue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	15 (0.4)	(0.2, 0.6)	9 (0.2)	(0.1, 0.4)	24 (0.3)	(0.2, 0.4)
Anxiety	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Insomnia	4 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Panic attack	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nightmare	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sleep disorder	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental status changes	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mood swings	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	11 (0.3)	(0.1, 0.5)	7 (0.2)	(0.1, 0.3)	18 (0.2)	(0.1, 0.3)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Dysuria	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Haematuria	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pollakiuria	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pruritus genital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast calcifications	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	37 (0.9)	(0.6, 1.2)	25 (0.6)	(0.4, 0.9)	62 (0.7)	(0.6, 1.0)
Oropharyngeal pain	5 (0.1)	(0.0, 0.3)	6 (0.1)	(0.1, 0.3)	11 (0.1)	(0.1, 0.2)
Cough	6 (0.1)	(0.1, 0.3)	3 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Nasal congestion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rhinorrhoea	6 (0.1)	(0.1, 0.3)	4 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Dyspnoea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthma	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Throat irritation	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Productive cough	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysphonia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	42 (1.0)	(0.7, 1.4)	36 (0.9)	(0.6, 1.2)	78 (0.9)	(0.7, 1.2)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rash	6 (0.1)	(0.1, 0.3)	10 (0.2)	(0.1, 0.4)	16 (0.2)	(0.1, 0.3)
Pruritus	8 (0.2)	(0.1, 0.4)	2 (0.0)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Dermatitis contact	4 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Hyperhidrosis	3 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Rash pruritic	2 (0.0)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Urticaria	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermal cyst	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dermatitis allergic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Night sweats	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rosacea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Alopecia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alopecia areata	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blister	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug eruption	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin induration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urticaria chronic	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	12 (0.3)	(0.1, 0.5)	6 (0.1)	(0.1, 0.3)	18 (0.2)	(0.1, 0.3)
Dental implantation	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tooth extraction	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardioversion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hip surgery	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hospitalisation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.419. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lens extraction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	0	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
BROWNISH EJACULATION@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RIB INJURY FROM FALL@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	10 (0.2)	(0.1, 0.4)	22 (0.5)	(0.3, 0.8)	32 (0.4)	(0.3, 0.5)
Hypertension	6 (0.1)	(0.1, 0.3)	12 (0.3)	(0.1, 0.5)	18 (0.2)	(0.1, 0.3)
Haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypotension	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertensive crisis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Phlebolith	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Raynaud's phenomenon	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_soc_2mpd2_age_p23_saf

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	5770 (26.7)	(26.1, 27.3)	2638 (12.2)	(11.8, 12.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	90 (0.4)	(0.3, 0.5)	17 (0.1)	(0.0, 0.1)
Lymphadenopathy	70 (0.3)	(0.3, 0.4)	7 (0.0)	(0.0, 0.1)
Anaemia	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Leukopenia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	52 (0.2)	(0.2, 0.3)	44 (0.2)	(0.1, 0.3)
Palpitations	7 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Tachycardia	11 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Acute coronary syndrome	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	61 (0.3)	(0.2, 0.4)	41 (0.2)	(0.1, 0.3)
Vertigo	23 (0.1)	(0.1, 0.2)	18 (0.1)	(0.0, 0.1)
Tinnitus	9 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Ear pain	11 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vertigo positional	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Excessive cerumen production	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypothyroidism	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hypogonadism	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid mass	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	54 (0.2)	(0.2, 0.3)	44 (0.2)	(0.1, 0.3)
Cataract	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Eye pain	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vision blurred	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Eye irritation	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vitreous detachment	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	617 (2.9)	(2.6, 3.1)	403 (1.9)	(1.7, 2.1)
Diarrhoea	220 (1.0)	(0.9, 1.2)	166 (0.8)	(0.7, 0.9)
Nausea	238 (1.1)	(1.0, 1.2)	75 (0.3)	(0.3, 0.4)
Vomiting	54 (0.2)	(0.2, 0.3)	35 (0.2)	(0.1, 0.2)
Toothache	22 (0.1)	(0.1, 0.2)	18 (0.1)	(0.0, 0.1)
Abdominal pain	17 (0.1)	(0.0, 0.1)	20 (0.1)	(0.1, 0.1)
Abdominal pain upper	23 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Dyspepsia	13 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	7 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Odynophagia	12 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Constipation	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Dental caries	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Gastritis	3 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Aphthous ulcer	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Haemorrhoids	2 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Abdominal discomfort	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Abdominal distension	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dry mouth	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Abdominal pain lower	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Flatulence	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Small intestinal obstruction	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Stomatitis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rectal haemorrhage	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis microscopic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Swollen tongue	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4007 (18.5)	(18.0, 19.1)	829 (3.8)	(3.6, 4.1)
Injection site pain	2440 (11.3)	(10.9, 11.7)	322 (1.5)	(1.3, 1.7)
Fatigue	1145 (5.3)	(5.0, 5.6)	294 (1.4)	(1.2, 1.5)
Pyrexia	1255 (5.8)	(5.5, 6.1)	68 (0.3)	(0.2, 0.4)
Chills	1111 (5.1)	(4.8, 5.4)	100 (0.5)	(0.4, 0.6)
Pain	507 (2.3)	(2.1, 2.6)	45 (0.2)	(0.2, 0.3)
Injection site erythema	155 (0.7)	(0.6, 0.8)	23 (0.1)	(0.1, 0.2)
Injection site swelling	107 (0.5)	(0.4, 0.6)	20 (0.1)	(0.1, 0.1)
Malaise	104 (0.5)	(0.4, 0.6)	18 (0.1)	(0.0, 0.1)
Asthenia	72 (0.3)	(0.3, 0.4)	26 (0.1)	(0.1, 0.2)
Injection site pruritus	31 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Vaccination site pain	25 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Chest pain	15 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Influenza like illness	21 (0.1)	(0.1, 0.1)	4 (0.0)	(0.0, 0.0)
Injection site bruising	11 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Injection site warmth	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Axillary pain	11 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Chest discomfort	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Injection site induration	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Injection site oedema	10 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Oedema peripheral	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Peripheral swelling	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Injection site mass	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Medical device pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cholelithiasis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Biliary colic	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gallbladder disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	26 (0.1)	(0.1, 0.2)	22 (0.1)	(0.1, 0.2)
Seasonal allergy	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Drug hypersensitivity	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	322 (1.5)	(1.3, 1.7)	320 (1.5)	(1.3, 1.6)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Urinary tract infection	49 (0.2)	(0.2, 0.3)	50 (0.2)	(0.2, 0.3)
Tooth infection	24 (0.1)	(0.1, 0.2)	26 (0.1)	(0.1, 0.2)
Sinusitis	20 (0.1)	(0.1, 0.1)	22 (0.1)	(0.1, 0.2)
Cellulitis	10 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Herpes zoster	14 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Ear infection	8 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Gastroenteritis	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Cystitis	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Conjunctivitis	8 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Rhinitis	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	10 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Diverticulitis	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Otitis media	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Oral herpes	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth abscess	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Otitis externa	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Appendicitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Gingivitis	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Furuncle	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Nasopharyngitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Skin infection	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Periodontitis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Folliculitis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Influenza	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media acute	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyelonephritis	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Escherichia urinary tract infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected bite	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pustule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pustular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis A	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes virus infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster cutaneous disseminated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Pharyngitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulval abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	184 (0.9)	(0.7, 1.0)	220 (1.0)	(0.9, 1.2)
Fall	35 (0.2)	(0.1, 0.2)	39 (0.2)	(0.1, 0.2)
Ligament sprain	15 (0.1)	(0.0, 0.1)	21 (0.1)	(0.1, 0.1)
Skin laceration	12 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Contusion	11 (0.1)	(0.0, 0.1)	17 (0.1)	(0.0, 0.1)
Muscle strain	14 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Skin abrasion	7 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Arthropod bite	11 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Road traffic accident	6 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Exposure during pregnancy	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Limb injury	4 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Foot fracture	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth fracture	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Meniscus injury	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Procedural pain	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Animal bite	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Joint dislocation	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint injury	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Facial bones fracture	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Rib fracture	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Ankle fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Vaccination complication	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest injury	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Concussion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Thermal burn	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand fracture	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Radius fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone contusion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Head injury	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal compression fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Administration related reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone fissure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Burns first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heat stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tibia fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	145 (0.7)	(0.6, 0.8)	40 (0.2)	(0.1, 0.3)
Body temperature increased	100 (0.5)	(0.4, 0.6)	11 (0.1)	(0.0, 0.1)
Blood pressure increased	4 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood cholesterol increased	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alanine aminotransferase increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood urea increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mean cell haemoglobin decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mean cell volume increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	86 (0.4)	(0.3, 0.5)	61 (0.3)	(0.2, 0.4)
Decreased appetite	34 (0.2)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.0)	(0.0, 0.0)	9 (0.0)	(0.0, 0.1)
Hyperlipidaemia	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Hypokalaemia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Vitamin D deficiency	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Dyslipidaemia	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Dehydration	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Gout	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hyperglycaemia	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypoglycaemia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Insulin resistance	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1511 (7.0)	(6.7, 7.3)	435 (2.0)	(1.8, 2.2)
Myalgia	999 (4.6)	(4.3, 4.9)	142 (0.7)	(0.6, 0.8)
Arthralgia	224 (1.0)	(0.9, 1.2)	89 (0.4)	(0.3, 0.5)
Pain in extremity	183 (0.8)	(0.7, 1.0)	34 (0.2)	(0.1, 0.2)
Back pain	87 (0.4)	(0.3, 0.5)	74 (0.3)	(0.3, 0.4)
Neck pain	25 (0.1)	(0.1, 0.2)	29 (0.1)	(0.1, 0.2)
Muscle spasms	24 (0.1)	(0.1, 0.2)	10 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	12 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Osteoarthritis	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Muscle contracture	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Muscular weakness	10 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Tendonitis	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Bursitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Plantar fasciitis	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Arthritis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Flank pain	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Exostosis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Joint stiffness	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Costochondritis	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Synovial cyst	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal deformity	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	29 (0.1)	(0.1, 0.2)	31 (0.1)	(0.1, 0.2)
Basal cell carcinoma	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Lipoma	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostate cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1277 (5.9)	(5.6, 6.2)	501 (2.3)	(2.1, 2.5)
Headache	1084 (5.0)	(4.7, 5.3)	345 (1.6)	(1.4, 1.8)
Dizziness	61 (0.3)	(0.2, 0.4)	54 (0.2)	(0.2, 0.3)
Paraesthesia	16 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Migraine	21 (0.1)	(0.1, 0.1)	9 (0.0)	(0.0, 0.1)
Lethargy	21 (0.1)	(0.1, 0.1)	5 (0.0)	(0.0, 0.1)
Sciatica	9 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Syncope	8 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Somnolence	8 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Tension headache	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Dysgeusia	8 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Presyncope	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tremor	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypoaesthesia	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Burning sensation	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cerebrovascular accident	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parosmia	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paralysis	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Transient ischaemic attack	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	84 (0.4)	(0.3, 0.5)	58 (0.3)	(0.2, 0.3)
Anxiety	19 (0.1)	(0.1, 0.1)	16 (0.1)	(0.0, 0.1)
Insomnia	24 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Depression	11 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Anxiety disorder	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Irritability	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sleep disorder	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adjustment disorder with depressed mood	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	30 (0.1)	(0.1, 0.2)	24 (0.1)	(0.1, 0.2)
Nephrolithiasis	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysuria	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Haematuria	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pollakiuria	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute kidney injury	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	35 (0.2)	(0.1, 0.2)	36 (0.2)	(0.1, 0.2)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Dysmenorrhoea	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Ovarian cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Amenorrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	187 (0.9)	(0.7, 1.0)	169 (0.8)	(0.7, 0.9)
Oropharyngeal pain	38 (0.2)	(0.1, 0.2)	40 (0.2)	(0.1, 0.3)
Nasal congestion	24 (0.1)	(0.1, 0.2)	29 (0.1)	(0.1, 0.2)
Cough	26 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.1)
Rhinorrhoea	22 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Rhinitis allergic	10 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Asthma	11 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dyspnoea	8 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinus congestion	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Epistaxis	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Pulmonary embolism	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bronchospasm	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry throat	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	196 (0.9)	(0.8, 1.0)	136 (0.6)	(0.5, 0.7)
Rash	45 (0.2)	(0.2, 0.3)	37 (0.2)	(0.1, 0.2)
Pruritus	21 (0.1)	(0.1, 0.1)	17 (0.1)	(0.0, 0.1)
Hyperhidrosis	26 (0.1)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Dermatitis contact	13 (0.1)	(0.0, 0.1)	17 (0.1)	(0.0, 0.1)
Urticaria	15 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Night sweats	15 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Rash pruritic	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Erythema	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eczema	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Rash maculo-papular	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Alopecia	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Skin lesion	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Dermal cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Angioedema	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Dermatitis allergic	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acne	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erythema nodosum	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress at work	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	29 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Tooth extraction	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Endodontic procedure	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardioversion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Micrographic skin surgery	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salpingectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	38 (0.2)	(0.1, 0.2)	23 (0.1)	(0.1, 0.2)
INJECTION SITE PAIN@@	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
FATIGUE@@	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEADACHE@@	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
CHILLS@@	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L ARM SITE INJECTION PAIN@@	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ANEMIC SYNDROME@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BILATERAL EYE ITCHINESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BILATERAL EYE REDNESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BROWNISH EJACULATION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED TEMPERATURE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FOLLICULITIS RIGHT AXILLARY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEAT AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HYPERTENSION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
KIDNEY STONE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
L ARM - SITE INJECTION PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L OPEN HEAVINESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LETHARGY@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NECK PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIB INJURY FROM FALL@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SHORTNESS OF BREATH@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
THROAT ITCHINESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UTERINE FIBROIDS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
WORSENING OF DIZZINESS@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	65 (0.3)	(0.2, 0.4)	69 (0.3)	(0.2, 0.4)
Hypertension	31 (0.1)	(0.1, 0.2)	37 (0.2)	(0.1, 0.2)
Hot flush	7 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)

14.420. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Flushing	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Haematoma	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Hypotension	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebitis superficial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_all_p23_saf

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3660 (28.8)	(28.0, 29.6)	1605 (12.6)	(12.0, 13.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	70 (0.6)	(0.4, 0.7)	9 (0.1)	(0.0, 0.1)
Lymphadenopathy	59 (0.5)	(0.4, 0.6)	4 (0.0)	(0.0, 0.1)
Anaemia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	22 (0.2)	(0.1, 0.3)	24 (0.2)	(0.1, 0.3)
Palpitations	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Tachycardia	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Left ventricular hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	33 (0.3)	(0.2, 0.4)	20 (0.2)	(0.1, 0.2)
Vertigo	10 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Tinnitus	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Ear pain	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vertigo positional	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Excessive cerumen production	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypogonadism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Basedow's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	31 (0.2)	(0.2, 0.3)	20 (0.2)	(0.1, 0.2)
Eye pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye irritation	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chalazion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vitreous detachment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	377 (3.0)	(2.7, 3.3)	255 (2.0)	(1.8, 2.3)
Diarrhoea	131 (1.0)	(0.9, 1.2)	107 (0.8)	(0.7, 1.0)
Nausea	159 (1.3)	(1.1, 1.5)	50 (0.4)	(0.3, 0.5)
Vomiting	43 (0.3)	(0.2, 0.5)	23 (0.2)	(0.1, 0.3)
Toothache	14 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Abdominal pain	10 (0.1)	(0.0, 0.1)	15 (0.1)	(0.1, 0.2)
Abdominal pain upper	16 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Dyspepsia	8 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Odynophagia	9 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dental caries	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haemorrhoids	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abdominal discomfort	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abdominal pain lower	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Large intestine polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2656 (20.9)	(20.2, 21.6)	562 (4.4)	(4.1, 4.8)
Injection site pain	1599 (12.6)	(12.0, 13.2)	224 (1.8)	(1.5, 2.0)
Fatigue	776 (6.1)	(5.7, 6.5)	206 (1.6)	(1.4, 1.8)
Pyrexia	897 (7.1)	(6.6, 7.5)	46 (0.4)	(0.3, 0.5)
Chills	775 (6.1)	(5.7, 6.5)	64 (0.5)	(0.4, 0.6)
Pain	345 (2.7)	(2.4, 3.0)	29 (0.2)	(0.2, 0.3)
Injection site erythema	98 (0.8)	(0.6, 0.9)	14 (0.1)	(0.1, 0.2)
Injection site swelling	60 (0.5)	(0.4, 0.6)	11 (0.1)	(0.0, 0.2)
Malaise	66 (0.5)	(0.4, 0.7)	9 (0.1)	(0.0, 0.1)
Asthenia	42 (0.3)	(0.2, 0.4)	18 (0.1)	(0.1, 0.2)
Injection site pruritus	17 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Vaccination site pain	16 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Chest pain	11 (0.1)	(0.0, 0.2)	11 (0.1)	(0.0, 0.2)
Influenza like illness	13 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site bruising	7 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Axillary pain	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest discomfort	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Injection site induration	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Oedema peripheral	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Peripheral swelling	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Illness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Medical device pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	22 (0.2)	(0.1, 0.3)	12 (0.1)	(0.0, 0.2)
Seasonal allergy	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Drug hypersensitivity	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	180 (1.4)	(1.2, 1.6)	187 (1.5)	(1.3, 1.7)
Urinary tract infection	25 (0.2)	(0.1, 0.3)	23 (0.2)	(0.1, 0.3)
Tooth infection	10 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Sinusitis	9 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Cellulitis	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Herpes zoster	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ear infection	6 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cystitis	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Conjunctivitis	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Rhinitis	6 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hordeolum	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Otitis media	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Oral herpes	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth abscess	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Appendicitis	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gingivitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Furuncle	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nasopharyngitis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodontitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Folliculitis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Paronychia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Escherichia urinary tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Herpes simplex	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash pustular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis A	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster cutaneous disseminated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea versicolour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulval abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	94 (0.7)	(0.6, 0.9)	107 (0.8)	(0.7, 1.0)
Fall	12 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Ligament sprain	6 (0.0)	(0.0, 0.1)	13 (0.1)	(0.1, 0.2)
Skin laceration	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Contusion	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Muscle strain	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Skin abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arthropod bite	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Road traffic accident	6 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Exposure during pregnancy	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Limb injury	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Meniscus injury	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Procedural pain	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Animal bite	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint dislocation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint injury	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rib fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Corneal abrasion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thermal burn	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone contusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Epicondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone fissure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heat stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	85 (0.7)	(0.5, 0.8)	20 (0.2)	(0.1, 0.2)
Body temperature increased	63 (0.5)	(0.4, 0.6)	8 (0.1)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Blood glucose increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alanine aminotransferase increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood potassium decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	49 (0.4)	(0.3, 0.5)	33 (0.3)	(0.2, 0.4)
Decreased appetite	23 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Dehydration	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gout	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	993 (7.8)	(7.4, 8.3)	254 (2.0)	(1.8, 2.2)
Myalgia	692 (5.4)	(5.1, 5.9)	87 (0.7)	(0.5, 0.8)
Arthralgia	143 (1.1)	(0.9, 1.3)	44 (0.3)	(0.3, 0.5)
Pain in extremity	105 (0.8)	(0.7, 1.0)	18 (0.1)	(0.1, 0.2)
Back pain	47 (0.4)	(0.3, 0.5)	50 (0.4)	(0.3, 0.5)
Neck pain	17 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.2)
Muscle spasms	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Osteoarthritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Muscle contracture	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tendonitis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bursitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flank pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exostosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costochondritis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Spondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal deformity	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	12 (0.1)	(0.0, 0.2)	11 (0.1)	(0.0, 0.2)
Lipoma	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	844 (6.6)	(6.2, 7.1)	323 (2.5)	(2.3, 2.8)
Headache	732 (5.8)	(5.4, 6.2)	232 (1.8)	(1.6, 2.1)
Dizziness	34 (0.3)	(0.2, 0.4)	28 (0.2)	(0.1, 0.3)
Paraesthesia	11 (0.1)	(0.0, 0.2)	12 (0.1)	(0.0, 0.2)
Migraine	20 (0.2)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Lethargy	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Sciatica	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Syncope	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Tension headache	6 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Presyncope	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tremor	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	56 (0.4)	(0.3, 0.6)	39 (0.3)	(0.2, 0.4)
Anxiety	15 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Insomnia	16 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Depression	10 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Anxiety disorder	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adjustment disorder with depressed mood	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	(95% CI[c])	Placebo (N[a]=12756) n[b] (%)	(95% CI[c])
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	12 (0.1)	(0.0, 0.2)	12 (0.1)	(0.0, 0.2)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysuria	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Haematuria	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	24 (0.2)	(0.1, 0.3)	28 (0.2)	(0.1, 0.3)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ovarian cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pelvic pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	106 (0.8)	(0.7, 1.0)	118 (0.9)	(0.8, 1.1)
Oropharyngeal pain	25 (0.2)	(0.1, 0.3)	30 (0.2)	(0.2, 0.3)
Nasal congestion	17 (0.1)	(0.1, 0.2)	26 (0.2)	(0.1, 0.3)
Cough	15 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Rhinorrhoea	12 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.1)
Rhinitis allergic	9 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Asthma	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspnoea	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Sinus congestion	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Epistaxis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pleuritic pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	107 (0.8)	(0.7, 1.0)	72 (0.6)	(0.4, 0.7)
Rash	26 (0.2)	(0.1, 0.3)	20 (0.2)	(0.1, 0.2)
Pruritus	9 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Hyperhidrosis	14 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Urticaria	9 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Night sweats	8 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash pruritic	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erythema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eczema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermal cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angioedema	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acne	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hand dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash papular	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erythema nodosum	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress at work	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	13 (0.1)	(0.1, 0.2)	13 (0.1)	(0.1, 0.2)
Dental implantation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth extraction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Endodontic procedure	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wisdom teeth removal	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	(95% CI[c])	Placebo (N[a]=12756) n[b] (%)	(95% CI[c])
Salpingectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	27 (0.2)	(0.1, 0.3)	12 (0.1)	(0.0, 0.2)
INJECTION SITE PAIN@@	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
FATIGUE@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ANEMIC SYNDROME@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BILATERAL EYE ITCHINESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BILATERAL EYE REDNESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BLEPHARITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED TEMPERATURE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROESOPHAGEAL REFLUX@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HYPERTENSION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
KIDNEY STONE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L ARM - SITE INJECTION PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LETHARGY@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NECK PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED LEFT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SPRAINED RIGHT FOOT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
THROAT ITCHINESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER RESPIRATORY INFECCION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
URINARY TRACT INFECTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UTERINE FIBROIDS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VERTIGO@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
WORSENING OF DIZZINESS@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	33 (0.3)	(0.2, 0.4)	34 (0.3)	(0.2, 0.4)
Hypertension	12 (0.1)	(0.0, 0.2)	17 (0.1)	(0.1, 0.2)
Hot flush	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Flushing	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebitis superficial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.421. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut vax all p23 saf

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Any event	2110 (23.7)	(22.8, 24.6)	1033 (11.6)	(11.0, 12.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	20 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Lymphadenopathy	11 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Anaemia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Leukopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	30 (0.3)	(0.2, 0.5)	20 (0.2)	(0.1, 0.3)
Palpitations	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tachycardia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Mitral valve incompetence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	28 (0.3)	(0.2, 0.5)	21 (0.2)	(0.1, 0.4)
Vertigo	13 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.2)
Tinnitus	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ear pain	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vertigo positional	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ear discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniere's disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Deafness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	23 (0.3)	(0.2, 0.4)	24 (0.3)	(0.2, 0.4)
Cataract	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vision blurred	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Keratitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retinal detachment	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	240 (2.7)	(2.4, 3.0)	148 (1.7)	(1.4, 2.0)
Diarrhoea	89 (1.0)	(0.8, 1.2)	59 (0.7)	(0.5, 0.9)
Nausea	79 (0.9)	(0.7, 1.1)	25 (0.3)	(0.2, 0.4)
Vomiting	11 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Toothache	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Abdominal pain	7 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Abdominal pain upper	7 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Dyspepsia	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Odynophagia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Constipation	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Dental caries	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemorrhoids	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal distension	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Stomatitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	(95% CI[c])	Placebo (N[a]=8875) n[b] (%)	(95% CI[c])
Diverticulum	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Faeces soft	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Food poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis microscopic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swollen tongue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1351 (15.2)	(14.4, 15.9)	267 (3.0)	(2.7, 3.4)
Injection site pain	841 (9.4)	(8.8, 10.1)	98 (1.1)	(0.9, 1.3)
Fatigue	369 (4.1)	(3.7, 4.6)	88 (1.0)	(0.8, 1.2)
Pyrexia	358 (4.0)	(3.6, 4.4)	22 (0.2)	(0.2, 0.4)
Chills	336 (3.8)	(3.4, 4.2)	36 (0.4)	(0.3, 0.6)
Pain	162 (1.8)	(1.6, 2.1)	16 (0.2)	(0.1, 0.3)
Injection site erythema	57 (0.6)	(0.5, 0.8)	9 (0.1)	(0.0, 0.2)
Injection site swelling	47 (0.5)	(0.4, 0.7)	9 (0.1)	(0.0, 0.2)
Malaise	38 (0.4)	(0.3, 0.6)	9 (0.1)	(0.0, 0.2)
Asthenia	30 (0.3)	(0.2, 0.5)	8 (0.1)	(0.0, 0.2)
Injection site pruritus	14 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Vaccination site pain	9 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Chest pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Injection site bruising	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Injection site warmth	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedema peripheral	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Peripheral swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cyst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	10 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Cholelithiasis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cholecystitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gallbladder disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	10 (0.1)	(0.1, 0.2)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Immunisation reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food allergy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to arthropod bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	142 (1.6)	(1.3, 1.9)	133 (1.5)	(1.3, 1.8)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Urinary tract infection	24 (0.3)	(0.2, 0.4)	27 (0.3)	(0.2, 0.4)
Tooth infection	14 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Sinusitis	11 (0.1)	(0.1, 0.2)	10 (0.1)	(0.1, 0.2)
Cellulitis	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Herpes zoster	7 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Ear infection	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Cystitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Conjunctivitis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hordeolum	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diverticulitis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis media	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Oral herpes	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth abscess	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Otitis externa	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingivitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Furuncle	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nasopharyngitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bronchitis	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Influenza	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis media acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	(95% CI[c])	Placebo (N[a]=8875) n[b] (%)	(95% CI[c])
Gingival abscess	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Onychomycosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Erysipelas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rash pustular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sialoadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinusitis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trichomoniasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bone abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cellulitis orbital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endocarditis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye infection bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Herpes virus infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	90 (1.0)	(0.8, 1.2)	113 (1.3)	(1.1, 1.5)
Fall	23 (0.3)	(0.2, 0.4)	31 (0.3)	(0.2, 0.5)
Ligament sprain	9 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Skin laceration	4 (0.0)	(0.0, 0.1)	12 (0.1)	(0.1, 0.2)
Contusion	4 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Muscle strain	7 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Skin abrasion	4 (0.0)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)
Arthropod bite	9 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Limb injury	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Procedural pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.0)	6 (0.1)	(0.0, 0.1)
Joint dislocation	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint injury	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rib fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vaccination complication	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thermal burn	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Fibula fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Hand fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Muscle injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wound	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Overdose	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scapula fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stress fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Sunburn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tibia fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	60 (0.7)	(0.5, 0.9)	20 (0.2)	(0.1, 0.3)
Body temperature increased	37 (0.4)	(0.3, 0.6)	3 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood testosterone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood urea increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Body temperature decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mean cell haemoglobin decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mean cell volume increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Platelet count increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	(95% CI[c])	Placebo (N[a]=8875) n[b] (%)	(95% CI[c])
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	37 (0.4)	(0.3, 0.6)	28 (0.3)	(0.2, 0.5)
Decreased appetite	11 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypokalaemia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vitamin D deficiency	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	518 (5.8)	(5.3, 6.3)	181 (2.0)	(1.8, 2.4)
Myalgia	307 (3.4)	(3.1, 3.8)	55 (0.6)	(0.5, 0.8)
Arthralgia	81 (0.9)	(0.7, 1.1)	45 (0.5)	(0.4, 0.7)
Pain in extremity	78 (0.9)	(0.7, 1.1)	16 (0.2)	(0.1, 0.3)
Back pain	40 (0.4)	(0.3, 0.6)	24 (0.3)	(0.2, 0.4)
Neck pain	8 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Muscle spasms	15 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Osteoarthritis	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle contracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tendonitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bursitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint swelling	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rotator cuff syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Arthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Exostosis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigger finger	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	(95% CI[c])	Placebo (N[a]=8875) n[b] (%)	(95% CI[c])
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	17 (0.2)	(0.1, 0.3)	20 (0.2)	(0.1, 0.3)
Basal cell carcinoma	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Lipoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Colon adenoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	433 (4.9)	(4.4, 5.3)	178 (2.0)	(1.7, 2.3)
Headache	352 (3.9)	(3.6, 4.4)	113 (1.3)	(1.1, 1.5)
Dizziness	27 (0.3)	(0.2, 0.4)	26 (0.3)	(0.2, 0.4)
Paraesthesia	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Migraine	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lethargy	15 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Sciatica	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Syncope	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Somnolence	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Presyncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tremor	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Burning sensation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphasia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Migraine without aura	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cervical radiculopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Migraine with aura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Balance disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intention tremor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device connection issue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	28 (0.3)	(0.2, 0.5)	19 (0.2)	(0.1, 0.3)
Anxiety	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Insomnia	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sleep disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Libido decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	18 (0.2)	(0.1, 0.3)	12 (0.1)	(0.1, 0.2)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dysuria	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haematuria	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	(95% CI[c])	Placebo (N[a]=8875) n[b] (%)	(95% CI[c])
Acute kidney injury	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hydronephrosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	11 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Prostatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaginal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostatomegaly	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	81 (0.9)	(0.7, 1.1)	51 (0.6)	(0.4, 0.8)
Oropharyngeal pain	13 (0.1)	(0.1, 0.2)	10 (0.1)	(0.1, 0.2)
Nasal congestion	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Cough	11 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.2)
Rhinorrhoea	10 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.1)
Rhinitis allergic	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthma	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyspnoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Sinus congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Epistaxis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bronchospasm	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	89 (1.0)	(0.8, 1.2)	64 (0.7)	(0.6, 0.9)
Rash	19 (0.2)	(0.1, 0.3)	17 (0.2)	(0.1, 0.3)
Pruritus	12 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	(95% CI[c])	Placebo (N[a]=8875) n[b] (%)	(95% CI[c])
Hyperhidrosis	12 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Dermatitis contact	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Urticaria	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Rash pruritic	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Erythema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin lesion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermal cyst	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angioedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis allergic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rosacea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	16 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Dental implantation	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	(95% CI[c])	Placebo (N[a]=8875) n[b] (%)	(95% CI[c])
Tooth extraction	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Apicectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardioversion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hip surgery	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Micrographic skin surgery	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sebaceous cyst excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	11 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
L ARM SITE INJECTION PAIN@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
BODY ACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
BROWNISH EJACULATION@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FOLLICULITIS RIGHT AXILLARY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FRACTURED LEFT ELBOW@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEAT AT INJECTION SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HYPERLIPIDEMIA@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
L OPEN HEAVINESS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.422. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RIB INJURY FROM FALL@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SHORTNESS OF BREATH@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SWOLLEN LYMPH NODE IN RIGHT AXILLA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	32 (0.4)	(0.2, 0.5)	35 (0.4)	(0.3, 0.5)
Hypertension	19 (0.2)	(0.1, 0.3)	20 (0.2)	(0.1, 0.3)
Hot flush	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypotension	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut vax all p23 saf

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2835 (13.1)	(12.7, 13.6)	1030 (4.8)	(4.5, 5.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	17 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	17 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tachycardia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	15 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Vertigo	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Tinnitus	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ear pain	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypothyroidism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	16 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Eye irritation	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chalazion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vision blurred	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	207 (1.0)	(0.8, 1.1)	162 (0.7)	(0.6, 0.9)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Diarrhoea	105 (0.5)	(0.4, 0.6)	88 (0.4)	(0.3, 0.5)
Nausea	58 (0.3)	(0.2, 0.3)	42 (0.2)	(0.1, 0.3)
Vomiting	12 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Abdominal pain upper	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Abdominal pain	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Constipation	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dyspepsia	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Toothache	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphthous ulcer	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental caries	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Flatulence	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis microscopic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2215 (10.2)	(9.8, 10.7)	488 (2.3)	(2.1, 2.5)
Injection site pain	1726 (8.0)	(7.6, 8.4)	206 (1.0)	(0.8, 1.1)
Fatigue	447 (2.1)	(1.9, 2.3)	172 (0.8)	(0.7, 0.9)
Chills	227 (1.0)	(0.9, 1.2)	53 (0.2)	(0.2, 0.3)
Pyrexia	233 (1.1)	(0.9, 1.2)	29 (0.1)	(0.1, 0.2)
Pain	115 (0.5)	(0.4, 0.6)	20 (0.1)	(0.1, 0.1)
Injection site erythema	73 (0.3)	(0.3, 0.4)	12 (0.1)	(0.0, 0.1)
Injection site swelling	59 (0.3)	(0.2, 0.4)	11 (0.1)	(0.0, 0.1)
Malaise	44 (0.2)	(0.1, 0.3)	8 (0.0)	(0.0, 0.1)
Asthenia	23 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Vaccination site pain	15 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site bruising	8 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Injection site pruritus	13 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Chest pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site induration	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site oedema	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site warmth	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Influenza like illness	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Axillary pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Induration	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sluggishness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Seasonal allergy	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug hypersensitivity	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Immunisation reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	50 (0.2)	(0.2, 0.3)	66 (0.3)	(0.2, 0.4)
Urinary tract infection	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Sinusitis	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tooth infection	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Ear infection	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cellulitis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Herpes zoster	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Hordeolum	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Otitis externa	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute sinusitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tooth abscess	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oral herpes	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodontitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	32 (0.1)	(0.1, 0.2)	41 (0.2)	(0.1, 0.3)
Fall	5 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Contusion	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Muscle strain	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthropod bite	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Exposure during pregnancy	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Meniscus injury	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament sprain	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthropod sting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Radius fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Wound	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thermal burn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	39 (0.2)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)
Body temperature increased	30 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatic specific antigen increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	19 (0.1)	(0.1, 0.1)	11 (0.1)	(0.0, 0.1)
Decreased appetite	10 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Hyperlipidaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dehydration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin D deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	471 (2.2)	(2.0, 2.4)	155 (0.7)	(0.6, 0.8)
Myalgia	290 (1.3)	(1.2, 1.5)	71 (0.3)	(0.3, 0.4)
Pain in extremity	93 (0.4)	(0.3, 0.5)	10 (0.0)	(0.0, 0.1)
Arthralgia	62 (0.3)	(0.2, 0.4)	36 (0.2)	(0.1, 0.2)
Back pain	20 (0.1)	(0.1, 0.1)	22 (0.1)	(0.1, 0.2)
Muscle spasms	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Neck pain	3 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendonitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint stiffness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	(95% CI[c])	Placebo (N[a]=21631) n[b] (%)	(95% CI[c])
Muscle fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	444 (2.1)	(1.9, 2.3)	220 (1.0)	(0.9, 1.2)
Headache	382 (1.8)	(1.6, 2.0)	172 (0.8)	(0.7, 0.9)
Dizziness	17 (0.1)	(0.0, 0.1)	26 (0.1)	(0.1, 0.2)
Paraesthesia	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Lethargy	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Migraine	9 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dysgeusia	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Somnolence	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	23 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.1)
Insomnia	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Anxiety	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Depression	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dysuria	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pollakiuria	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	10 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Pelvic pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ovarian cyst	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysmenorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	59 (0.3)	(0.2, 0.4)	54 (0.2)	(0.2, 0.3)
Oropharyngeal pain	15 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Cough	10 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Nasal congestion	10 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Rhinorrhoea	10 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspnoea	2 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Productive cough	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Rhinitis allergic	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epistaxis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	61 (0.3)	(0.2, 0.4)	45 (0.2)	(0.2, 0.3)
Rash	14 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Pruritus	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Hyperhidrosis	10 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Urticaria	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Dermatitis contact	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Rash pruritic	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis allergic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
UNCODED TERM	13 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
L ARM SITE INJECTION PAIN@@	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FATIGUE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FEVER@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEAT AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
KIDNEY STONE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L ARM - SITE INJECTION PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L OPEN HEAVINESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LETHARGY@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NECK PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	16 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Hypertension	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hot flush	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Haematoma	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Flushing	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.423. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut 7d1 p23 saf

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3295 (16.1)	(15.6, 16.6)	686 (3.4)	(3.1, 3.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	49 (0.2)	(0.2, 0.3)	6 (0.0)	(0.0, 0.1)
Lymphadenopathy	46 (0.2)	(0.2, 0.3)	3 (0.0)	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	22 (0.1)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=20443) n[b] (%)	(95% CI[c])	Placebo (N[a]=20409) n[b] (%)	(95% CI[c])
Tachycardia	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	17 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Vertigo	8 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tinnitus	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Ear pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo positional	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear discomfort	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypothyroidism	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	16 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Vision blurred	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Eye irritation	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=20443) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=20409) n[b] (%)	 (95% CI[c])
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	291 (1.4)	(1.3, 1.6)	97 (0.5)	(0.4, 0.6)
Nausea	170 (0.8)	(0.7, 1.0)	19 (0.1)	(0.1, 0.1)
Diarrhoea	88 (0.4)	(0.3, 0.5)	51 (0.2)	(0.2, 0.3)
Vomiting	35 (0.2)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Abdominal pain	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal pain upper	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dyspepsia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Toothache	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Aphthous ulcer	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Odynophagia	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dental caries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=20443) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=20409) n[b] (%)	 (95% CI[c])
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2721 (13.3)	(12.8, 13.8)	321 (1.6)	(1.4, 1.8)
Injection site pain	1233 (6.0)	(5.7, 6.4)	125 (0.6)	(0.5, 0.7)
Pyrexia	1080 (5.3)	(5.0, 5.6)	28 (0.1)	(0.1, 0.2)
Chills	927 (4.5)	(4.3, 4.8)	41 (0.2)	(0.1, 0.3)
Fatigue	823 (4.0)	(3.8, 4.3)	129 (0.6)	(0.5, 0.8)
Pain	410 (2.0)	(1.8, 2.2)	17 (0.1)	(0.0, 0.1)
Injection site erythema	84 (0.4)	(0.3, 0.5)	9 (0.0)	(0.0, 0.1)
Malaise	65 (0.3)	(0.2, 0.4)	8 (0.0)	(0.0, 0.1)
Injection site swelling	58 (0.3)	(0.2, 0.4)	6 (0.0)	(0.0, 0.1)
Asthenia	45 (0.2)	(0.2, 0.3)	9 (0.0)	(0.0, 0.1)
Injection site pruritus	17 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Influenza like illness	16 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vaccination site pain	11 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site warmth	9 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site bruising	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Axillary pain	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Feeling hot	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site induration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site oedema	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chest discomfort	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholelithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
IMMUNE SYSTEM DISORDERS	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Immunisation reaction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	36 (0.2)	(0.1, 0.2)	42 (0.2)	(0.1, 0.3)
Urinary tract infection	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tooth infection	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rhinitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ear infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hordeolum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vulvovaginal candidiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Folliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	26 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.1)
Fall	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Joint dislocation	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Muscle strain	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Procedural pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibula fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Limb injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination complication	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin abrasion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	81 (0.4)	(0.3, 0.5)	7 (0.0)	(0.0, 0.1)
Body temperature increased	63 (0.3)	(0.2, 0.4)	5 (0.0)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	32 (0.2)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Decreased appetite	24 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin D deficiency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyslipidaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	980 (4.8)	(4.5, 5.1)	101 (0.5)	(0.4, 0.6)
Myalgia	774 (3.8)	(3.5, 4.1)	51 (0.2)	(0.2, 0.3)
Arthralgia	136 (0.7)	(0.6, 0.8)	17 (0.1)	(0.0, 0.1)
Pain in extremity	80 (0.4)	(0.3, 0.5)	9 (0.0)	(0.0, 0.1)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Back pain	24 (0.1)	(0.1, 0.2)	13 (0.1)	(0.0, 0.1)
Neck pain	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Musculoskeletal stiffness	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Muscle spasms	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint stiffness	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscular weakness	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bone pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exostosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	843 (4.1)	(3.9, 4.4)	147 (0.7)	(0.6, 0.8)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Headache	768 (3.8)	(3.5, 4.0)	108 (0.5)	(0.4, 0.6)
Dizziness	34 (0.2)	(0.1, 0.2)	13 (0.1)	(0.0, 0.1)
Lethargy	15 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Paraesthesia	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Migraine	9 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Somnolence	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Dysgeusia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Hyperaesthesia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tremor	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus headache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	21 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.1)
Insomnia	11 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Anxiety	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Depression	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysuria	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pollakiuria	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	46 (0.2)	(0.2, 0.3)	23 (0.1)	(0.1, 0.2)
Oropharyngeal pain	13 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Nasal congestion	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cough	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=20443) n[b] (%)	(95% CI[c])	Placebo (N[a]=20409) n[b] (%)	(95% CI[c])
Rhinorrhoea	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Dyspnoea	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Asthma	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus congestion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Throat irritation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	73 (0.4)	(0.3, 0.4)	30 (0.1)	(0.1, 0.2)
Rash	15 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Hyperhidrosis	14 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Night sweats	12 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pruritus	10 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erythema	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blister	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eczema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urticaria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rosacea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	16 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
FEVER@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CHILLS@@	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED TEMPERATURE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.424. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=20443)		Placebo (N[a]=20409)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	14 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Flushing	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hot flush	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
Note: Only subjects who received Dose 2 are included in the table.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_7d2_p23_saf

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1877 (14.8)	(14.2, 15.4)	682 (5.3)	(5.0, 5.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	13 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	13 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tachycardia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vertigo	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tinnitus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypothyroidism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	12 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Eye irritation	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	131 (1.0)	(0.9, 1.2)	112 (0.9)	(0.7, 1.1)
Diarrhoea	65 (0.5)	(0.4, 0.7)	62 (0.5)	(0.4, 0.6)
Nausea	40 (0.3)	(0.2, 0.4)	27 (0.2)	(0.1, 0.3)
Vomiting	11 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.1)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal pain upper	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abdominal pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Constipation	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspepsia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Toothache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphthous ulcer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental caries	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1514 (11.9)	(11.4, 12.5)	344 (2.7)	(2.4, 3.0)
Injection site pain	1166 (9.2)	(8.7, 9.7)	147 (1.2)	(1.0, 1.4)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fatigue	319 (2.5)	(2.2, 2.8)	126 (1.0)	(0.8, 1.2)
Chills	177 (1.4)	(1.2, 1.6)	36 (0.3)	(0.2, 0.4)
Pyrexia	185 (1.5)	(1.3, 1.7)	24 (0.2)	(0.1, 0.3)
Pain	81 (0.6)	(0.5, 0.8)	12 (0.1)	(0.0, 0.2)
Injection site erythema	47 (0.4)	(0.3, 0.5)	9 (0.1)	(0.0, 0.1)
Injection site swelling	36 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Malaise	32 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Asthenia	13 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Vaccination site pain	10 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site bruising	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Injection site pruritus	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site oedema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site warmth	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Influenza like illness	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oedema peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	25 (0.2)	(0.1, 0.3)	41 (0.3)	(0.2, 0.4)
Urinary tract infection	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinusitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tooth infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ear infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cellulitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hordeolum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis externa	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute sinusitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oral herpes	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodontitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	20 (0.2)	(0.1, 0.2)	17 (0.1)	(0.1, 0.2)
Fall	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Contusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle strain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Meniscus injury	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Radius fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thermal burn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	21 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.1)
Body temperature increased	17 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Colonoscopy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endoscopy upper gastrointestinal tract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	15 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Decreased appetite	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperlipidaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin D deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	323 (2.5)	(2.3, 2.8)	89 (0.7)	(0.6, 0.9)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myalgia	216 (1.7)	(1.5, 1.9)	49 (0.4)	(0.3, 0.5)
Pain in extremity	53 (0.4)	(0.3, 0.5)	3 (0.0)	(0.0, 0.1)
Arthralgia	46 (0.4)	(0.3, 0.5)	18 (0.1)	(0.1, 0.2)
Back pain	13 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Muscle spasms	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Neck pain	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendonitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	315 (2.5)	(2.2, 2.8)	150 (1.2)	(1.0, 1.4)
Headache	278 (2.2)	(1.9, 2.5)	119 (0.9)	(0.8, 1.1)
Dizziness	9 (0.1)	(0.0, 0.1)	16 (0.1)	(0.1, 0.2)
Paraesthesia	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lethargy	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Migraine	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	19 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.1)
Insomnia	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pollakiuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Haematuria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12756) n[b] (%)	 (95% CI[c])
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysmenorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	32 (0.3)	(0.2, 0.4)	37 (0.3)	(0.2, 0.4)
Oropharyngeal pain	9 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Cough	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Nasal congestion	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Rhinorrhoea	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyspnoea	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Throat irritation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Asthma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rhinitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	29 (0.2)	(0.2, 0.3)	30 (0.2)	(0.2, 0.3)
Rash	6 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Pruritus	1 (0.0)	(0.0, 0.0)	10 (0.1)	(0.0, 0.1)
Hyperhidrosis	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urticaria	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash pruritic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis allergic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Polypectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	8 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
HEADACHE@@	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
CORONARY ARTERY DISEASE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED LOW-DENSITY LIPOPROTEIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
FEVER@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
KIDNEY STONE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L ARM - SITE INJECTION PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LETHARGY@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NECK PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.425. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
POSITIVE HERPES SIMPLEX VIRUS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	7 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hot flush	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Haematoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut 7d1 p23 age saf

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	958 (10.7)	(10.1, 11.4)	348 (3.9)	(3.5, 4.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenopathy	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	9 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Vertigo	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tinnitus	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	4 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cataract	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vision blurred	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	76 (0.9)	(0.7, 1.1)	50 (0.6)	(0.4, 0.7)
Diarrhoea	40 (0.4)	(0.3, 0.6)	26 (0.3)	(0.2, 0.4)
Nausea	18 (0.2)	(0.1, 0.3)	15 (0.2)	(0.1, 0.3)
Vomiting	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspepsia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Toothache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental caries	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Colitis microscopic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	701 (7.9)	(7.3, 8.4)	144 (1.6)	(1.4, 1.9)
Injection site pain	560 (6.3)	(5.8, 6.8)	59 (0.7)	(0.5, 0.9)
Fatigue	128 (1.4)	(1.2, 1.7)	46 (0.5)	(0.4, 0.7)
Chills	50 (0.6)	(0.4, 0.7)	17 (0.2)	(0.1, 0.3)
Pyrexia	48 (0.5)	(0.4, 0.7)	5 (0.1)	(0.0, 0.1)
Pain	34 (0.4)	(0.3, 0.5)	8 (0.1)	(0.0, 0.2)
Injection site erythema	26 (0.3)	(0.2, 0.4)	3 (0.0)	(0.0, 0.1)
Injection site swelling	23 (0.3)	(0.2, 0.4)	7 (0.1)	(0.0, 0.2)
Malaise	12 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Asthenia	10 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Vaccination site pain	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site bruising	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site pruritus	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	25 (0.3)	(0.2, 0.4)	25 (0.3)	(0.2, 0.4)
Urinary tract infection	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sinusitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth infection	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctivitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hordeolum	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis externa	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tooth abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye infection bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Onychomycosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	12 (0.1)	(0.1, 0.2)	24 (0.3)	(0.2, 0.4)
Fall	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Contusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle strain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthropod bite	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Ligament sprain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthropod sting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Limb injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Radius fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin abrasion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Wound	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	18 (0.2)	(0.1, 0.3)	3 (0.0)	(0.0, 0.1)
Body temperature increased	13 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Blood pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emergency care examination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostatic specific antigen increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	4 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Decreased appetite	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dehydration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	148 (1.7)	(1.4, 1.9)	66 (0.7)	(0.6, 0.9)
Myalgia	74 (0.8)	(0.7, 1.0)	22 (0.2)	(0.2, 0.4)
Pain in extremity	40 (0.4)	(0.3, 0.6)	7 (0.1)	(0.0, 0.2)
Arthralgia	16 (0.2)	(0.1, 0.3)	18 (0.2)	(0.1, 0.3)
Back pain	7 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Muscle spasms	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Neck pain	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bursitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	129 (1.4)	(1.2, 1.7)	70 (0.8)	(0.6, 1.0)
Headache	104 (1.2)	(1.0, 1.4)	53 (0.6)	(0.4, 0.8)
Dizziness	8 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Paraesthesia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lethargy	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Somnolence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tremor	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Insomnia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Anxiety	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dysuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	27 (0.3)	(0.2, 0.4)	17 (0.2)	(0.1, 0.3)
Oropharyngeal pain	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Cough	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nasal congestion	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinorrhoea	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epistaxis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sneezing	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	32 (0.4)	(0.2, 0.5)	15 (0.2)	(0.1, 0.3)
Rash	8 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Pruritus	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperhidrosis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urticaria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rash pruritic	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angioedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urticaria chronic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
L ARM SITE INJECTION PAIN@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEAT AT INJECTION SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
L OPEN HEAVINESS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.426. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
VASCULAR DISORDERS	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Hypertension	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut 7d1 p23 age saf

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2116 (17.9)	(17.2, 18.6)	418 (3.5)	(3.2, 3.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	43 (0.4)	(0.3, 0.5)	2 (0.0)	(0.0, 0.1)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lymphadenopathy	40 (0.3)	(0.2, 0.5)	1 (0.0)	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	12 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Tachycardia	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	9 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Vertigo	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tinnitus	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Ear pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypothyroidism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	11 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye irritation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	178 (1.5)	(1.3, 1.7)	66 (0.6)	(0.4, 0.7)
Nausea	111 (0.9)	(0.8, 1.1)	15 (0.1)	(0.1, 0.2)
Diarrhoea	46 (0.4)	(0.3, 0.5)	32 (0.3)	(0.2, 0.4)
Vomiting	27 (0.2)	(0.2, 0.3)	2 (0.0)	(0.0, 0.1)
Abdominal pain	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Abdominal pain upper	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyspepsia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Toothache	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Odynophagia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain lower	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental caries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1770 (15.0)	(14.3, 15.6)	206 (1.7)	(1.5, 2.0)
Injection site pain	766 (6.5)	(6.0, 6.9)	83 (0.7)	(0.6, 0.9)
Pyrexia	759 (6.4)	(6.0, 6.9)	16 (0.1)	(0.1, 0.2)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chills	634 (5.4)	(5.0, 5.8)	24 (0.2)	(0.1, 0.3)
Fatigue	541 (4.6)	(4.2, 5.0)	86 (0.7)	(0.6, 0.9)
Pain	272 (2.3)	(2.0, 2.6)	11 (0.1)	(0.0, 0.2)
Injection site erythema	52 (0.4)	(0.3, 0.6)	5 (0.0)	(0.0, 0.1)
Malaise	35 (0.3)	(0.2, 0.4)	3 (0.0)	(0.0, 0.1)
Injection site swelling	30 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Asthenia	28 (0.2)	(0.2, 0.3)	6 (0.1)	(0.0, 0.1)
Injection site pruritus	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaccination site pain	6 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site bruising	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Axillary pain	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site oedema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oedema peripheral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling face	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Immunisation reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	21 (0.2)	(0.1, 0.3)	26 (0.2)	(0.1, 0.3)
Urinary tract infection	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth infection	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Rhinitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Herpes zoster	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ear infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hordeolum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Folliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11 (0.1)	(0.0, 0.2)	10 (0.1)	(0.0, 0.2)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	51 (0.4)	(0.3, 0.6)	5 (0.0)	(0.0, 0.1)
Body temperature increased	42 (0.4)	(0.3, 0.5)	4 (0.0)	(0.0, 0.1)
Blood pressure increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	19 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.1)
Decreased appetite	15 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vitamin D deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyslipidaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	660 (5.6)	(5.2, 6.0)	57 (0.5)	(0.4, 0.6)
Myalgia	530 (4.5)	(4.1, 4.9)	30 (0.3)	(0.2, 0.4)
Arthralgia	86 (0.7)	(0.6, 0.9)	10 (0.1)	(0.0, 0.2)
Pain in extremity	46 (0.4)	(0.3, 0.5)	6 (0.1)	(0.0, 0.1)
Back pain	15 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Neck pain	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costochondritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	537 (4.5)	(4.2, 4.9)	93 (0.8)	(0.6, 1.0)
Headache	495 (4.2)	(3.8, 4.6)	68 (0.6)	(0.4, 0.7)
Dizziness	17 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Lethargy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Paraesthesia	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Migraine	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Somnolence	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dysgeusia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nerve compression	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	10 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Insomnia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Anxiety	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematuria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	30 (0.3)	(0.2, 0.4)	16 (0.1)	(0.1, 0.2)
Oropharyngeal pain	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Nasal congestion	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cough	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinorrhoea	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Throat irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Epistaxis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	41 (0.3)	(0.2, 0.5)	14 (0.1)	(0.1, 0.2)
Rash	10 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Hyperhidrosis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Night sweats	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pruritus	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	12 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
DIVERTICULITIS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED TEMPERATURE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.427. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11839)		Placebo (N[a]=11859)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE SORENESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MYALGIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VOMITING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	9 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hot flush	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
Note: Only subjects who received Dose 2 are included in the table.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_7d2_p23_age_saf

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1179 (13.7)	(13.0, 14.4)	268 (3.1)	(2.8, 3.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	6 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Lymphadenopathy	6 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	10 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Tachycardia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	8 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Vertigo	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tinnitus	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo positional	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	113 (1.3)	(1.1, 1.6)	31 (0.4)	(0.2, 0.5)
Nausea	59 (0.7)	(0.5, 0.9)	4 (0.0)	(0.0, 0.1)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diarrhoea	42 (0.5)	(0.4, 0.7)	19 (0.2)	(0.1, 0.3)
Vomiting	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toothache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	951 (11.1)	(10.4, 11.7)	115 (1.3)	(1.1, 1.6)
Injection site pain	467 (5.4)	(5.0, 5.9)	42 (0.5)	(0.4, 0.7)
Pyrexia	321 (3.7)	(3.3, 4.2)	12 (0.1)	(0.1, 0.2)
Chills	293 (3.4)	(3.0, 3.8)	17 (0.2)	(0.1, 0.3)
Fatigue	282 (3.3)	(2.9, 3.7)	43 (0.5)	(0.4, 0.7)
Pain	138 (1.6)	(1.3, 1.9)	6 (0.1)	(0.0, 0.2)
Injection site erythema	32 (0.4)	(0.3, 0.5)	4 (0.0)	(0.0, 0.1)
Malaise	30 (0.3)	(0.2, 0.5)	5 (0.1)	(0.0, 0.1)
Injection site swelling	28 (0.3)	(0.2, 0.5)	2 (0.0)	(0.0, 0.1)
Asthenia	17 (0.2)	(0.1, 0.3)	3 (0.0)	(0.0, 0.1)
Injection site pruritus	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Vaccination site pain	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site bruising	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Axillary pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oedema peripheral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholelithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Seasonal allergy	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Immunisation reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	15 (0.2)	(0.1, 0.3)	16 (0.2)	(0.1, 0.3)
Urinary tract infection	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tooth infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sinusitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Herpes zoster	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parotitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pneumonia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Furuncle	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15 (0.2)	(0.1, 0.3)	9 (0.1)	(0.0, 0.2)
Fall	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint dislocation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meniscus injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscle strain	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tooth fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibula fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb injury	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaccination complication	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthropod bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin abrasion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	30 (0.3)	(0.2, 0.5)	2 (0.0)	(0.0, 0.1)
Body temperature increased	21 (0.2)	(0.2, 0.4)	1 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Heart rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	13 (0.2)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)
Decreased appetite	9 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	320 (3.7)	(3.3, 4.1)	44 (0.5)	(0.4, 0.7)
Myalgia	244 (2.8)	(2.5, 3.2)	21 (0.2)	(0.2, 0.4)
Arthralgia	50 (0.6)	(0.4, 0.8)	7 (0.1)	(0.0, 0.2)
Pain in extremity	34 (0.4)	(0.3, 0.6)	3 (0.0)	(0.0, 0.1)
Back pain	9 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Neck pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle spasms	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Exostosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mobility decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	306 (3.6)	(3.2, 4.0)	54 (0.6)	(0.5, 0.8)
Headache	273 (3.2)	(2.8, 3.6)	40 (0.5)	(0.3, 0.6)
Dizziness	17 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Lethargy	13 (0.2)	(0.1, 0.3)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Migraine	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Somnolence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysgeusia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tremor	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine with aura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus headache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	11 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.2)
Insomnia	7 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Depression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Dysuria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	16 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Oropharyngeal pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nasal congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinorrhoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspnoea	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Throat irritation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	32 (0.4)	(0.3, 0.5)	16 (0.2)	(0.1, 0.3)
Rash	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hyperhidrosis	9 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Night sweats	6 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Pruritus	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eczema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rosacea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FUNGUS, TOES, RIGHT (SKIN OF TOES)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
FUNGUS, TOES, RIGHT (TOENAILS)@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL CALCULUS, WORSENING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Hypertension	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.428. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2 (as of Data Cutoff Date of 14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8604)		Placebo (N[a]=8550)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
Note: Only subjects who received Dose 2 are included in the table.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:30)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_7d2_p23_age_saf

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3915 (20.8)	(20.2, 21.4)	953 (5.1)	(4.8, 5.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	50 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Lymphadenopathy	47 (0.2)	(0.2, 0.3)	4 (0.0)	(0.0, 0.1)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	11 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Tachycardia	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vertigo	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Ear pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	14 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Eye pain	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye irritation	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	352 (1.9)	(1.7, 2.1)	155 (0.8)	(0.7, 1.0)
Diarrhoea	144 (0.8)	(0.6, 0.9)	95 (0.5)	(0.4, 0.6)
Nausea	189 (1.0)	(0.9, 1.2)	39 (0.2)	(0.1, 0.3)
Vomiting	33 (0.2)	(0.1, 0.2)	10 (0.1)	(0.0, 0.1)
Abdominal pain	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Abdominal pain upper	10 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dyspepsia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal discomfort	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Aphthous ulcer	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toothache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3426 (18.2)	(17.7, 18.8)	628 (3.3)	(3.1, 3.6)
Injection site pain	2106 (11.2)	(10.8, 11.7)	275 (1.5)	(1.3, 1.6)
Fatigue	1001 (5.3)	(5.0, 5.7)	233 (1.2)	(1.1, 1.4)
Pyrexia	1133 (6.0)	(5.7, 6.4)	50 (0.3)	(0.2, 0.4)
Chills	992 (5.3)	(5.0, 5.6)	75 (0.4)	(0.3, 0.5)
Pain	451 (2.4)	(2.2, 2.6)	28 (0.1)	(0.1, 0.2)
Injection site erythema	138 (0.7)	(0.6, 0.9)	17 (0.1)	(0.1, 0.1)
Injection site swelling	92 (0.5)	(0.4, 0.6)	16 (0.1)	(0.0, 0.1)
Malaise	95 (0.5)	(0.4, 0.6)	10 (0.1)	(0.0, 0.1)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Asthenia	56 (0.3)	(0.2, 0.4)	11 (0.1)	(0.0, 0.1)
Injection site pruritus	27 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Influenza like illness	20 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.0)
Injection site bruising	10 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Vaccination site pain	13 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site induration	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site oedema	8 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary pain	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rhinitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaccination complication	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	92 (0.5)	(0.4, 0.6)	9 (0.0)	(0.0, 0.1)
Body temperature increased	84 (0.4)	(0.4, 0.6)	6 (0.0)	(0.0, 0.1)
Heart rate increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	30 (0.2)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Decreased appetite	27 (0.1)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gout	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1148 (6.1)	(5.8, 6.5)	150 (0.8)	(0.7, 0.9)
Myalgia	880 (4.7)	(4.4, 5.0)	106 (0.6)	(0.5, 0.7)
Arthralgia	156 (0.8)	(0.7, 1.0)	25 (0.1)	(0.1, 0.2)
Pain in extremity	143 (0.8)	(0.6, 0.9)	11 (0.1)	(0.0, 0.1)
Back pain	22 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	10 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscle spasms	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Neck pain	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Muscular weakness	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendonitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bone pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	979 (5.2)	(4.9, 5.5)	257 (1.4)	(1.2, 1.5)
Headache	902 (4.8)	(4.5, 5.1)	215 (1.1)	(1.0, 1.3)
Dizziness	36 (0.2)	(0.1, 0.3)	23 (0.1)	(0.1, 0.2)
Lethargy	21 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Paraesthesia	7 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Somnolence	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysgeusia	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Migraine	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tremor	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Presyncope	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus headache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	27 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Insomnia	16 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anxiety	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Irritability	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	46 (0.2)	(0.2, 0.3)	30 (0.2)	(0.1, 0.2)
Oropharyngeal pain	14 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Nasal congestion	10 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Rhinorrhoea	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cough	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Throat irritation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	84 (0.4)	(0.4, 0.6)	35 (0.2)	(0.1, 0.3)
Rash	17 (0.1)	(0.1, 0.1)	11 (0.1)	(0.0, 0.1)
Hyperhidrosis	20 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Night sweats	14 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pruritus	6 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Urticaria	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	15 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
FEVER@@	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	10 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Hot flush	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Flushing	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.429. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_rel_p3_saf

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2551 (23.5)	(22.7, 24.3)	622 (5.7)	(5.3, 6.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	43 (0.4)	(0.3, 0.5)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	40 (0.4)	(0.3, 0.5)	2 (0.0)	(0.0, 0.1)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tachycardia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Palpitations	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vertigo	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vertigo positional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	10 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Eye pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye irritation	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lacrimation increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	220 (2.0)	(1.8, 2.3)	101 (0.9)	(0.8, 1.1)
Diarrhoea	84 (0.8)	(0.6, 1.0)	65 (0.6)	(0.5, 0.8)
Nausea	123 (1.1)	(0.9, 1.4)	25 (0.2)	(0.1, 0.3)
Vomiting	24 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Abdominal pain upper	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspepsia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Odynophagia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2247 (20.7)	(20.0, 21.5)	421 (3.9)	(3.5, 4.3)
Injection site pain	1356 (12.5)	(11.9, 13.1)	188 (1.7)	(1.5, 2.0)
Fatigue	672 (6.2)	(5.8, 6.7)	162 (1.5)	(1.3, 1.7)
Pyrexia	812 (7.5)	(7.0, 8.0)	35 (0.3)	(0.2, 0.4)
Chills	692 (6.4)	(5.9, 6.9)	49 (0.5)	(0.3, 0.6)
Pain	305 (2.8)	(2.5, 3.1)	19 (0.2)	(0.1, 0.3)
Injection site erythema	87 (0.8)	(0.6, 1.0)	12 (0.1)	(0.1, 0.2)
Injection site swelling	52 (0.5)	(0.4, 0.6)	8 (0.1)	(0.0, 0.1)
Malaise	59 (0.5)	(0.4, 0.7)	4 (0.0)	(0.0, 0.1)
Asthenia	31 (0.3)	(0.2, 0.4)	7 (0.1)	(0.0, 0.1)
Injection site pruritus	15 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Influenza like illness	12 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Injection site bruising	7 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Vaccination site pain	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Axillary pain	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Application site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaccination site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Immunisation reaction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rhinitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	10 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	60 (0.6)	(0.4, 0.7)	8 (0.1)	(0.0, 0.1)
Body temperature increased	55 (0.5)	(0.4, 0.7)	6 (0.1)	(0.0, 0.1)
Heart rate increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Weight decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	23 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Decreased appetite	21 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gout	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	781 (7.2)	(6.7, 7.7)	91 (0.8)	(0.7, 1.0)
Myalgia	612 (5.6)	(5.2, 6.1)	69 (0.6)	(0.5, 0.8)
Arthralgia	102 (0.9)	(0.8, 1.1)	15 (0.1)	(0.1, 0.2)
Pain in extremity	82 (0.8)	(0.6, 0.9)	4 (0.0)	(0.0, 0.1)
Back pain	16 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle spasms	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neck pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscular weakness	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendonitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle tightness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	643 (5.9)	(5.5, 6.4)	172 (1.6)	(1.4, 1.8)
Headache	600 (5.5)	(5.1, 6.0)	145 (1.3)	(1.1, 1.6)
Dizziness	19 (0.2)	(0.1, 0.3)	13 (0.1)	(0.1, 0.2)
Lethargy	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Paraesthesia	6 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysgeusia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Migraine	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tremor	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ageusia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tension headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental impairment	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	16 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Insomnia	10 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anxiety	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Menorrhagia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	27 (0.2)	(0.2, 0.4)	20 (0.2)	(0.1, 0.3)
Oropharyngeal pain	9 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Nasal congestion	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Rhinorrhoea	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cough	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Asthma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nasal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	49 (0.5)	(0.3, 0.6)	20 (0.2)	(0.1, 0.3)
Rash	13 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Hyperhidrosis	11 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Urticaria	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rash pruritic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alopecia areata	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	10 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.430. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	6 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hot flush	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 rel age p3 saf

14.431. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1364 (17.1)	(16.3, 18.0)	331 (4.2)	(3.7, 4.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	7 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	4 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Tachycardia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	6 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Vertigo	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	132 (1.7)	(1.4, 2.0)	54 (0.7)	(0.5, 0.9)
Diarrhoea	60 (0.8)	(0.6, 1.0)	30 (0.4)	(0.3, 0.5)
Nausea	66 (0.8)	(0.6, 1.1)	14 (0.2)	(0.1, 0.3)
Vomiting	9 (0.1)	(0.1, 0.2)	4 (0.1)	(0.0, 0.1)
Abdominal pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspepsia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry mouth	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.431. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toothache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1179 (14.8)	(14.0, 15.6)	207 (2.6)	(2.3, 3.0)
Injection site pain	750 (9.4)	(8.8, 10.1)	87 (1.1)	(0.9, 1.4)
Fatigue	329 (4.1)	(3.7, 4.6)	71 (0.9)	(0.7, 1.1)
Pyrexia	321 (4.0)	(3.6, 4.5)	15 (0.2)	(0.1, 0.3)
Chills	300 (3.8)	(3.4, 4.2)	26 (0.3)	(0.2, 0.5)
Pain	146 (1.8)	(1.6, 2.2)	9 (0.1)	(0.1, 0.2)
Injection site erythema	51 (0.6)	(0.5, 0.8)	5 (0.1)	(0.0, 0.1)
Injection site swelling	40 (0.5)	(0.4, 0.7)	8 (0.1)	(0.0, 0.2)
Malaise	36 (0.5)	(0.3, 0.6)	6 (0.1)	(0.0, 0.2)
Asthenia	25 (0.3)	(0.2, 0.5)	4 (0.1)	(0.0, 0.1)
Injection site pruritus	12 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Injection site bruising	3 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Vaccination site pain	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	4 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.431. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Immunisation reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Influenza	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination complication	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	32 (0.4)	(0.3, 0.6)	1 (0.0)	(0.0, 0.1)
Body temperature increased	29 (0.4)	(0.2, 0.5)	0	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Decreased appetite	6 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	367 (4.6)	(4.2, 5.1)	59 (0.7)	(0.6, 1.0)
Myalgia	268 (3.4)	(3.0, 3.8)	37 (0.5)	(0.3, 0.6)
Arthralgia	54 (0.7)	(0.5, 0.9)	10 (0.1)	(0.1, 0.2)
Pain in extremity	61 (0.8)	(0.6, 1.0)	7 (0.1)	(0.0, 0.2)
Back pain	6 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Muscle spasms	4 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neck pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.431. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	336 (4.2)	(3.8, 4.7)	85 (1.1)	(0.9, 1.3)
Headache	302 (3.8)	(3.4, 4.2)	70 (0.9)	(0.7, 1.1)
Dizziness	17 (0.2)	(0.1, 0.3)	10 (0.1)	(0.1, 0.2)
Lethargy	15 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Paraesthesia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysgeusia	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Tremor	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Presyncope	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus headache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	11 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Insomnia	6 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.431. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	19 (0.2)	(0.1, 0.4)	10 (0.1)	(0.1, 0.2)
Oropharyngeal pain	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Nasal congestion	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinorrhoea	3 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Cough	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Throat irritation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	35 (0.4)	(0.3, 0.6)	15 (0.2)	(0.1, 0.3)
Rash	4 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hyperhidrosis	9 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Pruritus	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urticaria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.431. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	5 (0.1)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CHILLS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 rel age p3 saf

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4484 (20.7)	(20.2, 21.3)	1095 (5.1)	(4.8, 5.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	53 (0.2)	(0.2, 0.3)	4 (0.0)	(0.0, 0.0)
Lymphadenopathy	50 (0.2)	(0.2, 0.3)	4 (0.0)	(0.0, 0.0)
Lymph node pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	11 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Tachycardia	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	11 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Vertigo	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Ear pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	15 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Eye pain	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye irritation	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	397 (1.8)	(1.7, 2.0)	183 (0.8)	(0.7, 1.0)
Diarrhoea	166 (0.8)	(0.7, 0.9)	113 (0.5)	(0.4, 0.6)
Nausea	211 (1.0)	(0.8, 1.1)	50 (0.2)	(0.2, 0.3)
Vomiting	40 (0.2)	(0.1, 0.3)	13 (0.1)	(0.0, 0.1)
Abdominal pain	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Abdominal pain upper	10 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dyspepsia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal discomfort	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Aphthous ulcer	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retching	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toothache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3924 (18.1)	(17.6, 18.7)	720 (3.3)	(3.1, 3.6)
Injection site pain	2437 (11.3)	(10.9, 11.7)	316 (1.5)	(1.3, 1.6)
Fatigue	1118 (5.2)	(4.9, 5.5)	268 (1.2)	(1.1, 1.4)
Pyrexia	1242 (5.7)	(5.4, 6.1)	57 (0.3)	(0.2, 0.3)
Chills	1103 (5.1)	(4.8, 5.4)	89 (0.4)	(0.3, 0.5)
Pain	502 (2.3)	(2.1, 2.5)	37 (0.2)	(0.1, 0.2)
Injection site erythema	155 (0.7)	(0.6, 0.8)	20 (0.1)	(0.1, 0.1)
Injection site swelling	106 (0.5)	(0.4, 0.6)	19 (0.1)	(0.1, 0.1)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Malaise	103 (0.5)	(0.4, 0.6)	13 (0.1)	(0.0, 0.1)
Asthenia	63 (0.3)	(0.2, 0.4)	11 (0.1)	(0.0, 0.1)
Injection site pruritus	31 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Vaccination site pain	25 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Injection site bruising	11 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Influenza like illness	20 (0.1)	(0.1, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site warmth	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Injection site induration	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Injection site oedema	10 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Axillary pain	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Induration	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaccination site oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Feeling abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rhinitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	16 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaccination complication	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Procedural pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	104 (0.5)	(0.4, 0.6)	12 (0.1)	(0.0, 0.1)
Body temperature increased	95 (0.4)	(0.4, 0.5)	8 (0.0)	(0.0, 0.1)
Heart rate increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	35 (0.2)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Decreased appetite	32 (0.1)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gout	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1261 (5.8)	(5.5, 6.2)	172 (0.8)	(0.7, 0.9)
Myalgia	971 (4.5)	(4.2, 4.8)	120 (0.6)	(0.5, 0.7)
Arthralgia	168 (0.8)	(0.7, 0.9)	30 (0.1)	(0.1, 0.2)
Pain in extremity	160 (0.7)	(0.6, 0.9)	11 (0.1)	(0.0, 0.1)
Back pain	24 (0.1)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscle spasms	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Neck pain	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscular weakness	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendonitis	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint stiffness	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Limb discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1097 (5.1)	(4.8, 5.4)	296 (1.4)	(1.2, 1.5)
Headache	1012 (4.7)	(4.4, 5.0)	249 (1.2)	(1.0, 1.3)
Dizziness	39 (0.2)	(0.1, 0.2)	24 (0.1)	(0.1, 0.2)
Lethargy	21 (0.1)	(0.1, 0.1)	4 (0.0)	(0.0, 0.0)
Paraesthesia	7 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Somnolence	8 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Dysgeusia	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Migraine	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tremor	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Presyncope	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus headache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	29 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Insomnia	17 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Anxiety	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	53 (0.2)	(0.2, 0.3)	39 (0.2)	(0.1, 0.2)
Oropharyngeal pain	14 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nasal congestion	11 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Cough	9 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Rhinorrhoea	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Asthma	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	91 (0.4)	(0.3, 0.5)	39 (0.2)	(0.1, 0.2)
Rash	18 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Hyperhidrosis	22 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Pruritus	8 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Night sweats	15 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urticaria	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Erythema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	26 (0.1)	(0.1, 0.2)	10 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
FEVER@@	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEADACHE@@	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
CHILLS@@	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L ARM SITE INJECTION PAIN@@	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED TEMPERATURE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEAT AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L ARM - SITE INJECTION PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L OPEN HEAVINESS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LETHARGY@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NECK PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.432. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	13 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Hot flush	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Flushing	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut rel all p3 saf

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2961 (23.3)	(22.6, 24.0)	728 (5.7)	(5.3, 6.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	45 (0.4)	(0.3, 0.5)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	42 (0.3)	(0.2, 0.4)	2 (0.0)	(0.0, 0.1)
Lymph node pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tachycardia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vertigo	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	11 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Eye pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye irritation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	255 (2.0)	(1.8, 2.3)	121 (0.9)	(0.8, 1.1)
Diarrhoea	98 (0.8)	(0.6, 0.9)	76 (0.6)	(0.5, 0.7)
Nausea	142 (1.1)	(0.9, 1.3)	34 (0.3)	(0.2, 0.4)
Vomiting	31 (0.2)	(0.2, 0.3)	7 (0.1)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Abdominal pain upper	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dyspepsia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2606 (20.5)	(19.8, 21.2)	491 (3.8)	(3.5, 4.2)
Injection site pain	1596 (12.6)	(12.0, 13.1)	220 (1.7)	(1.5, 2.0)
Fatigue	757 (6.0)	(5.6, 6.4)	193 (1.5)	(1.3, 1.7)
Pyrexia	889 (7.0)	(6.6, 7.5)	42 (0.3)	(0.2, 0.4)
Chills	772 (6.1)	(5.7, 6.5)	57 (0.4)	(0.3, 0.6)
Pain	342 (2.7)	(2.4, 3.0)	25 (0.2)	(0.1, 0.3)
Injection site erythema	98 (0.8)	(0.6, 0.9)	13 (0.1)	(0.1, 0.2)
Injection site swelling	60 (0.5)	(0.4, 0.6)	10 (0.1)	(0.0, 0.1)
Malaise	65 (0.5)	(0.4, 0.7)	5 (0.0)	(0.0, 0.1)
Asthenia	37 (0.3)	(0.2, 0.4)	7 (0.1)	(0.0, 0.1)
Injection site pruritus	17 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Vaccination site pain	16 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Injection site bruising	7 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Influenza like illness	12 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Injection site induration	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Axillary pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Immunisation reaction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rhinitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	68 (0.5)	(0.4, 0.7)	9 (0.1)	(0.0, 0.1)
Body temperature increased	62 (0.5)	(0.4, 0.6)	7 (0.1)	(0.0, 0.1)
Heart rate increased	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	24 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Decreased appetite	22 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gout	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	861 (6.8)	(6.3, 7.2)	107 (0.8)	(0.7, 1.0)
Myalgia	675 (5.3)	(4.9, 5.7)	80 (0.6)	(0.5, 0.8)
Arthralgia	112 (0.9)	(0.7, 1.1)	19 (0.1)	(0.1, 0.2)
Pain in extremity	93 (0.7)	(0.6, 0.9)	4 (0.0)	(0.0, 0.1)

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Back pain	17 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle spasms	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Neck pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscular weakness	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendonitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	729 (5.7)	(5.3, 6.2)	200 (1.6)	(1.4, 1.8)
Headache	680 (5.4)	(5.0, 5.8)	169 (1.3)	(1.1, 1.5)
Dizziness	21 (0.2)	(0.1, 0.3)	14 (0.1)	(0.1, 0.2)
Lethargy	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Paraesthesia	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Dysgeusia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Migraine	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tremor	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ageusia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Disturbance in attention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	16 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Insomnia	10 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	32 (0.3)	(0.2, 0.4)	28 (0.2)	(0.1, 0.3)
Oropharyngeal pain	9 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Nasal congestion	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Cough	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rhinorrhoea	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Throat irritation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	52 (0.4)	(0.3, 0.5)	24 (0.2)	(0.1, 0.3)
Rash	13 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Hyperhidrosis	11 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Pruritus	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Night sweats	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	18 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
INJECTION SITE PAIN@@	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
FEVER@@	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
CHILLS@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.433. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
BOTH UNDERARM LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ELEVATED TEMPERATURE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERALIZED RASH ON BODY@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION AT PAIN SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJECTION SITE PAIN LEFT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INTERMITTENT MUSCLE PAIN LEFT DELTOID@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
L ARM - SITE INJECTION PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LEFT FOREARM HIVES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LETHARGY@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NECK PAIN@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PAIN AT INJECTION SITE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SWOLLEN AXILLARY LYMPH NODE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Hot flush	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Flushing	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut rel age all p3 saf

14.434. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1523 (17.1)	(16.3, 17.9)	367 (4.1)	(3.7, 4.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tachycardia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Vertigo	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo positional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	142 (1.6)	(1.3, 1.9)	62 (0.7)	(0.5, 0.9)
Diarrhoea	68 (0.8)	(0.6, 1.0)	37 (0.4)	(0.3, 0.6)
Nausea	69 (0.8)	(0.6, 1.0)	16 (0.2)	(0.1, 0.3)
Vomiting	9 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Abdominal pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspepsia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dry mouth	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.434. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toothache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1318 (14.8)	(14.1, 15.5)	229 (2.6)	(2.3, 2.9)
Injection site pain	841 (9.4)	(8.8, 10.1)	96 (1.1)	(0.9, 1.3)
Fatigue	361 (4.0)	(3.6, 4.5)	75 (0.8)	(0.7, 1.1)
Pyrexia	353 (4.0)	(3.6, 4.4)	15 (0.2)	(0.1, 0.3)
Chills	331 (3.7)	(3.3, 4.1)	32 (0.4)	(0.2, 0.5)
Pain	160 (1.8)	(1.5, 2.1)	12 (0.1)	(0.1, 0.2)
Injection site erythema	57 (0.6)	(0.5, 0.8)	7 (0.1)	(0.0, 0.2)
Injection site swelling	46 (0.5)	(0.4, 0.7)	9 (0.1)	(0.0, 0.2)
Malaise	38 (0.4)	(0.3, 0.6)	8 (0.1)	(0.0, 0.2)
Asthenia	26 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Injection site pruritus	14 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Vaccination site pain	9 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Injection site bruising	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Injection site warmth	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Induration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.434. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Reactogenicity event	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Immunisation reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Influenza	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination complication	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	36 (0.4)	(0.3, 0.6)	3 (0.0)	(0.0, 0.1)
Body temperature increased	33 (0.4)	(0.3, 0.5)	1 (0.0)	(0.0, 0.1)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar puncture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	11 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.1)
Decreased appetite	10 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	400 (4.5)	(4.1, 4.9)	65 (0.7)	(0.6, 0.9)
Myalgia	296 (3.3)	(3.0, 3.7)	40 (0.5)	(0.3, 0.6)
Arthralgia	56 (0.6)	(0.5, 0.8)	11 (0.1)	(0.1, 0.2)
Pain in extremity	67 (0.8)	(0.6, 1.0)	7 (0.1)	(0.0, 0.2)
Back pain	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)

14.434. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle spasms	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neck pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	368 (4.1)	(3.7, 4.6)	96 (1.1)	(0.9, 1.3)
Headache	332 (3.7)	(3.3, 4.1)	80 (0.9)	(0.7, 1.1)
Dizziness	18 (0.2)	(0.1, 0.3)	10 (0.1)	(0.1, 0.2)
Lethargy	15 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Paraesthesia	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Somnolence	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysgeusia	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tremor	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Presyncope	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus headache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	13 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)

14.434. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Insomnia	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	21 (0.2)	(0.1, 0.4)	11 (0.1)	(0.1, 0.2)
Oropharyngeal pain	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Nasal congestion	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinorrhoea	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Throat irritation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sneezing	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	39 (0.4)	(0.3, 0.6)	15 (0.2)	(0.1, 0.3)
Rash	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hyperhidrosis	11 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Pruritus	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.434. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Night sweats	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Urticaria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	8 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
FEVER@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEADACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CHILLS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
L ARM SITE INJECTION PAIN@@	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
BODY ACHES@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERALIZED JOINT PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEAT AT INJECTION SITE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
L OPEN HEAVINESS@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCLE ACHES@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PAIN IN SITE OF INJECTION RIGHT ARM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RIGHT ARM PAIN WITH MOTION@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SORE LYMPH NODES, NECK, RIGHT@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
TONGUE AND THROAT SWELLING@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.434. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut rel age all p3 saf

14.435. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	78 (0.4)	(0.3, 0.5)	66 (0.4)	(0.3, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Nausea	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	65 (0.3)	(0.3, 0.4)	45 (0.2)	(0.2, 0.3)
Injection site pain	57 (0.3)	(0.2, 0.4)	35 (0.2)	(0.1, 0.3)
Injection site erythema	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fatigue	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pyrexia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site bruising	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site induration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site warmth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pain in extremity	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.435. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=18801) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=18785) n[b] (%)	 (95% CI[c])
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Dizziness	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Headache	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Dysgeusia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Throat irritation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 immd vax1 p3 saf

14.436. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18494)		Placebo (N[a]=18470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	52 (0.3)	(0.2, 0.4)	39 (0.2)	(0.2, 0.3)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Nausea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	43 (0.2)	(0.2, 0.3)	27 (0.1)	(0.1, 0.2)
Injection site pain	35 (0.2)	(0.1, 0.3)	23 (0.1)	(0.1, 0.2)
Pyrexia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chills	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fatigue	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site bruising	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site erythema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myalgia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Dizziness	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Headache	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

14.436. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18494)		Placebo (N[a]=18470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paraesthesia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dysgeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperhidrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
Note: Subjects who did not receive Dose 2 or who received a different vaccine at each dose were excluded from this table.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 immd vax2 p3 saf

14.437. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	101 (0.5)	(0.4, 0.6)	77 (0.4)	(0.3, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Nausea	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	83 (0.4)	(0.3, 0.5)	54 (0.2)	(0.2, 0.3)
Injection site pain	72 (0.3)	(0.3, 0.4)	42 (0.2)	(0.1, 0.3)
Fatigue	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site erythema	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyrexia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chills	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site bruising	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site warmth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.437. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pain in extremity	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	14 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Headache	9 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Dizziness	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Dysgeusia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Throat irritation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
INJECTION SITE PAIN@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
LEFT ARM BLEEDING AT INJECTION SITE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_immd_vax1_all_p3_saf

14.438. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=20433) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=20407) n[b] (%)	 (95% CI[c])
Any event	57 (0.3)	(0.2, 0.4)	46 (0.2)	(0.2, 0.3)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Nausea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	47 (0.2)	(0.2, 0.3)	30 (0.1)	(0.1, 0.2)
Injection site pain	38 (0.2)	(0.1, 0.3)	26 (0.1)	(0.1, 0.2)
Pyrexia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chills	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fatigue	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site bruising	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site erythema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Myalgia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Headache	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)

14.438. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=20433) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=20407) n[b] (%)	 (95% CI[c])
Dizziness	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dysgeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperhidrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
Note: Subjects who did not receive Dose 2 or who received a different vaccine at each dose were excluded from this table.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 immd vax2 all p3 saf

14.439. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	220 (1.2)	(1.0, 1.3)	109 (0.6)	(0.5, 0.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Lymphadenopathy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymph node pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	7 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vertigo	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.439. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	19 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Diarrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Abdominal pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nausea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	79 (0.4)	(0.3, 0.5)	4 (0.0)	(0.0, 0.1)
Pyrexia	30 (0.2)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Fatigue	20 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Injection site pain	17 (0.1)	(0.1, 0.1)	0	(0.0, 0.0)
Chills	13 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site swelling	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malaise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.439. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	20 (0.1)	(0.1, 0.2)	17 (0.1)	(0.1, 0.1)
Appendicitis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Urinary tract infection	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinusitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paronychia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	10 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Fall	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Road traffic accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.439. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Foot fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Joint dislocation	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Blood glucose increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	37 (0.2)	(0.1, 0.3)	11 (0.1)	(0.0, 0.1)

14.439. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myalgia	20 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.0)
Arthralgia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Back pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pain in extremity	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neck pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	37 (0.2)	(0.1, 0.3)	22 (0.1)	(0.1, 0.2)
Headache	23 (0.1)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.439. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinorrhoea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.439. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 sev p3 saf

14.440. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	18 (0.1)	(0.1, 0.2)	20 (0.1)	(0.1, 0.2)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Appendicitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.440. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 life p3 saf

14.441. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	131 (1.2)	(1.0, 1.4)	51 (0.5)	(0.4, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymphadenopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymph node pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	10 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Diarrhoea	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nausea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyspepsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	62 (0.6)	(0.4, 0.7)	3 (0.0)	(0.0, 0.1)
Pyrexia	27 (0.2)	(0.2, 0.4)	1 (0.0)	(0.0, 0.1)
Fatigue	15 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)

14.441. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site pain	12 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Chills	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	10 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.2)
Fall	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Road traffic accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint dislocation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.441. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	27 (0.2)	(0.2, 0.4)	5 (0.0)	(0.0, 0.1)
Myalgia	18 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Arthralgia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Back pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in extremity	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle contracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	19 (0.2)	(0.1, 0.3)	11 (0.1)	(0.1, 0.2)
Headache	13 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.441. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anxiety	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_sev_age_p3_saf

14.442. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	89 (1.1)	(0.9, 1.4)	58 (0.7)	(0.6, 0.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vertigo	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo positional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retinal detachment	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	9 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.1)
Diarrhoea	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.442. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Constipation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	17 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Pyrexia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fatigue	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site pain	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Chills	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malaise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Cholelithiasis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	10 (0.1)	(0.1, 0.2)	13 (0.2)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urinary tract infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinusitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.442. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paronychia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Fall	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Joint dislocation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	10 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.2)
Myalgia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in extremity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bursitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neck pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.442. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	18 (0.2)	(0.1, 0.4)	11 (0.1)	(0.1, 0.2)
Headache	10 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental status changes	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	4 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.442. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Night sweats	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 sev age p3 saf

14.443. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	7 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Appendicitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.443. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 life age p3 saf

14.444. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	11 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
CARDIAC DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Overdose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.444. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event", n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_life_age_p3_saf

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	240 (1.1)	(1.0, 1.3)	139 (0.6)	(0.5, 0.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Anaemia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymph node pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vertigo	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	22 (0.1)	(0.1, 0.2)	18 (0.1)	(0.0, 0.1)
Diarrhoea	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Abdominal pain	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Nausea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	83 (0.4)	(0.3, 0.5)	5 (0.0)	(0.0, 0.1)
Pyrexia	32 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Fatigue	21 (0.1)	(0.1, 0.1)	0	(0.0, 0.0)
Injection site pain	17 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Chills	14 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Chest pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malaise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	21 (0.1)	(0.1, 0.1)	21 (0.1)	(0.1, 0.1)
Appendicitis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Urinary tract infection	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sinusitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paronychia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	10 (0.0)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Fall	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Road traffic accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Joint dislocation	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood glucose increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypoglycaemia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	37 (0.2)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Myalgia	20 (0.1)	(0.1, 0.1)	2 (0.0)	(0.0, 0.0)
Arthralgia	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Back pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pain in extremity	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neck pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	40 (0.2)	(0.1, 0.3)	28 (0.1)	(0.1, 0.2)
Headache	24 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute kidney injury	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinorrhoea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
WORSENING OF DIZZINESS@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.445. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut sev all p3 saf

14.446. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	21 (0.1)	(0.1, 0.1)	24 (0.1)	(0.1, 0.2)
CARDIAC DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Appendicitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.446. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Overdose	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.446. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut life all p3 saf

14.447. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	135 (1.1)	(0.9, 1.3)	67 (0.5)	(0.4, 0.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymph node pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	10 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Diarrhoea	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nausea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.447. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	65 (0.5)	(0.4, 0.7)	3 (0.0)	(0.0, 0.1)
Pyrexia	29 (0.2)	(0.2, 0.3)	1 (0.0)	(0.0, 0.0)
Fatigue	15 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Injection site pain	12 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Chills	9 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	10 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Fall	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.447. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Road traffic accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint dislocation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	27 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.1)
Myalgia	18 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Arthralgia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Back pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pain in extremity	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neck pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.447. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12706) n[b] (%)	(95% CI[c])	Placebo (N[a]=12756) n[b] (%)	(95% CI[c])
Muscle contracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	20 (0.2)	(0.1, 0.2)	16 (0.1)	(0.1, 0.2)
Headache	14 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nephrolithiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.447. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
WORSENING OF DIZZINESS@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut sev age all p3 saf

14.448. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	105 (1.2)	(1.0, 1.4)	72 (0.8)	(0.6, 1.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	7 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vertigo	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo positional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retinal detachment	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	12 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)
Diarrhoea	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vomiting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.448. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	18 (0.2)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)
Pyrexia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fatigue	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site pain	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Chills	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malaise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	11 (0.1)	(0.1, 0.2)	15 (0.2)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urinary tract infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.448. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sinusitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paronychia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Fall	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Joint dislocation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)

14.448. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myalgia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in extremity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neck pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bursitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	20 (0.2)	(0.1, 0.3)	12 (0.1)	(0.1, 0.2)
Headache	10 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.448. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertensive crisis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.448. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut sev age all p3 saf

14.449. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	7 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Appendicitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.449. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut lif age all p3 saf

14.450. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	14 (0.2)	(0.1, 0.3)	14 (0.2)	(0.1, 0.3)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cardiac arrest	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticulitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Overdose	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.450. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut lif age all p3 saf

14.451. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	43 (0.4)	(0.3, 0.5)	32 (0.3)	(0.2, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.451. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INFECTIONS AND INFESTATIONS	12 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.451. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.451. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_age_p3_saf

14.452. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	60 (0.8)	(0.6, 1.0)	49 (0.6)	(0.5, 0.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	8 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	6 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.452. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	13 (0.2)	(0.1, 0.3)	12 (0.2)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Overdose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.452. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.452. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser age p3 saf

14.453. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=545)		Placebo (N[a]=580)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4 (0.7)	(0.2, 1.9)	1 (0.2)	(0.0, 1.0)
INFECTIONS AND INFESTATIONS	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Appendicitis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Overdose	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
Abortion spontaneous incomplete	0	(0.0, 0.7)	1 (0.2)	(0.0, 1.0)
VASCULAR DISORDERS	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.6)
Deep vein thrombosis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)
Arteriosclerosis	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.6)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_bs_p3_saf

14.454. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	97 (0.5)	(0.4, 0.7)	80 (0.4)	(0.4, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	14 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	8 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.454. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	23 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.1)
Appendicitis	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.454. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.454. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	7 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	15 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.454. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.454. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=17841)		Placebo (N[a]=17808)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser bs p3 saf

14.455. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=397)		Placebo (N[a]=429)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (0.5)	(0.1, 1.8)	1 (0.2)	(0.0, 1.3)
INFECTIONS AND INFESTATIONS	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Appendicitis	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
Abortion spontaneous incomplete	0	(0.0, 0.9)	1 (0.2)	(0.0, 1.3)
VASCULAR DISORDERS	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)
Deep vein thrombosis	1 (0.3)	(0.0, 1.4)	0	(0.0, 0.9)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser bsage p3 saf

14.456. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Positive Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=148)		Placebo (N[a]=151)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (1.4)	(0.2, 4.8)	0	(0.0, 2.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Overdose	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
VASCULAR DISORDERS	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)
Arteriosclerosis	1 (0.7)	(0.0, 3.7)	0	(0.0, 2.4)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_bsage_p3_saf

14.457. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	41 (0.4)	(0.3, 0.5)	31 (0.3)	(0.2, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	11 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)

14.457. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Appendicitis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.457. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.457. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10186)		Placebo (N[a]=10187)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser bsage p3 saf

14.458. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	56 (0.7)	(0.6, 0.9)	49 (0.6)	(0.5, 0.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	8 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	6 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.458. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	12 (0.2)	(0.1, 0.3)	12 (0.2)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Cellulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.458. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	10 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.458. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status and Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Baseline SARS-CoV-2 Status: Negative Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7655)		Placebo (N[a]=7621)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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. 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser bsage p3 saf

14.459. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	27 (0.5)	(0.3, 0.7)	21 (0.4)	(0.2, 0.6)
CARDIAC DISORDERS	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Aortic valve incompetence	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oesophageal food impaction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Influenza like illness	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	9 (0.2)	(0.1, 0.3)	4 (0.1)	(0.0, 0.2)
Appendicitis	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Pneumonia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Urosepsis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)
Road traffic accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Foot fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.459. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.2)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Urinary bladder polyp	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pulmonary mass	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
VASCULAR DISORDERS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.459. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=5253)		Placebo (N[a]=5269)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_eth_p3_saf

14.460. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	76 (0.6)	(0.4, 0.7)	60 (0.4)	(0.3, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	10 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.460. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	16 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.1)
Appendicitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cellulitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.460. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.460. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	12 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.460. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=13436)		Placebo (N[a]=13407)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_eth_p3_saf

14.461. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=112)		Placebo (N[a]=109)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 3.2)	0	(0.0, 3.3)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser eth p3 saf

14.462. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	81 (0.5)	(0.4, 0.6)	71 (0.5)	(0.4, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	11 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.462. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	19 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Appendicitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.462. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	7 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)

14.462. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	14 (0.1)	(0.0, 0.2)	12 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.462. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=15615)		Placebo (N[a]=15615)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_race_p3_saf

14.463. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1694)		Placebo (N[a]=1722)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	11 (0.6)	(0.3, 1.2)	9 (0.5)	(0.2, 1.0)
CARDIAC DISORDERS	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Myocardial infarction	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Coronary artery disease	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Obstructive pancreatitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Non-cardiac chest pain	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Bile duct stone	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	2 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.4)
Appendicitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Pneumonia	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Pharyngitis streptococcal	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Road traffic accident	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Toxicity to various agents	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
INVESTIGATIONS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Cardiac stress test abnormal	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Hyperglycaemia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Type 2 diabetes mellitus	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Uterine leiomyoma	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Cerebrovascular accident	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Abortion spontaneous incomplete	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Suicide attempt	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)

14.463. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1694)		Placebo (N[a]=1722)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Pneumonia aspiration	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pulmonary embolism	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Hypoxia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
VASCULAR DISORDERS	3 (0.2)	(0.0, 0.5)	0	(0.0, 0.2)
Deep vein thrombosis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Hypertension	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Hypertensive urgency	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser race p3 saf

14.464. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1492)		Placebo (N[a]=1448)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	11 (0.7)	(0.4, 1.3)	1 (0.1)	(0.0, 0.4)
CARDIAC DISORDERS	2 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.4)
Atrial fibrillation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.4)
Acute myocardial infarction	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Angina pectoris	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Heart disease congenital	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Shoulder injury related to vaccine administration	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	4 (0.3)	(0.1, 0.7)	0	(0.0, 0.3)
Appendicitis	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Urinary tract infection	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Appendicitis perforated	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Pyelonephritis acute	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Facial bones fracture	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Subarachnoid haemorrhage	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)
Breast hyperplasia	1 (0.1)	(0.0, 0.4)	0	(0.0, 0.3)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any 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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 1md2 ser race p3 saf

14.465. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	57 (0.6)	(0.4, 0.8)	43 (0.5)	(0.3, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	10 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.465. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cholelithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	13 (0.1)	(0.1, 0.2)	10 (0.1)	(0.1, 0.2)
Appendicitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Overdose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.465. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	10 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Loss of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.465. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9602)		Placebo (N[a]=9399)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_sex_p3_saf

14.466. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	46 (0.5)	(0.4, 0.7)	38 (0.4)	(0.3, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.466. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	12 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Appendicitis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.466. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.466. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Sex – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9199)		Placebo (N[a]=9386)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_ser_sex_p3_saf

14.467. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	124 (0.7)	(0.5, 0.8)	101 (0.5)	(0.4, 0.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	17 (0.1)	(0.1, 0.1)	15 (0.1)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.467. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GASTROINTESTINAL DISORDERS	10 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Small intestinal obstruction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.467. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INFECTIONS AND INFESTATIONS	27 (0.1)	(0.1, 0.2)	14 (0.1)	(0.0, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.467. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	11 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.467. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	18 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Cerebrovascular accident	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dizziness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)

14.467. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nephrolithiasis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SHORTNESS OF BREATH@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Deep vein thrombosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.467. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=18801)		Placebo (N[a]=18785)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_ser_vax2_p3_saf

14.468. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	47 (0.4)	(0.3, 0.6)	41 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.468. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	13 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hip fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.468. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.468. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_ser_vax2_age_p3_saf

14.469. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	77 (1.0)	(0.8, 1.2)	60 (0.8)	(0.6, 1.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	11 (0.1)	(0.1, 0.2)	9 (0.1)	(0.1, 0.2)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	8 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Small intestinal obstruction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.469. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cholecystitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	14 (0.2)	(0.1, 0.3)	12 (0.2)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.469. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Overdose	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	6 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	13 (0.2)	(0.1, 0.3)	9 (0.1)	(0.1, 0.2)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.469. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	6 (0.1)	(0.0, 0.2)	4 (0.1)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SHORTNESS OF BREATH@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.469. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 ser vax2 age p3 saf

14.470. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9531) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=9536) n[b] (%)	 (95% CI[c])	 Total (N[a]=19067) n[b] (%)	 (95% CI[c])
Any event	57 (0.6)	(0.5, 0.8)	53 (0.6)	(0.4, 0.7)	110 (0.6)	(0.5, 0.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	9 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.470. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	14 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)	23 (0.1)	(0.1, 0.2)
Appendicitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.470. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.470. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.470. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=9531)		Placebo (N[a]=9536)		Total (N[a]=19067)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:28)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc ser 2mpd2 p23 saf

14.471. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	24 (0.4)	(0.3, 0.7)	22 (0.4)	(0.3, 0.6)	46 (0.4)	(0.3, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrioventricular block second degree	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Influenza like illness	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	6 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Appendicitis	4 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal abscess	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.471. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urosepsis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Forearm fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplegia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.471. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5350)		Placebo (N[a]=5377)		Total (N[a]=10727)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urinary bladder polyp	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_soc_ser_2mpd2_age_p23

14.472. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	33 (0.8)	(0.5, 1.1)	31 (0.7)	(0.5, 1.1)	64 (0.8)	(0.6, 1.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	5 (0.1)	(0.0, 0.3)	4 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	3 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	8 (0.2)	(0.1, 0.4)	7 (0.2)	(0.1, 0.3)	15 (0.2)	(0.1, 0.3)
Pneumonia	2 (0.0)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Appendicitis perforated	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.472. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Complicated appendicitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary tract infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Diabetes mellitus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Scleroderma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	4 (0.1)	(0.0, 0.2)	3 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Ischaemic stroke	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Encephalopathy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.472. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Subjects With 2 Months Follow-Up Time After Dose 2 for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=4181)		Placebo (N[a]=4159)		Total (N[a]=8340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.2)	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.0)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hospitalisation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (16:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 soc ser 2mpd2 age p23

14.473. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	47 (0.4)	(0.3, 0.5)	45 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	6 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.473. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	13 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.473. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplegia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retained products of conception	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.473. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UNCODED TERM	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
JAMMED RIGHT INGUINAL HERNIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_sae_all_age_p23_saf

14.474. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Any event	79 (0.9)	(0.7, 1.1)	66 (0.7)	(0.6, 0.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	12 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Small intestinal obstruction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.474. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatic mass	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cholecystitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	14 (0.2)	(0.1, 0.3)	14 (0.2)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diverticulitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.474. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Overdose	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 test positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scleroderma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	13 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.474. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hospitalisation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
BILATERAL PULMONARY EMBOLISM@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SHORTNESS OF BREATH@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.474. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:02)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_sae_all_age_p23_saf

14.475. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	19 (0.2)	(0.1, 0.3)	15 (0.1)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fatigue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.475. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=10841)		Placebo (N[a]=10851)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain in extremity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anxiety	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (05:57)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_wd_age_p3_saf

14.476. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	15 (0.2)	(0.1, 0.3)	10 (0.1)	(0.1, 0.2)
CARDIAC DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	4 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diarrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chills	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Headache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.476. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – ~38000 Subjects for Phase 2/3 Analysis – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=7960)		Placebo (N[a]=7934)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Syncope	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Night sweats	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (05:57)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_1md2_wd_age_p3_saf

14.477. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21621)		Placebo (N[a]=21631)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	37 (0.2)	(0.1, 0.2)	30 (0.1)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Fatigue	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chills	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.477. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Exposure during pregnancy	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.477. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term – Phase 2/3 (All Subjects) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21621) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=21631) n[b] (%)	 (95% CI[c])
Depression	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
FATIGUE@@	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut wd all p3 saf

14.478. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	20 (0.2)	(0.1, 0.2)	18 (0.1)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Unevaluable event	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergy to vaccine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Exposure during pregnancy	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.478. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12706)		Placebo (N[a]=12756)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
UNCODED TERM	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
UPPER BODYRASH DUE TO VACCINE@@	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_s130_cut_wd_age_all_p3_saf

14.479. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8915)		Placebo (N[a]=8875)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	17 (0.2)	(0.1, 0.3)	12 (0.1)	(0.1, 0.2)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Diarrhoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chills	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Headache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

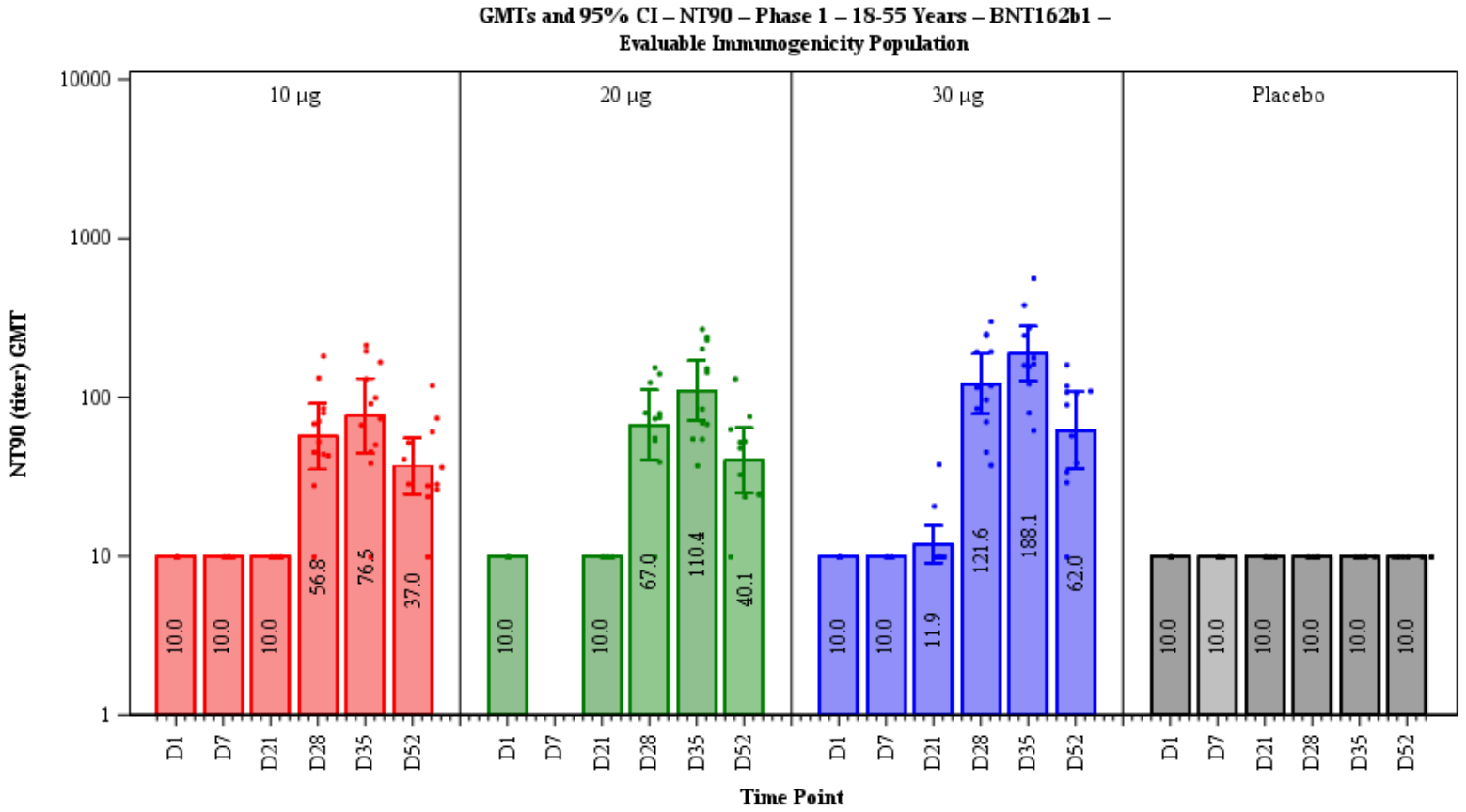
14.479. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to Data Cutoff Date (14NOV2020), by System Organ Class and Preferred Term, by Age Group – Phase 2/3 (All Subjects) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8915) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8875) n[b] (%)	 (95% CI[c])
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Night sweats	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
UNCODED TERM	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
FATIGUE@@	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Preferred terms with @@ denote uncoded terms.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
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: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (21:45)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 IA P3 2MPD2/adae s130 cut wd age all p3 saf

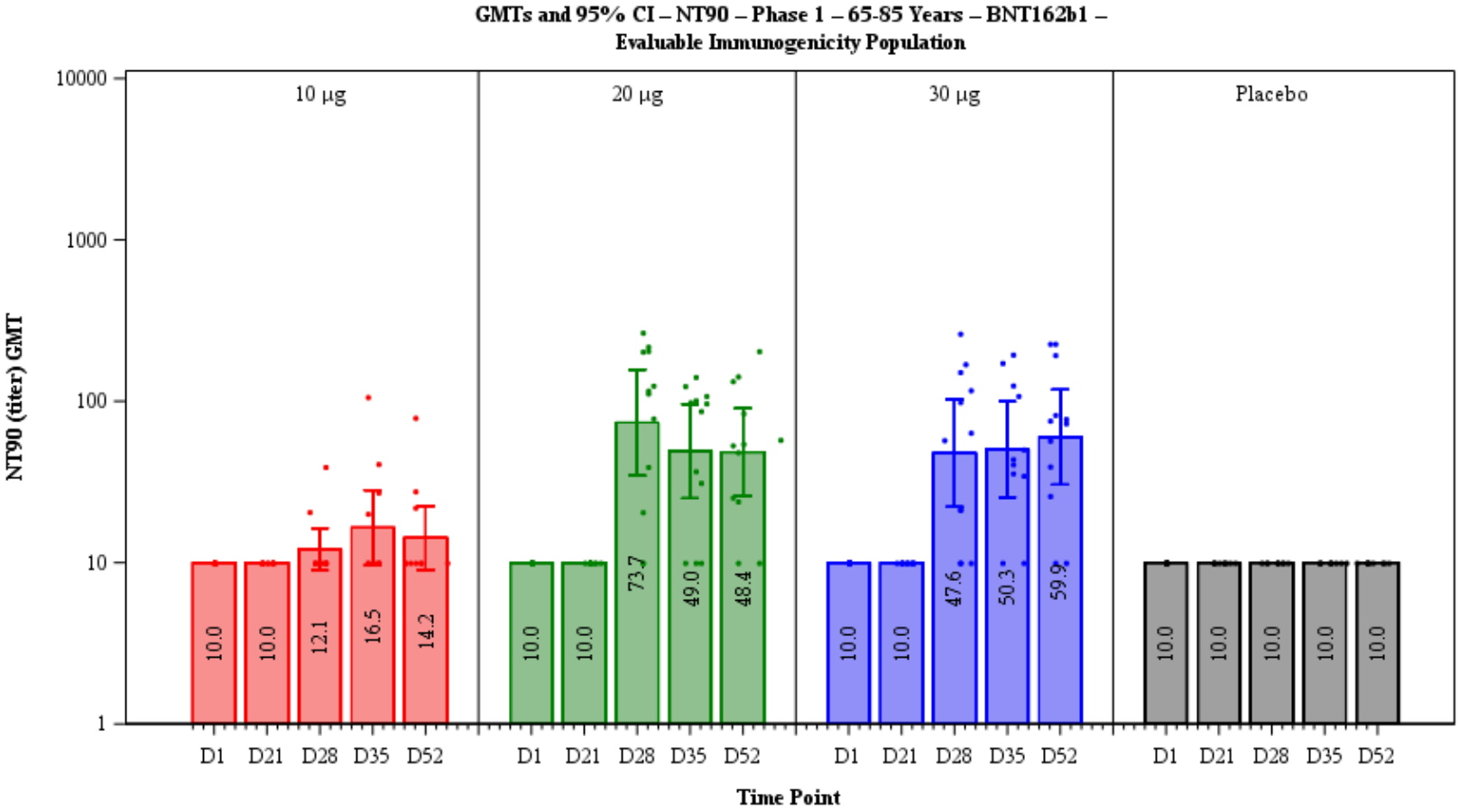
SUPPLEMENTAL FIGURES

14.1. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT90 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



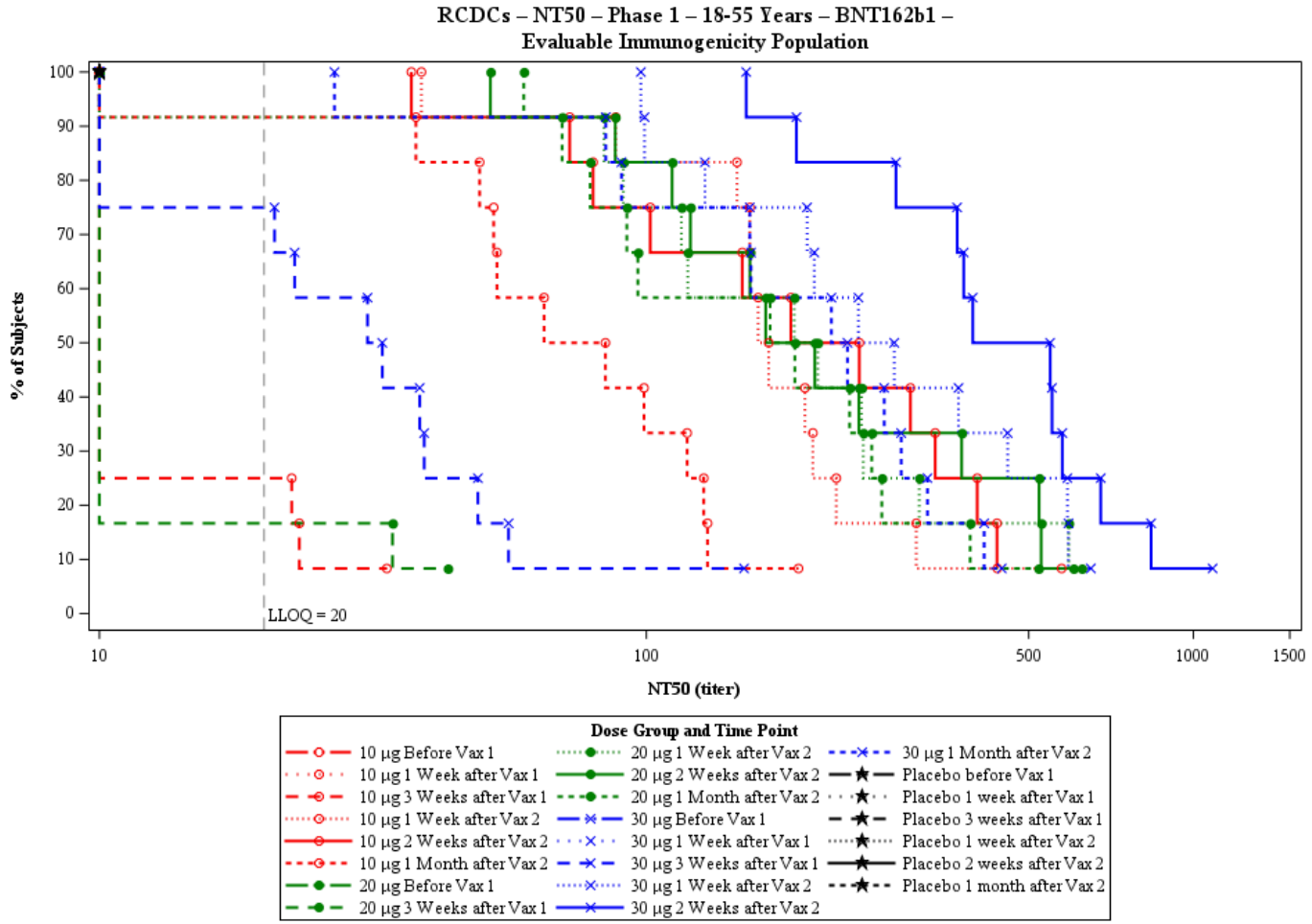
Abbreviations: GMT = geometric mean titer; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_90_18_b1_p1

14.2. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT90 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



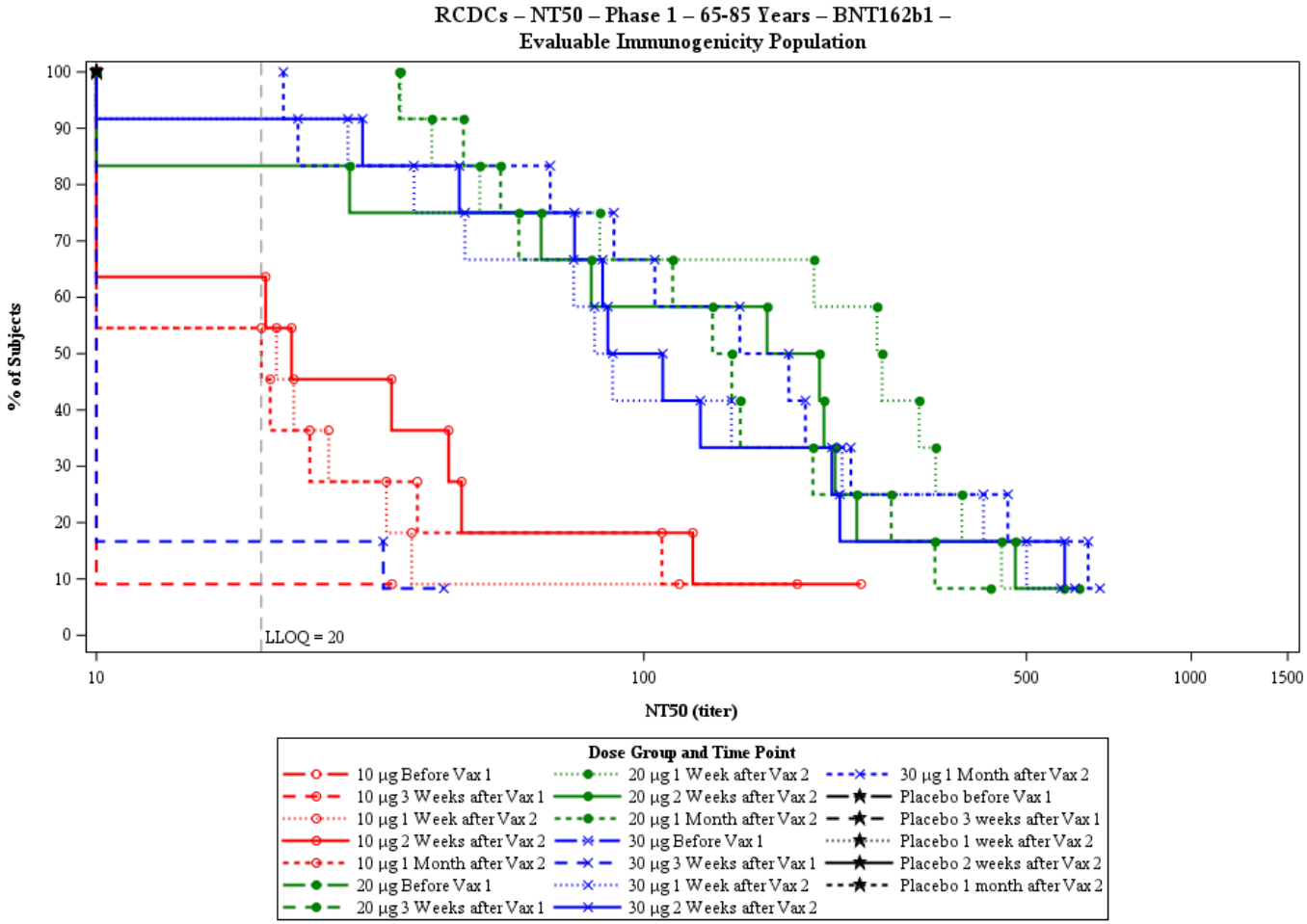
Abbreviations: GMT = geometric mean titer; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_90_65_b1_p1

14.3. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



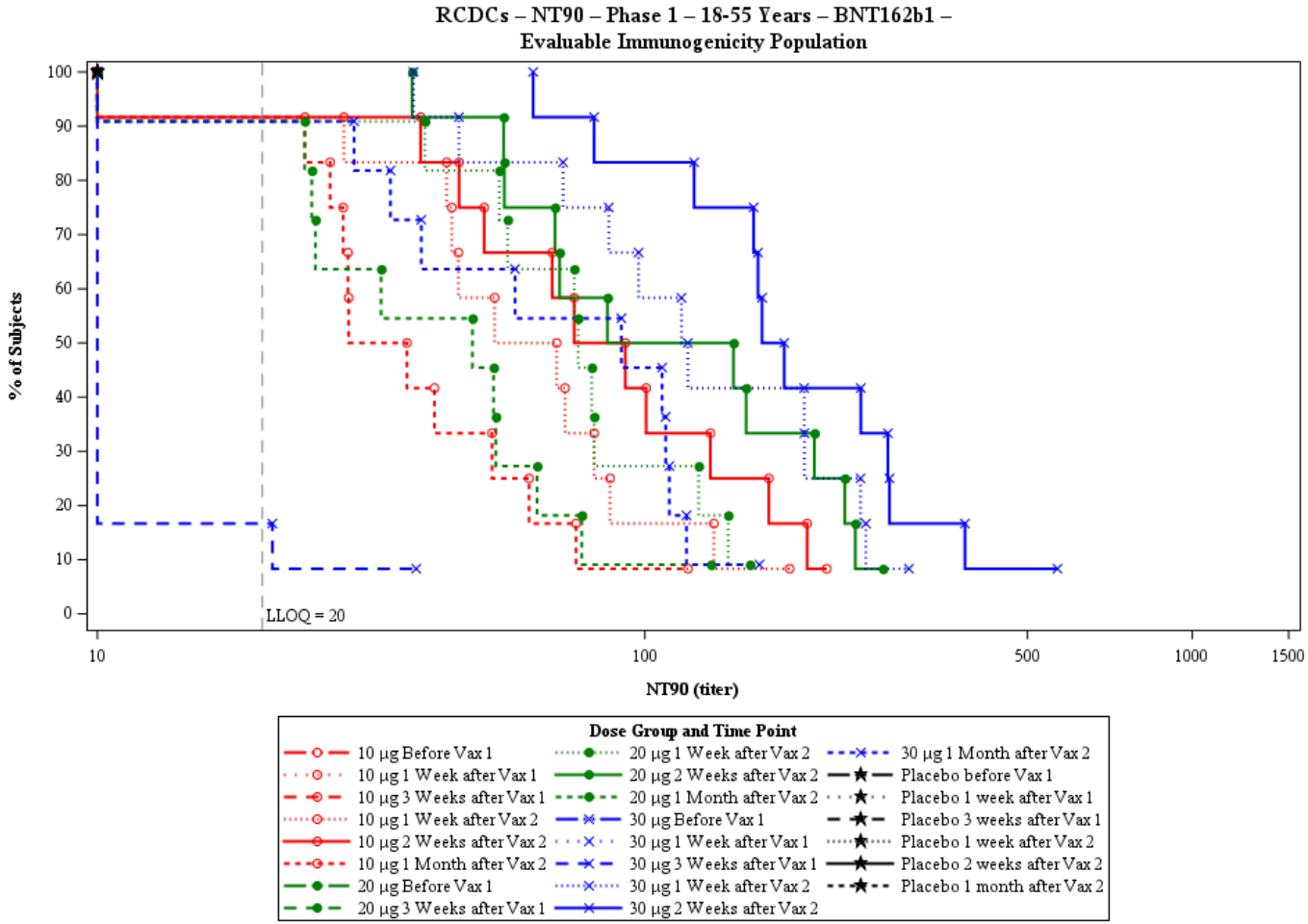
Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_50_18_b1_p1

14.4. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



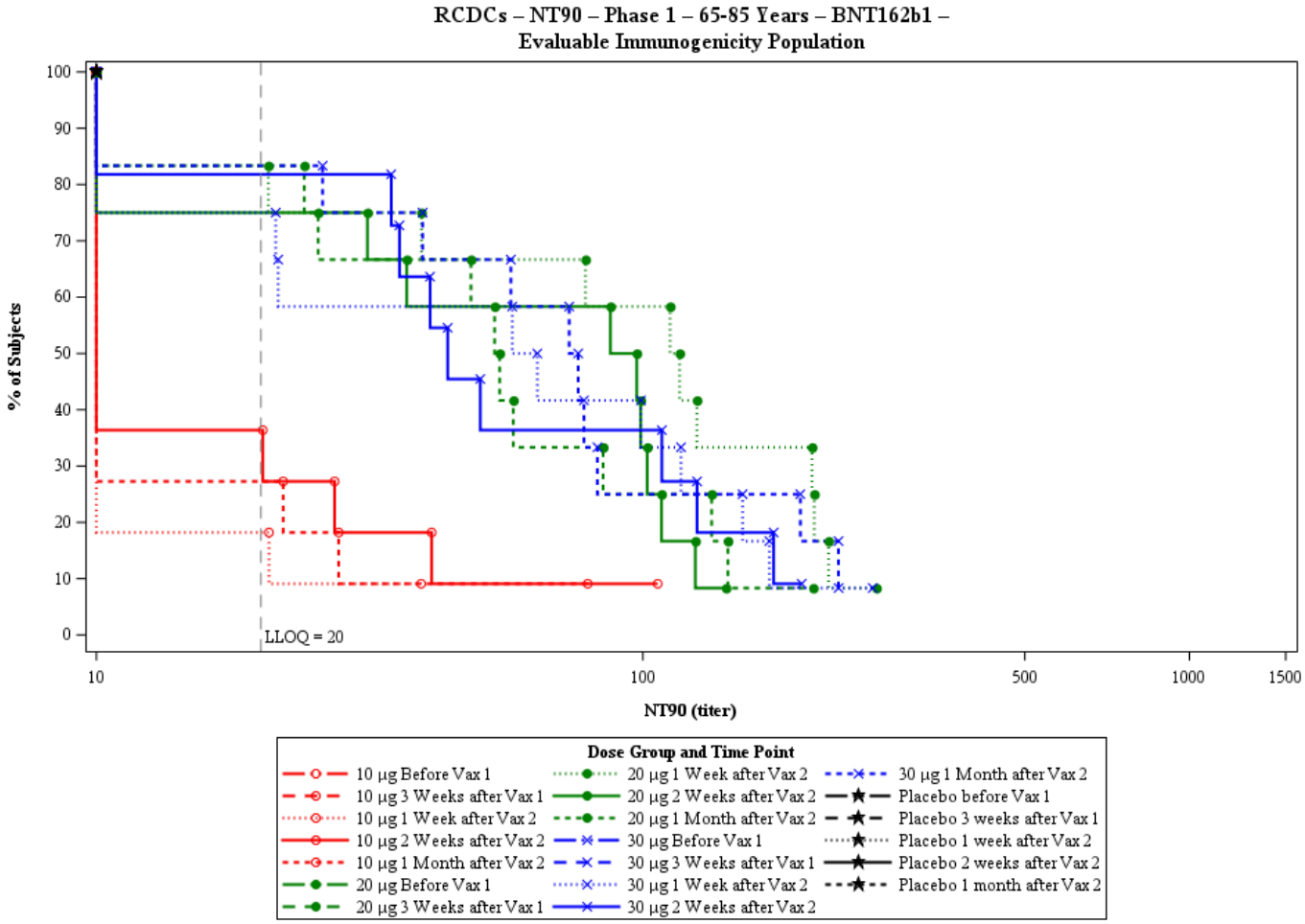
Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_50_65_b1_p1

14.5. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT90 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



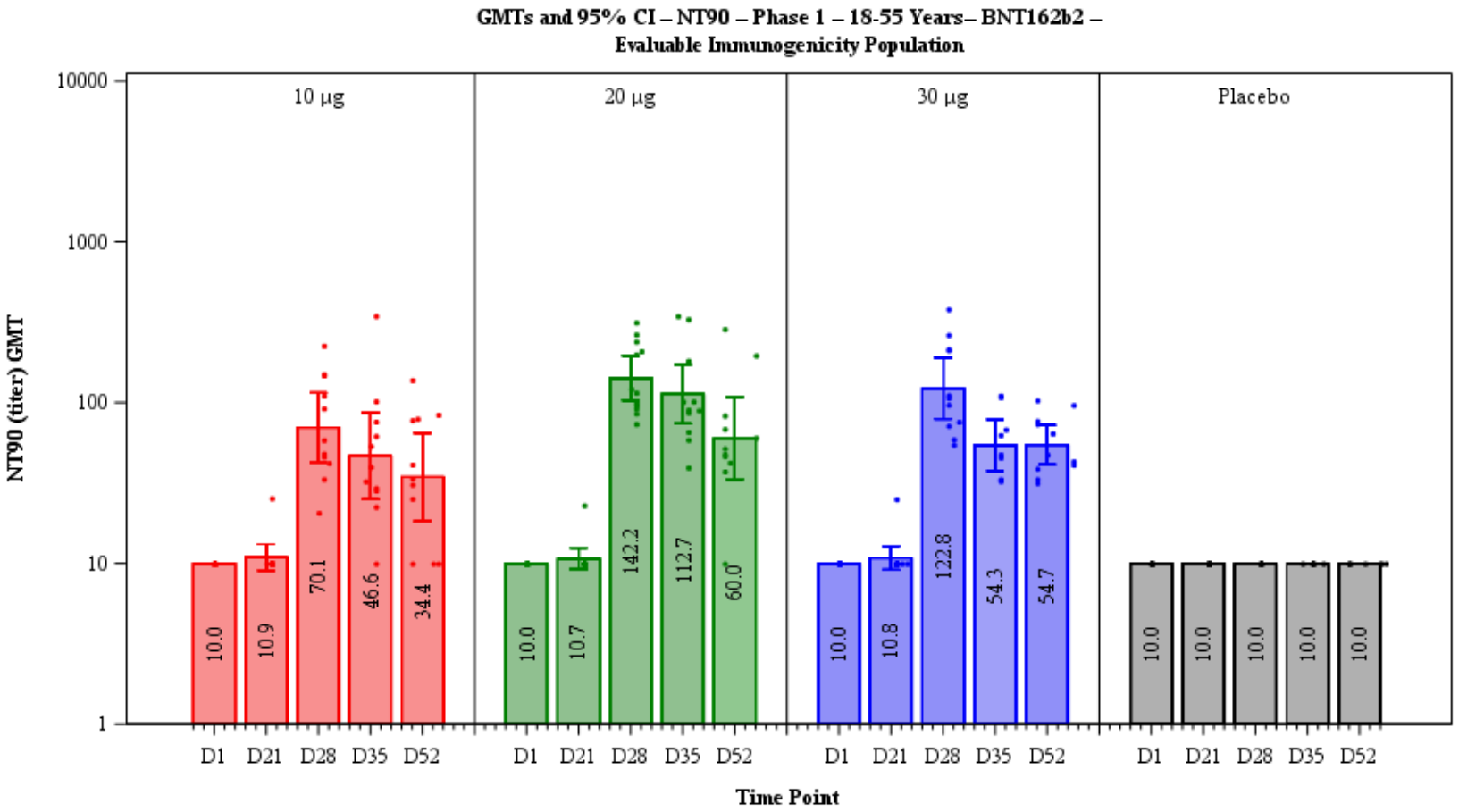
Abbreviations: LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_90_18_b1_p1

14.6. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT90 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



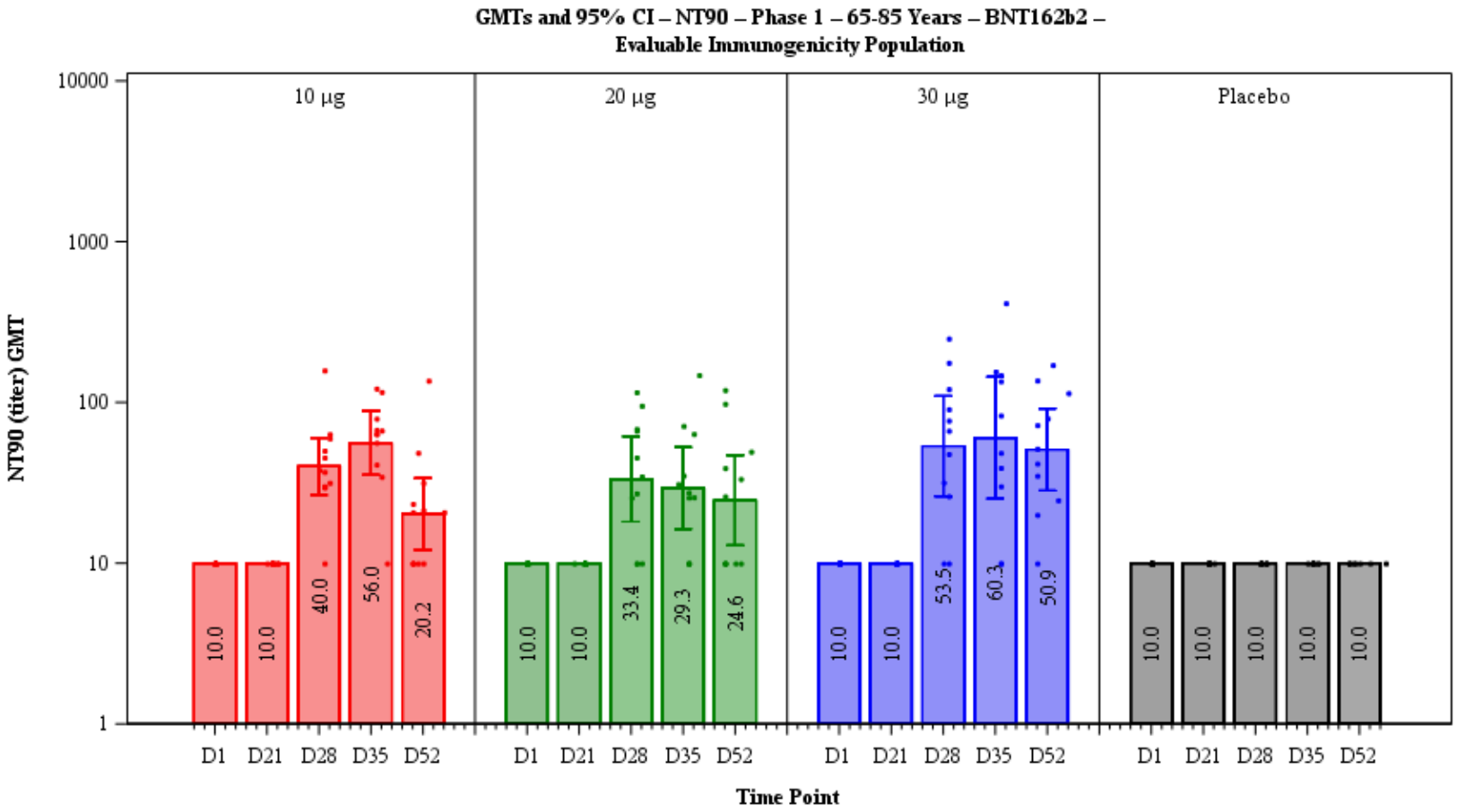
Abbreviations: LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_90_65_b1_p1

14.7. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT90 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



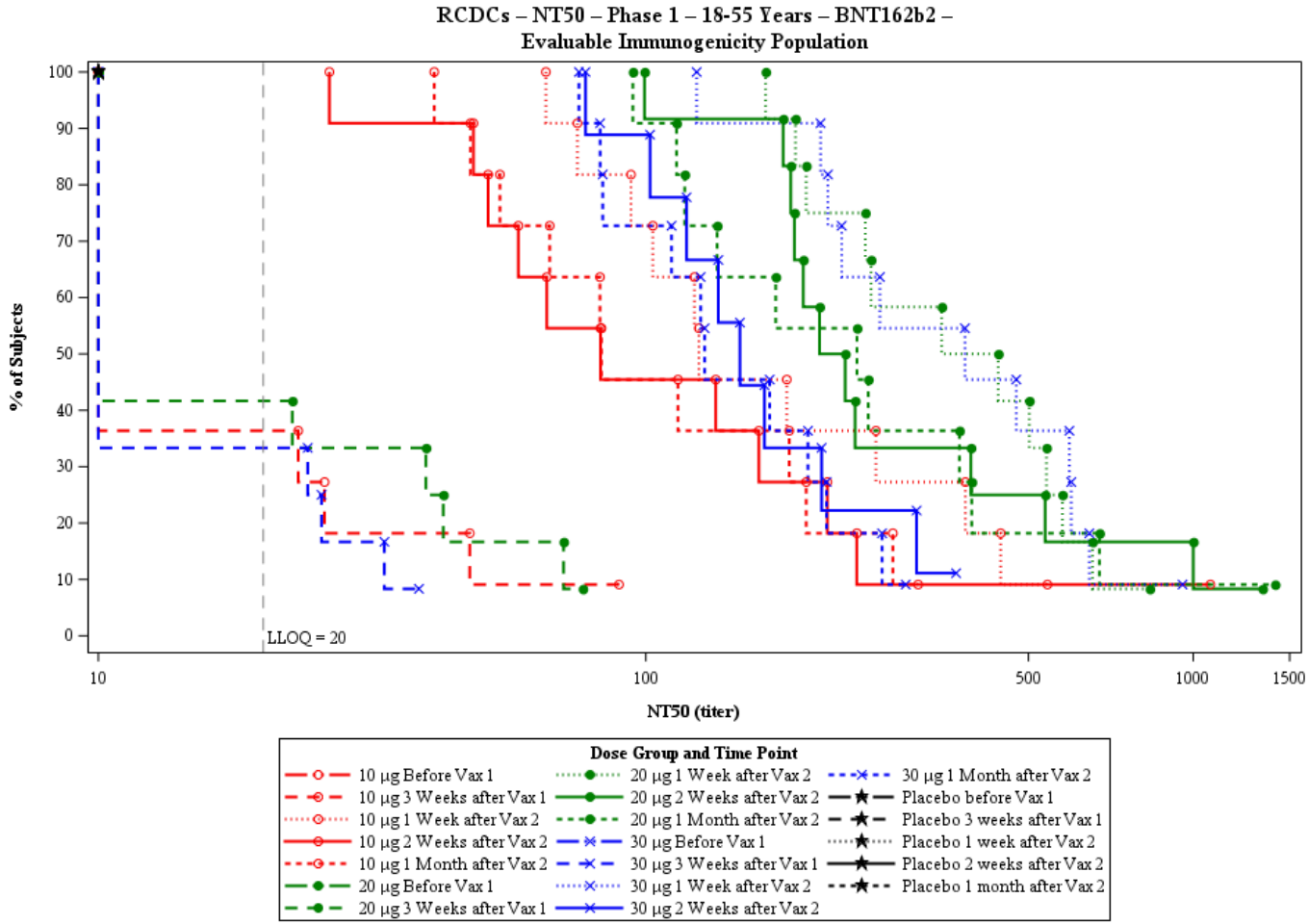
Abbreviations: GMT = geometric mean titer; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: /nda3/C4591001_IA_P1_Serology/adva_f002_sars_90_18_b2_p1

14.8. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT90 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



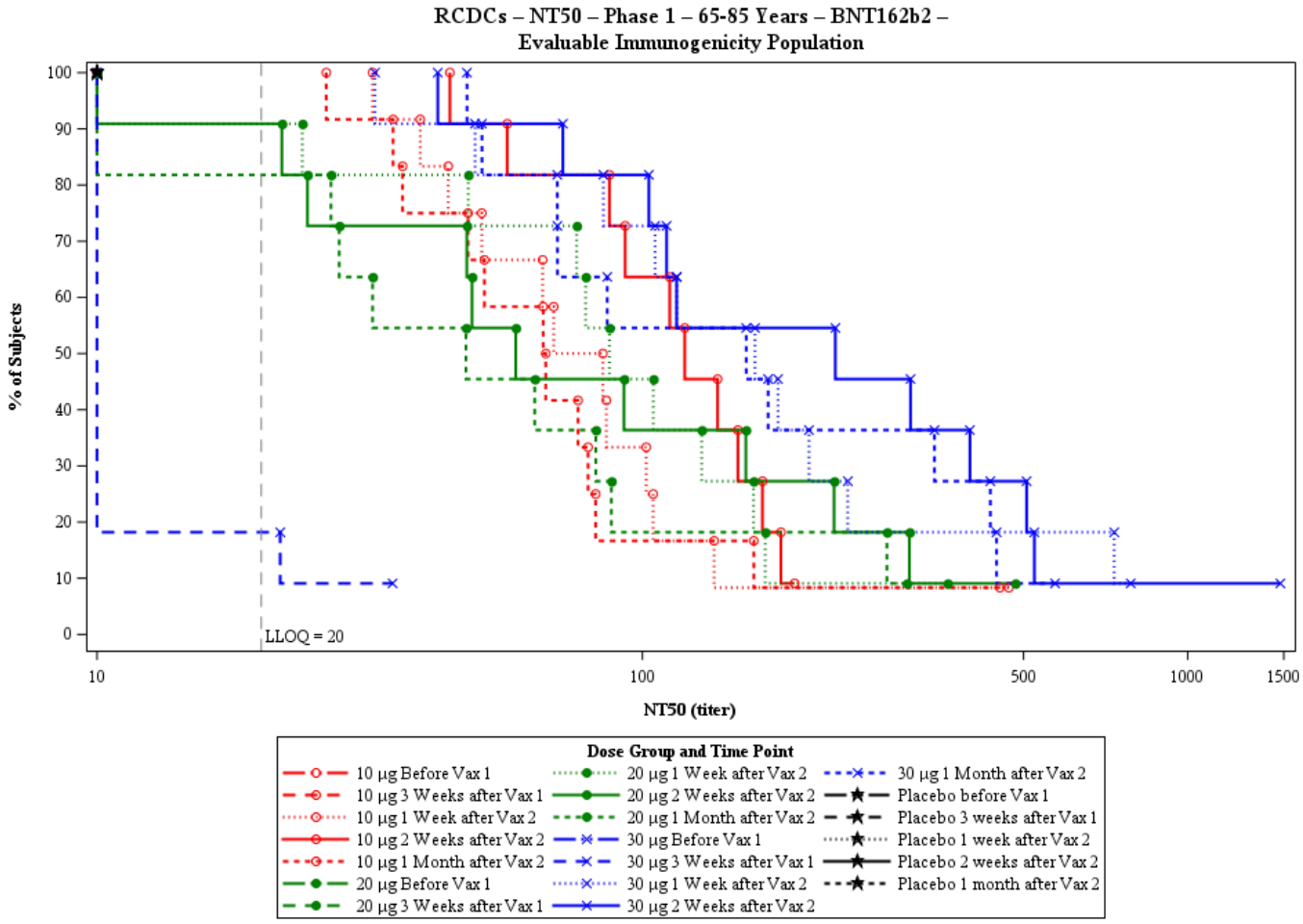
Abbreviations: GMT = geometric mean titer; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_90_65_b2_p1

14.9. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



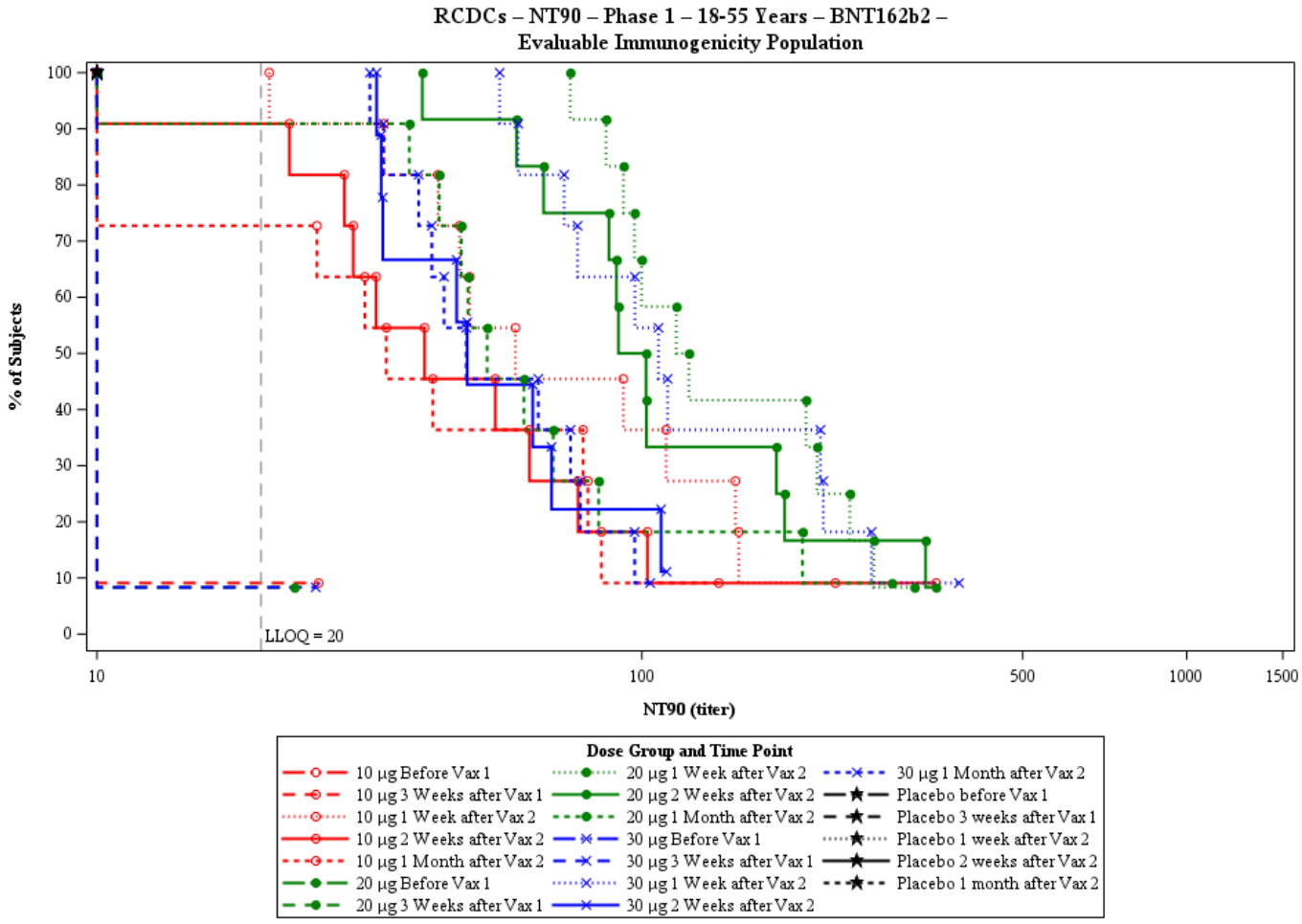
Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_50_18_b2_p1

14.10. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



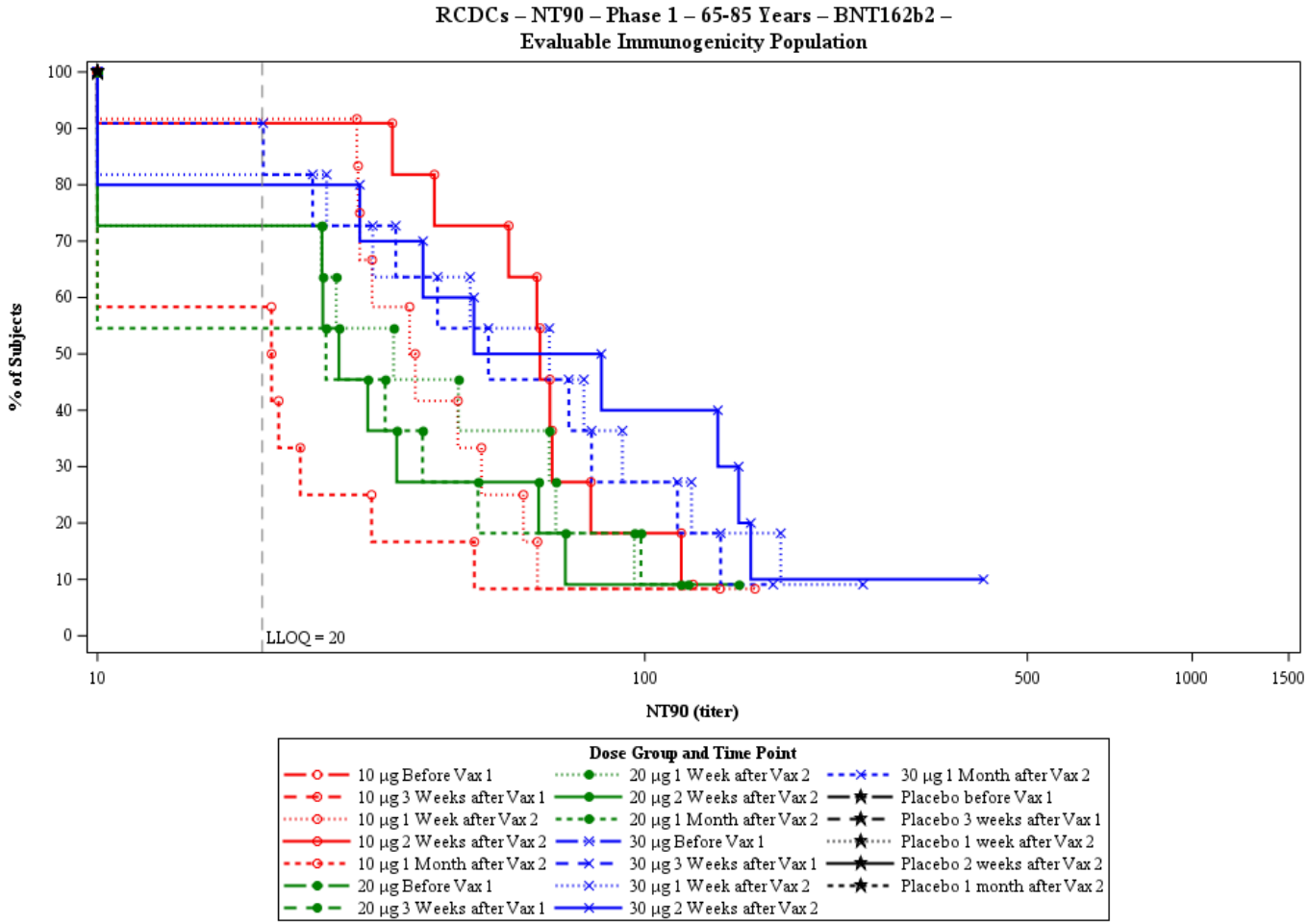
Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_50_65_b2_p1

14.11. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT90 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



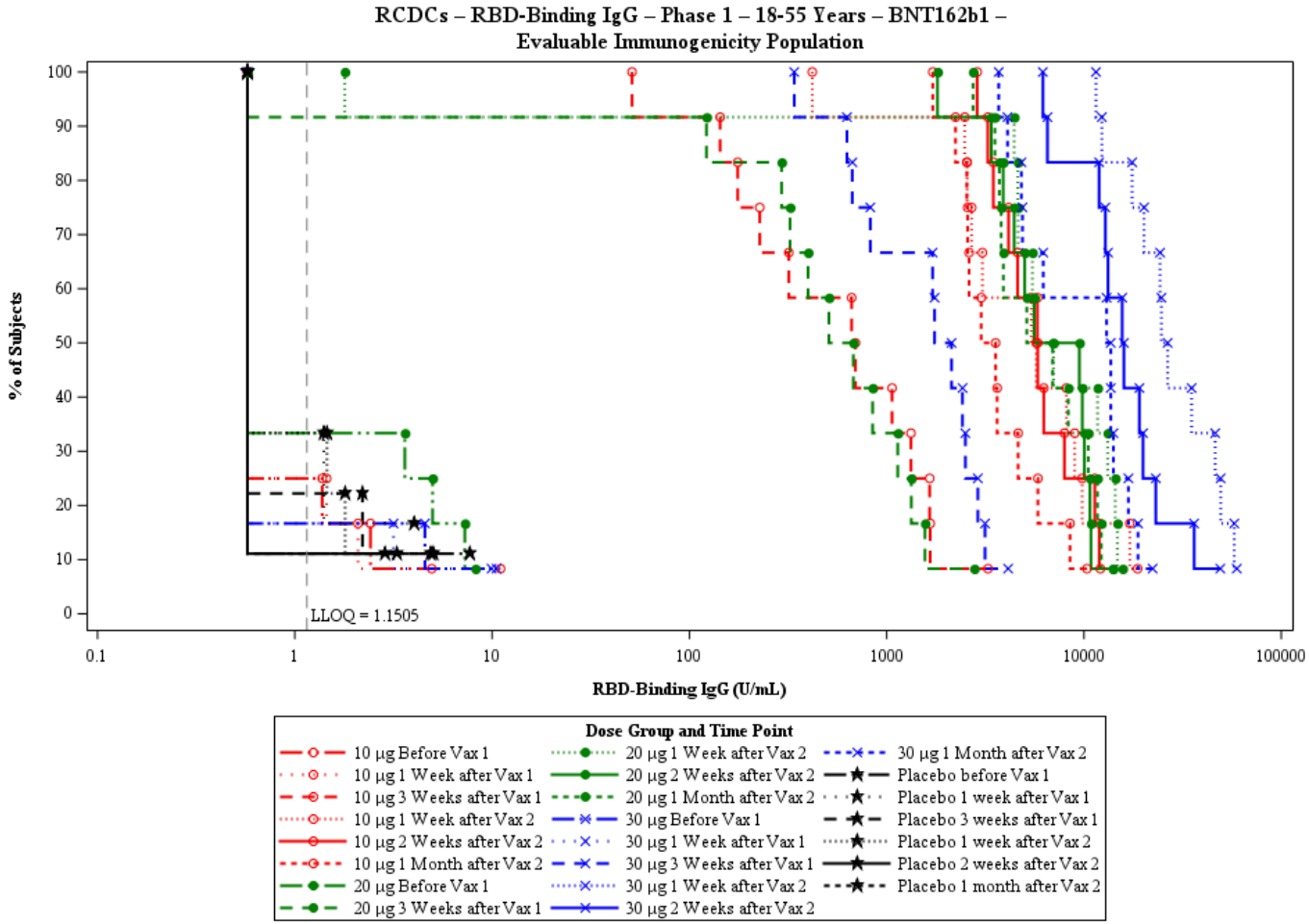
Abbreviations: LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_90_18_b2_p1

14.12. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT90 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



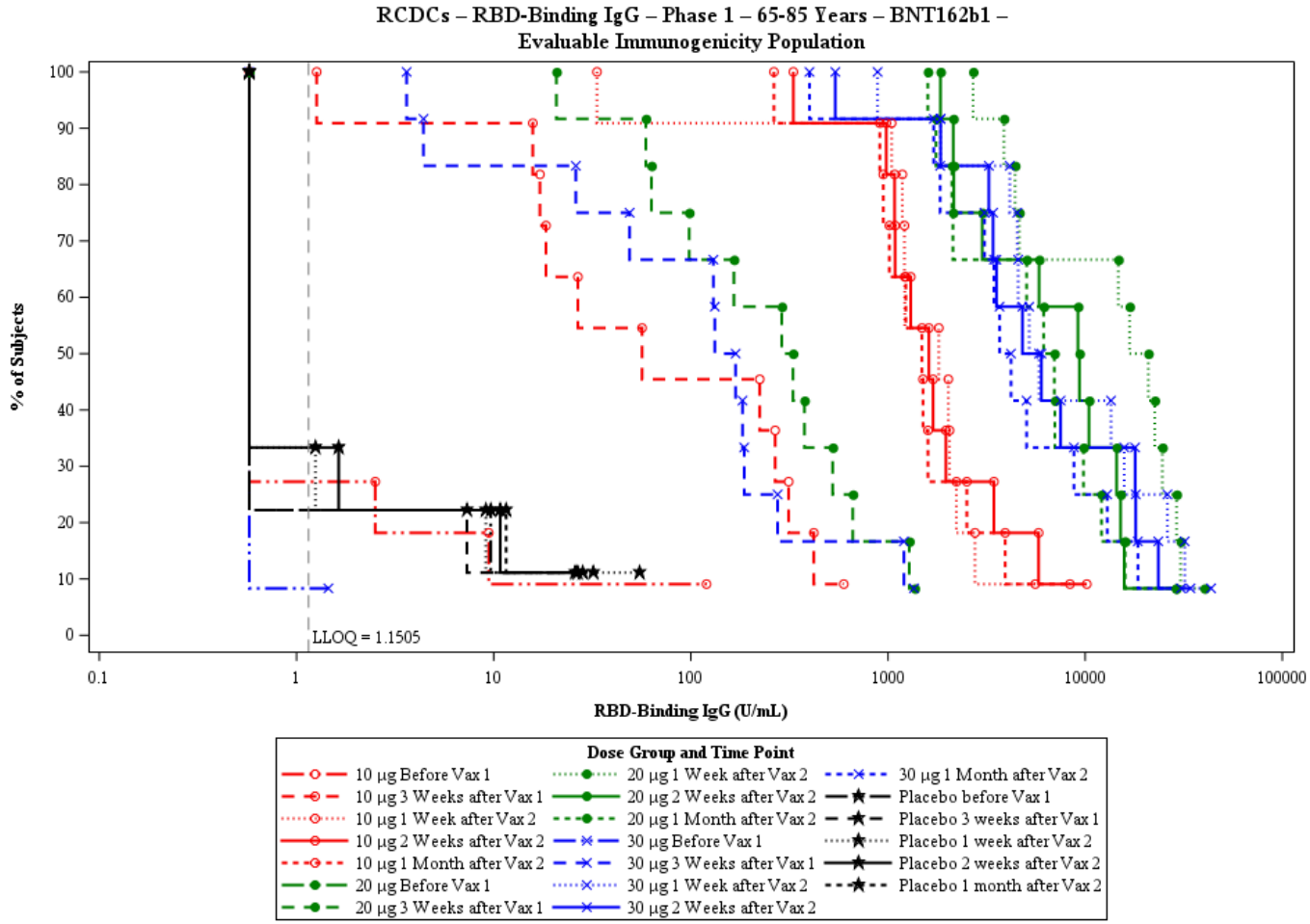
Abbreviations: LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_sars_90_65_b2_p1

14.13. Reverse Cumulative Distribution Curves, RBD-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



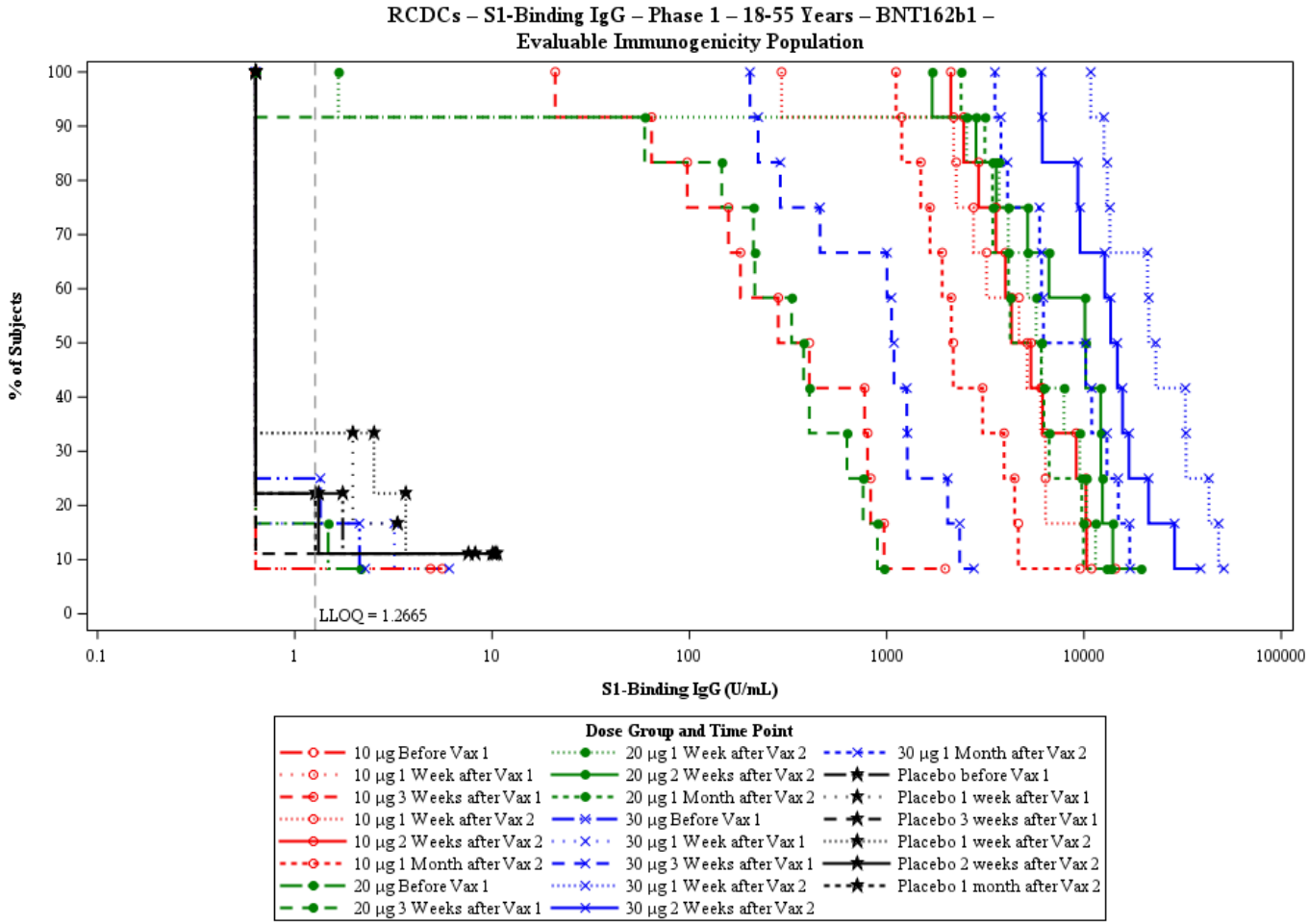
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RBD = receptor-binding domain; RCDC = reverse cumulative distribution curve.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_rbd_18_b1_p1

14.14. Reverse Cumulative Distribution Curves, RBD-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



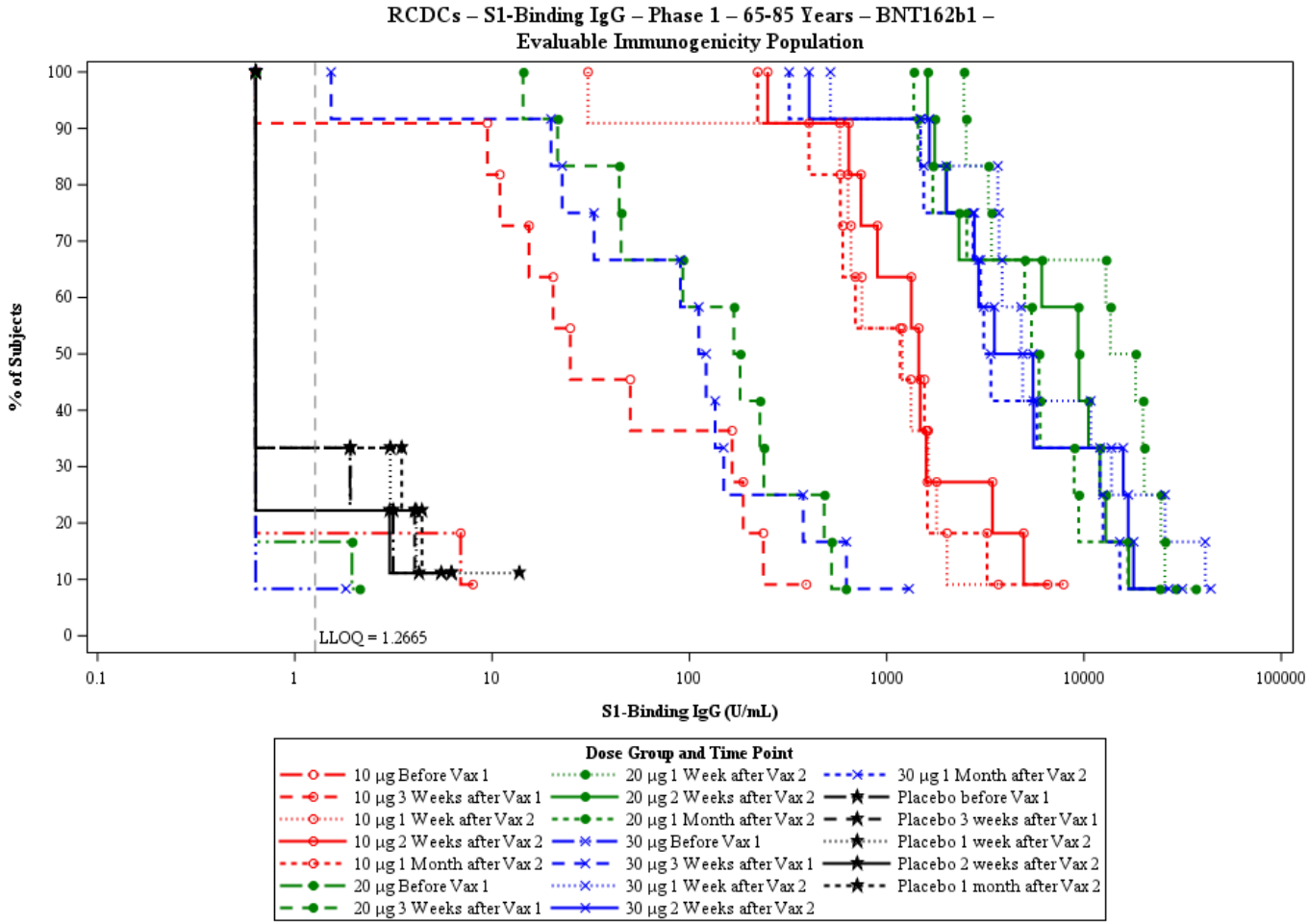
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RBD = receptor-binding domain; RCDC = reverse cumulative distribution curve.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_rbd_65_b1_p1

14.15. Reverse Cumulative Distribution Curves, S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



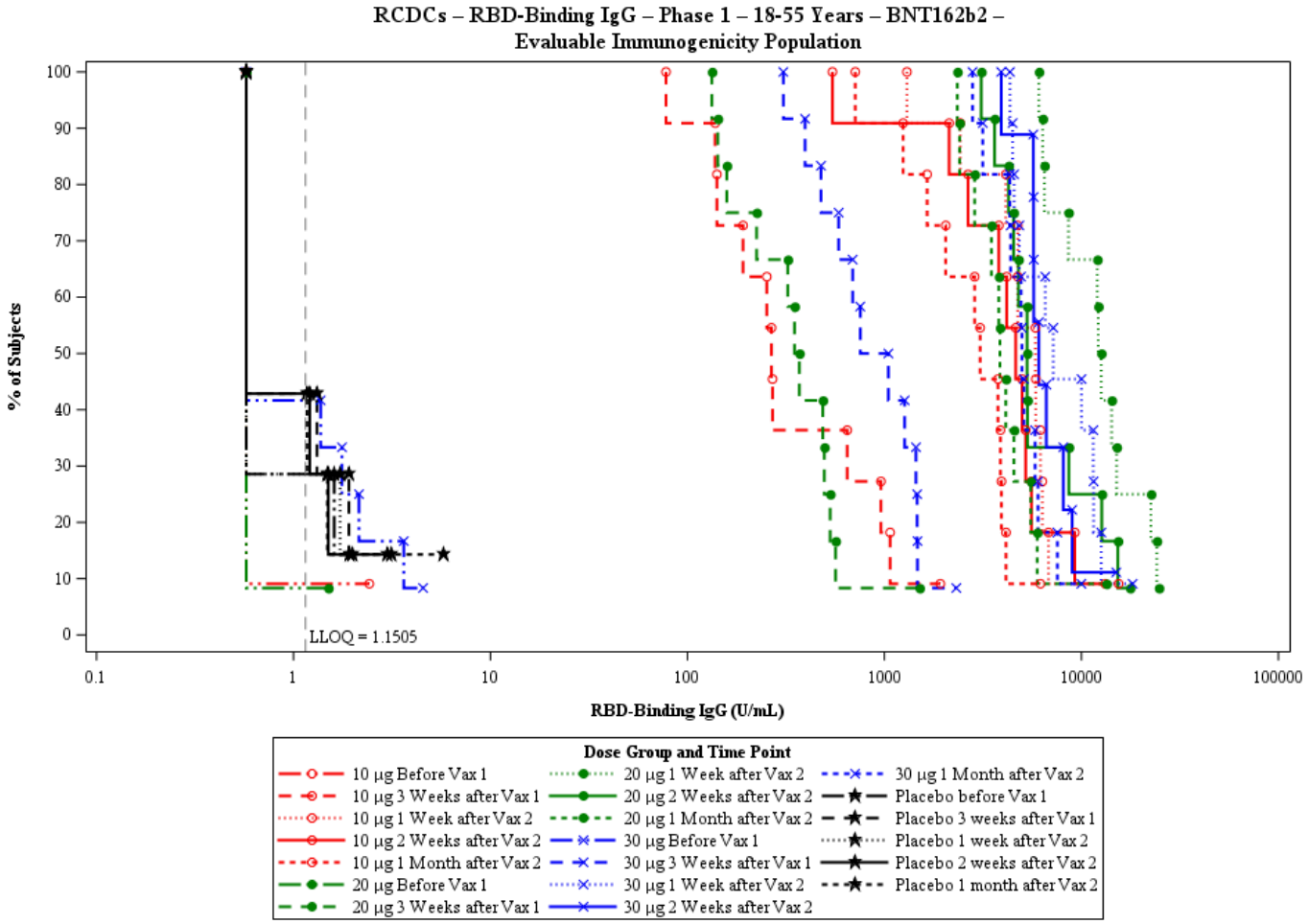
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S1 = spike protein S1 subunit.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_s1_18_b1_p1

14.16. Reverse Cumulative Distribution Curves, S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



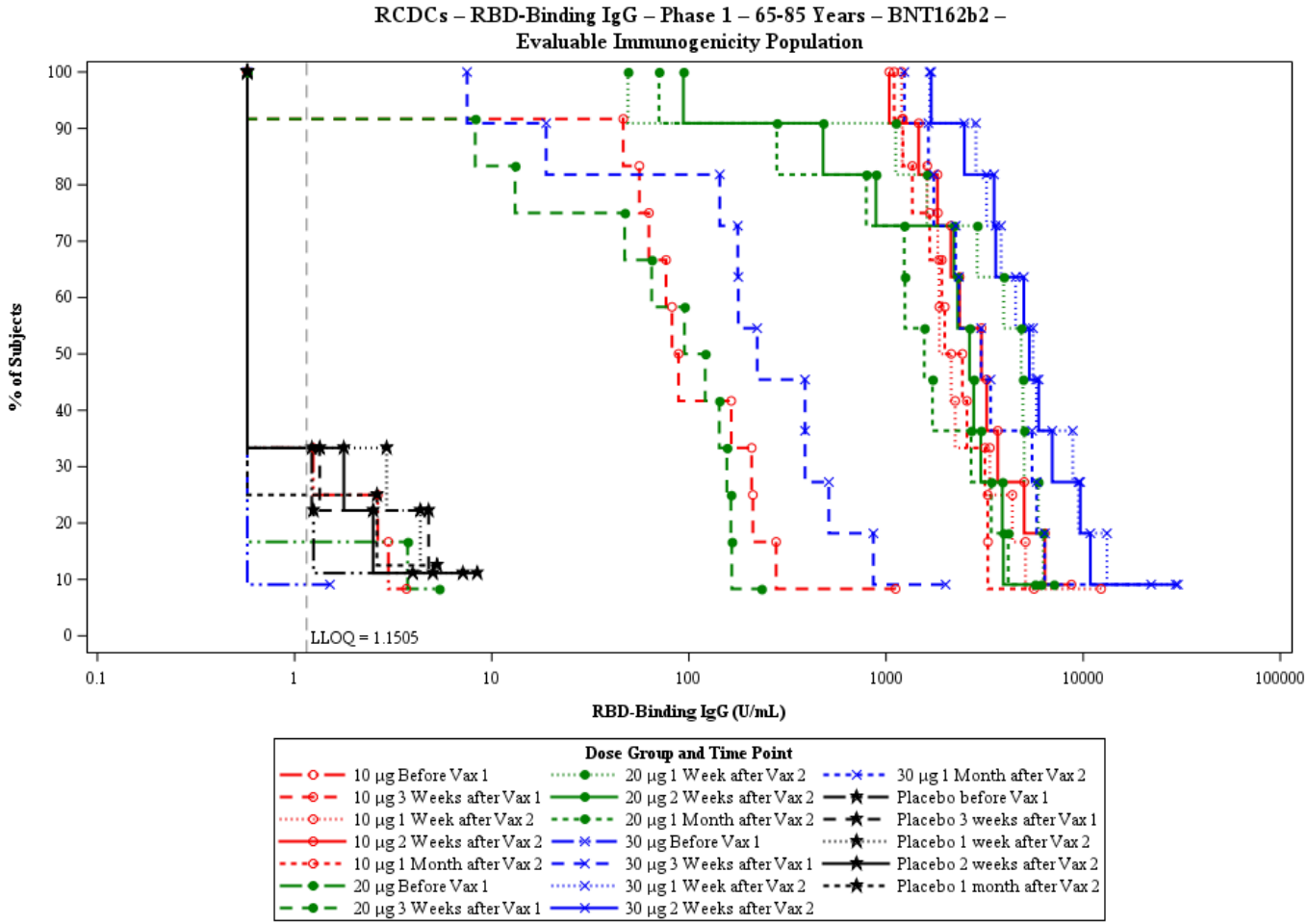
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S1 = spike protein S1 subunit.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_s1_65_b1_p1

14.17. Reverse Cumulative Distribution Curves, RBD-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



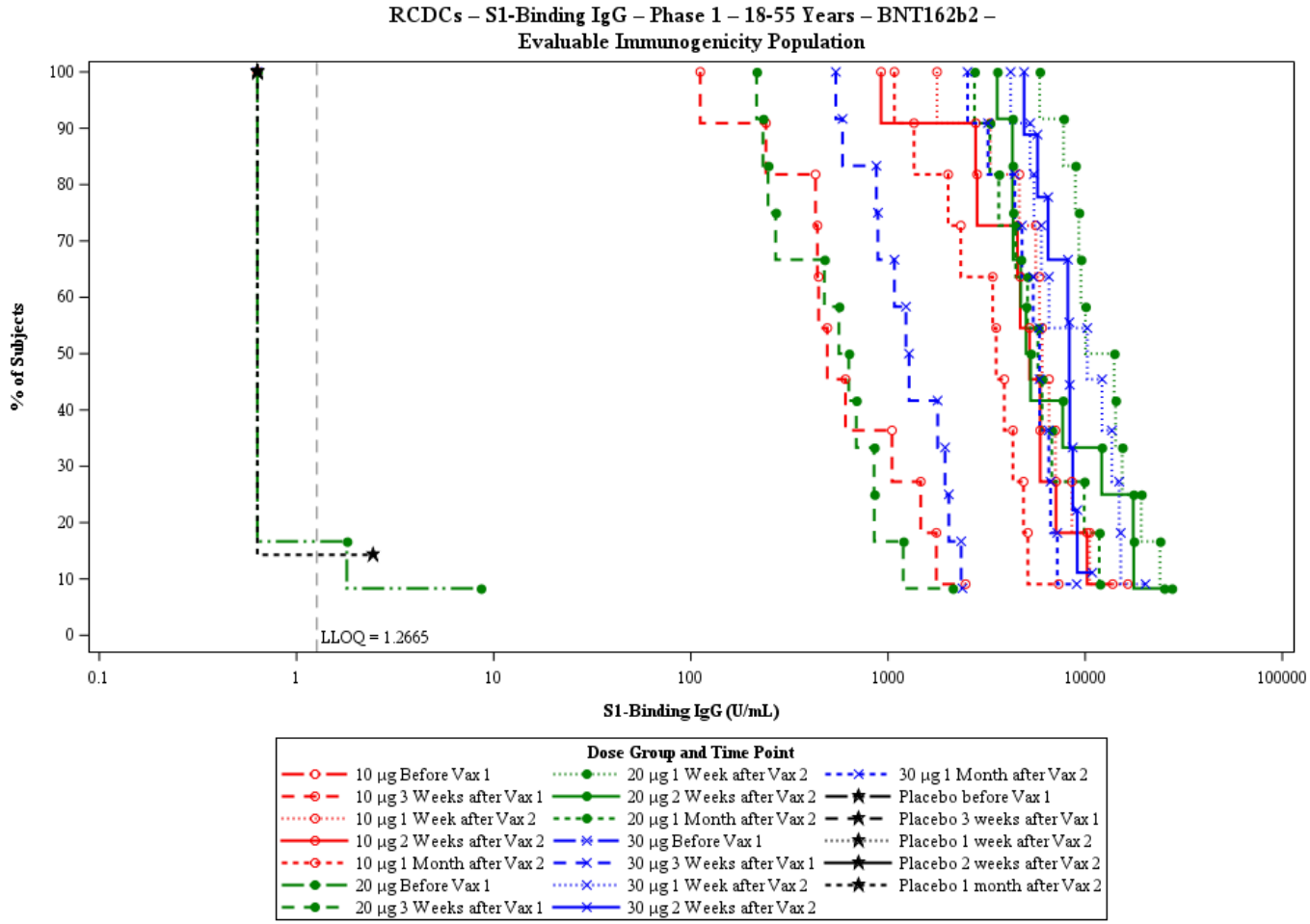
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RBD = receptor-binding domain; RCDC = reverse cumulative distribution curve.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_rbd_18_b2_p1

14.18. Reverse Cumulative Distribution Curves, RBD-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



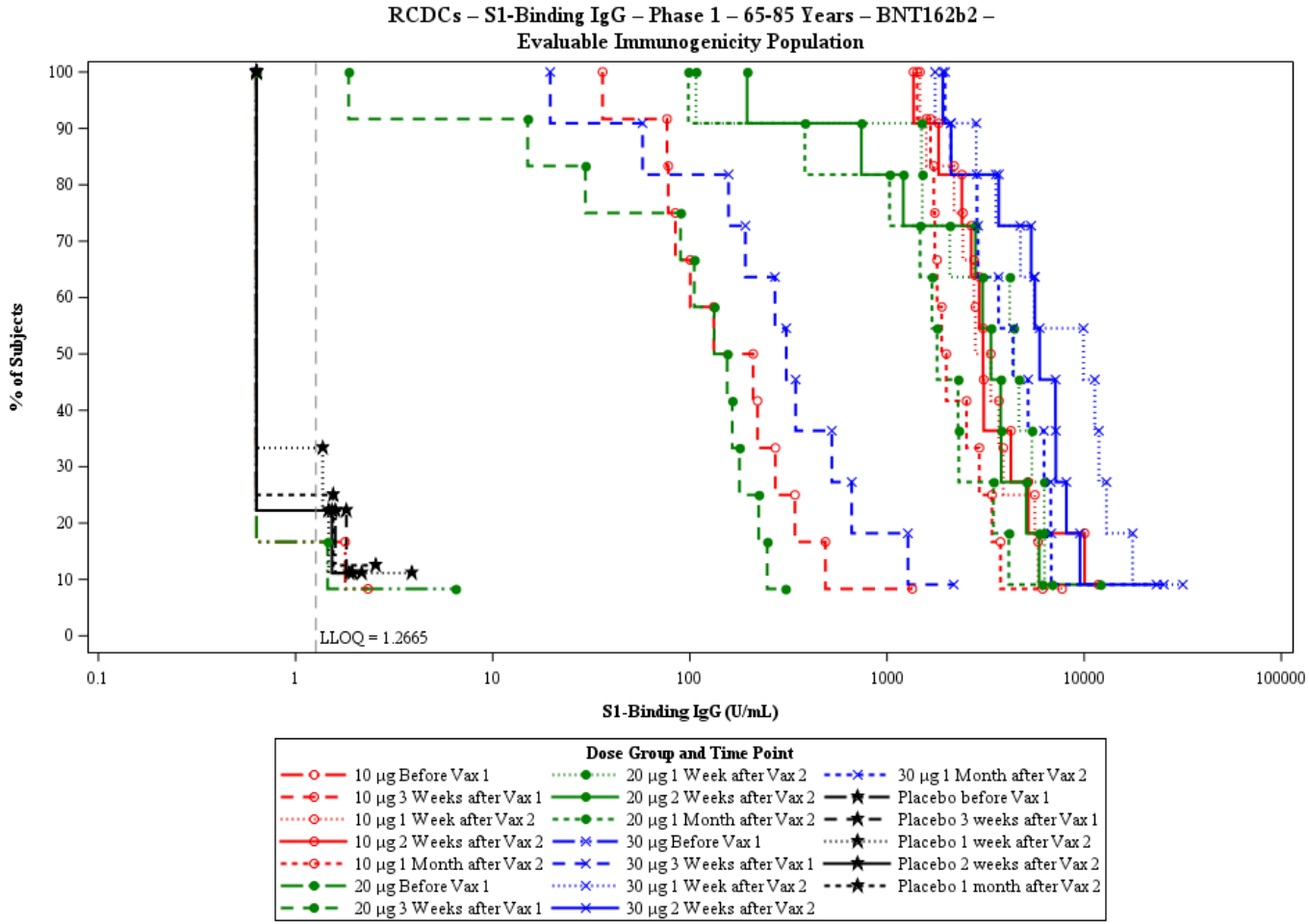
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RBD = receptor-binding domain; RCDC = reverse cumulative distribution curve.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_rbd_65_b2_p1

14.19. Reverse Cumulative Distribution Curves, S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



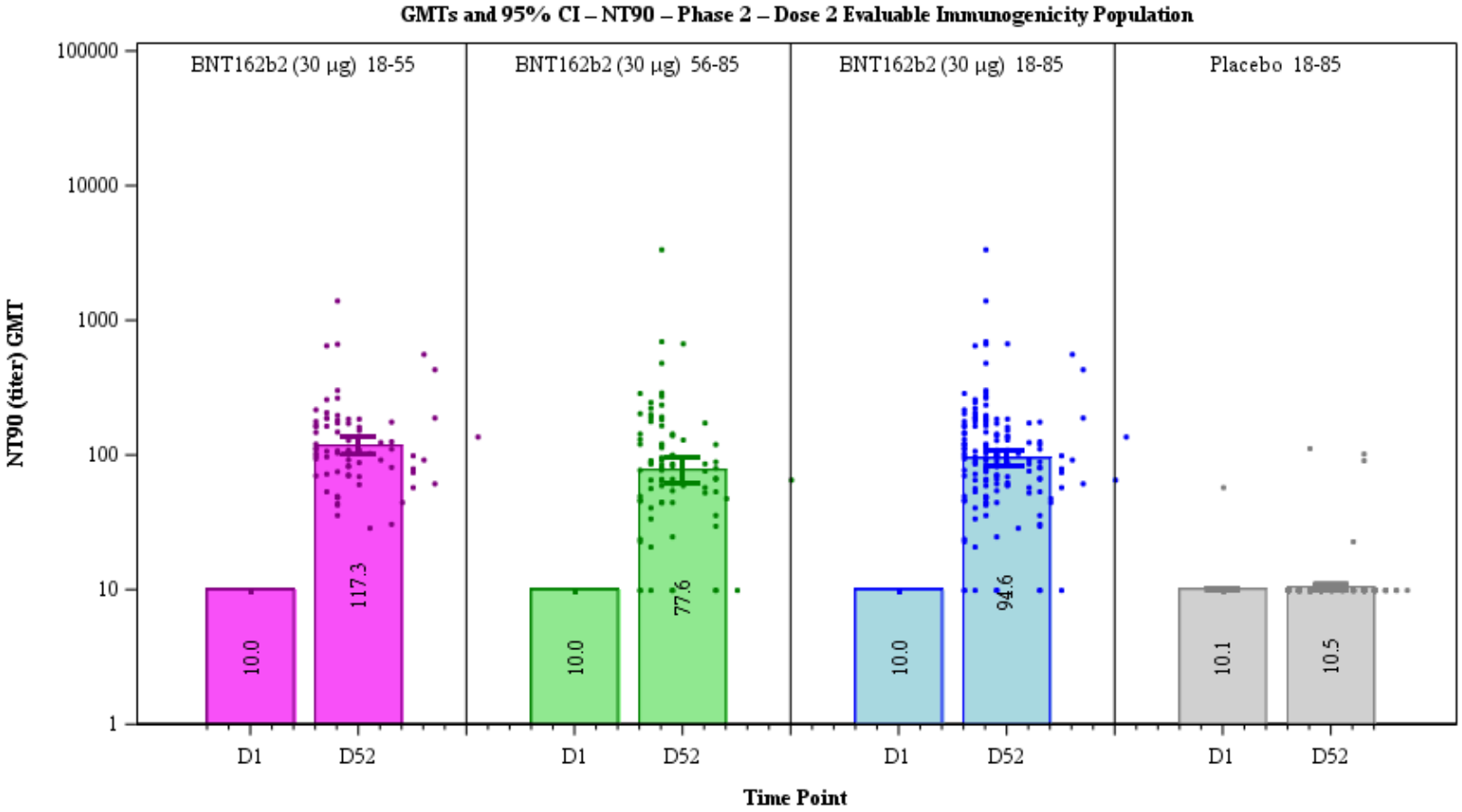
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S1 = spike protein S1 subunit.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_s1_18_b2_p1

14.20. Reverse Cumulative Distribution Curves, S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



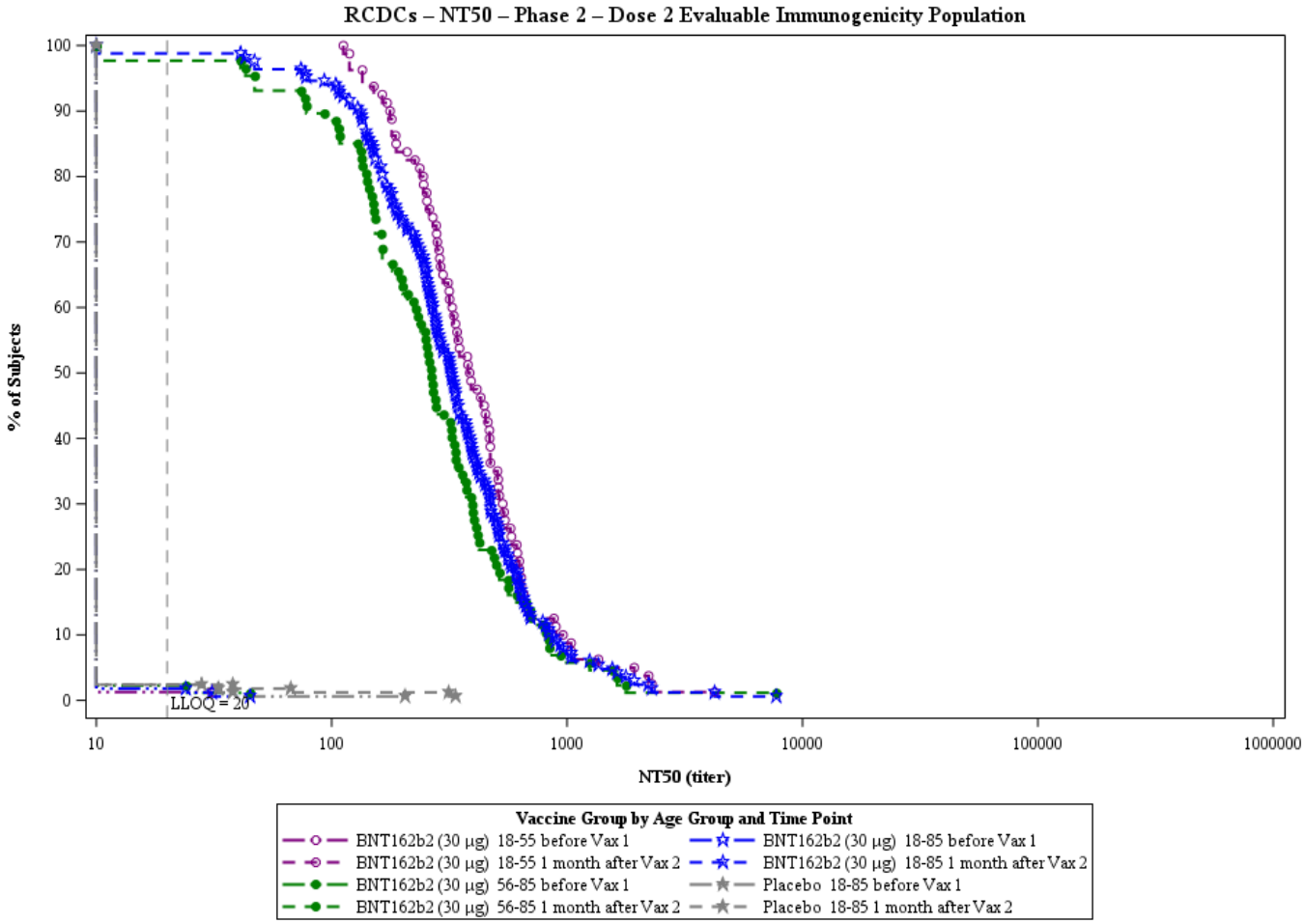
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S1 = spike protein S1 subunit.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f003_s1_65_b2_p1

14.21. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT90 – Phase 2 – Dose 2 Evaluable Immunogenicity Population



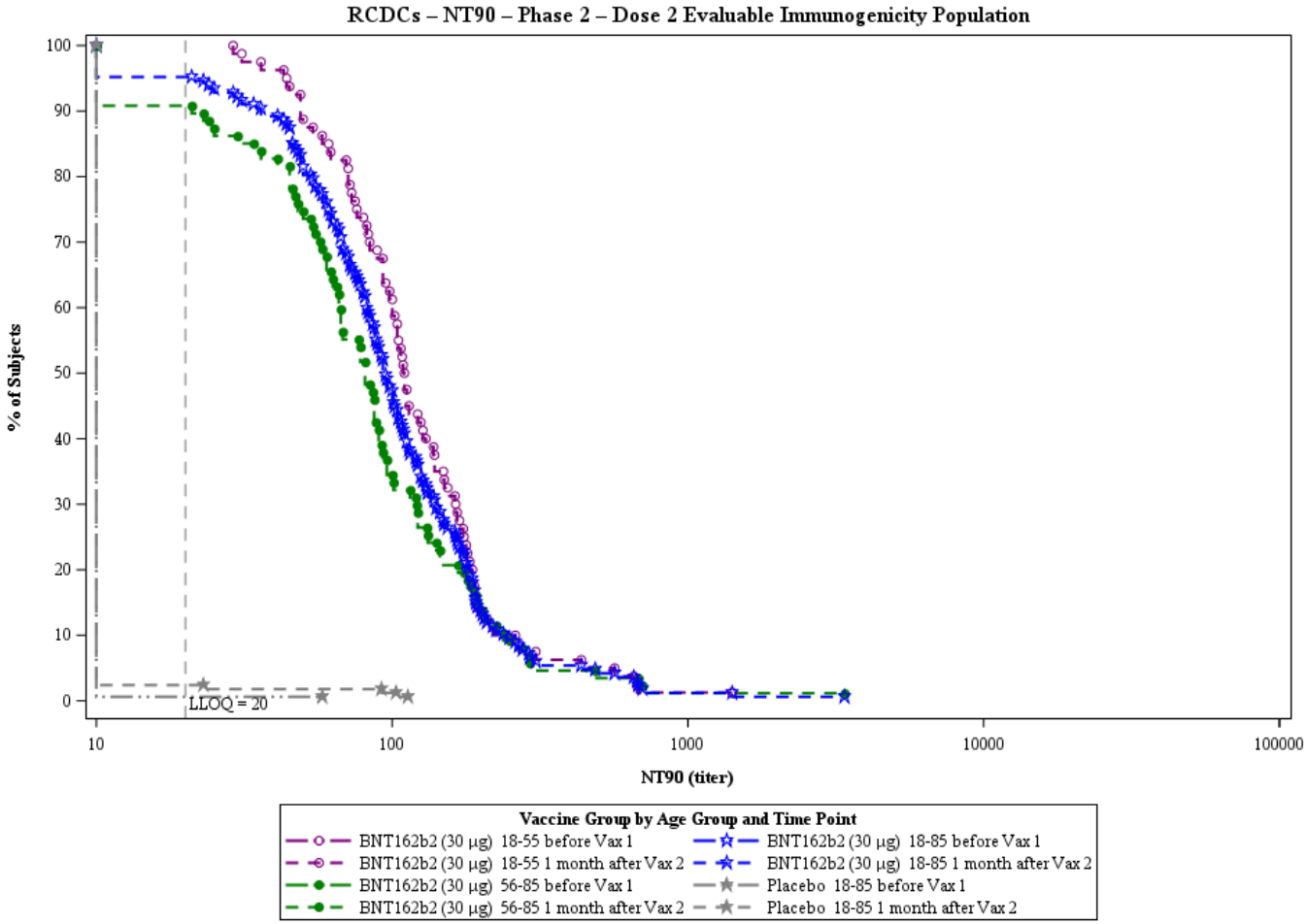
Abbreviations: GMT = geometric mean titer; NT90 = 90% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f002_sars_90_p2

14.22. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutraliation Assay – NT50 – Phase 2 – Dose 2 Evaluable Immunogenicity Population



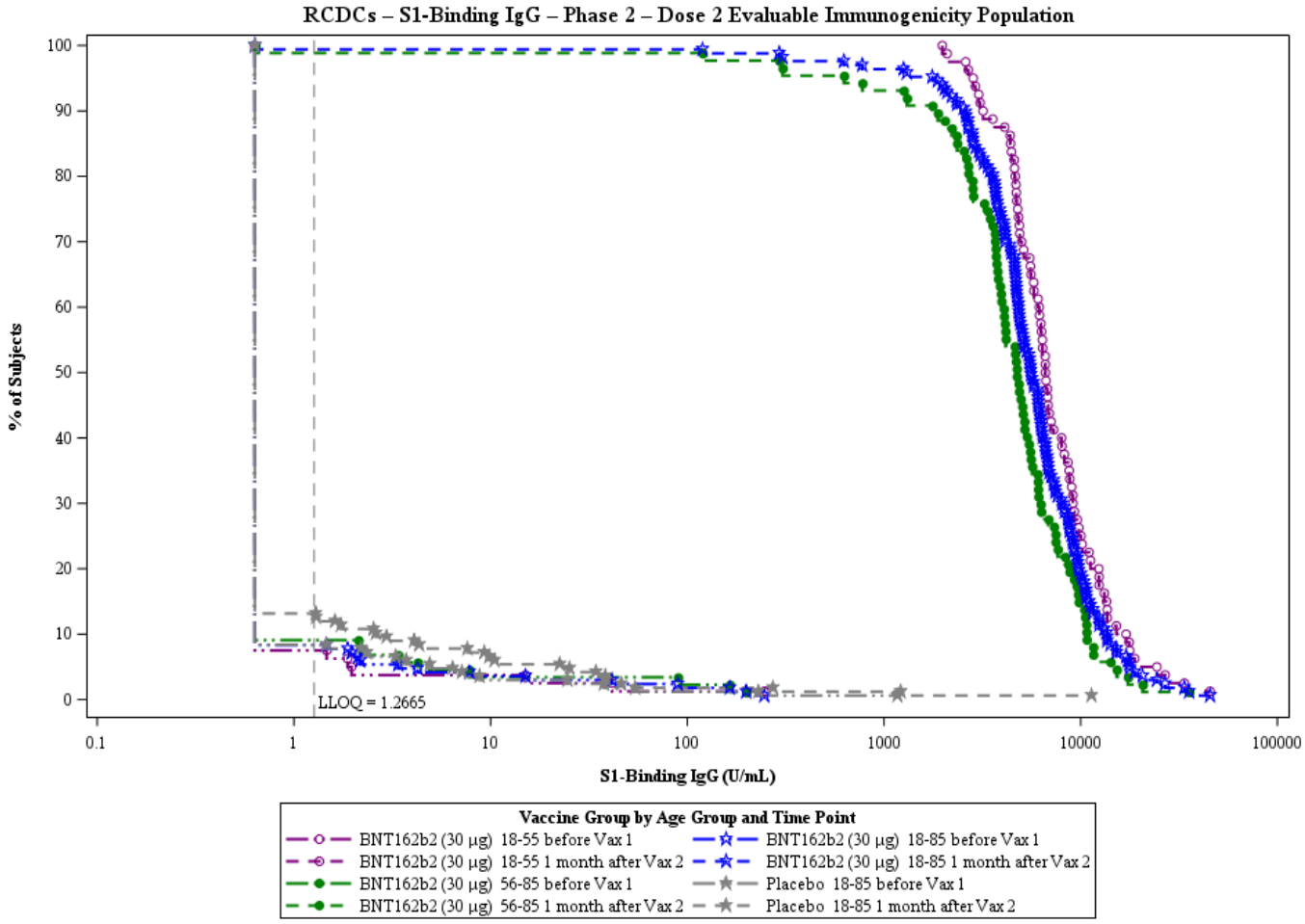
Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f003_sars_50_p2

14.23. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutraliation Assay – NT90 – Phase 2 – Dose 2 Evaluable Immunogenicity Population



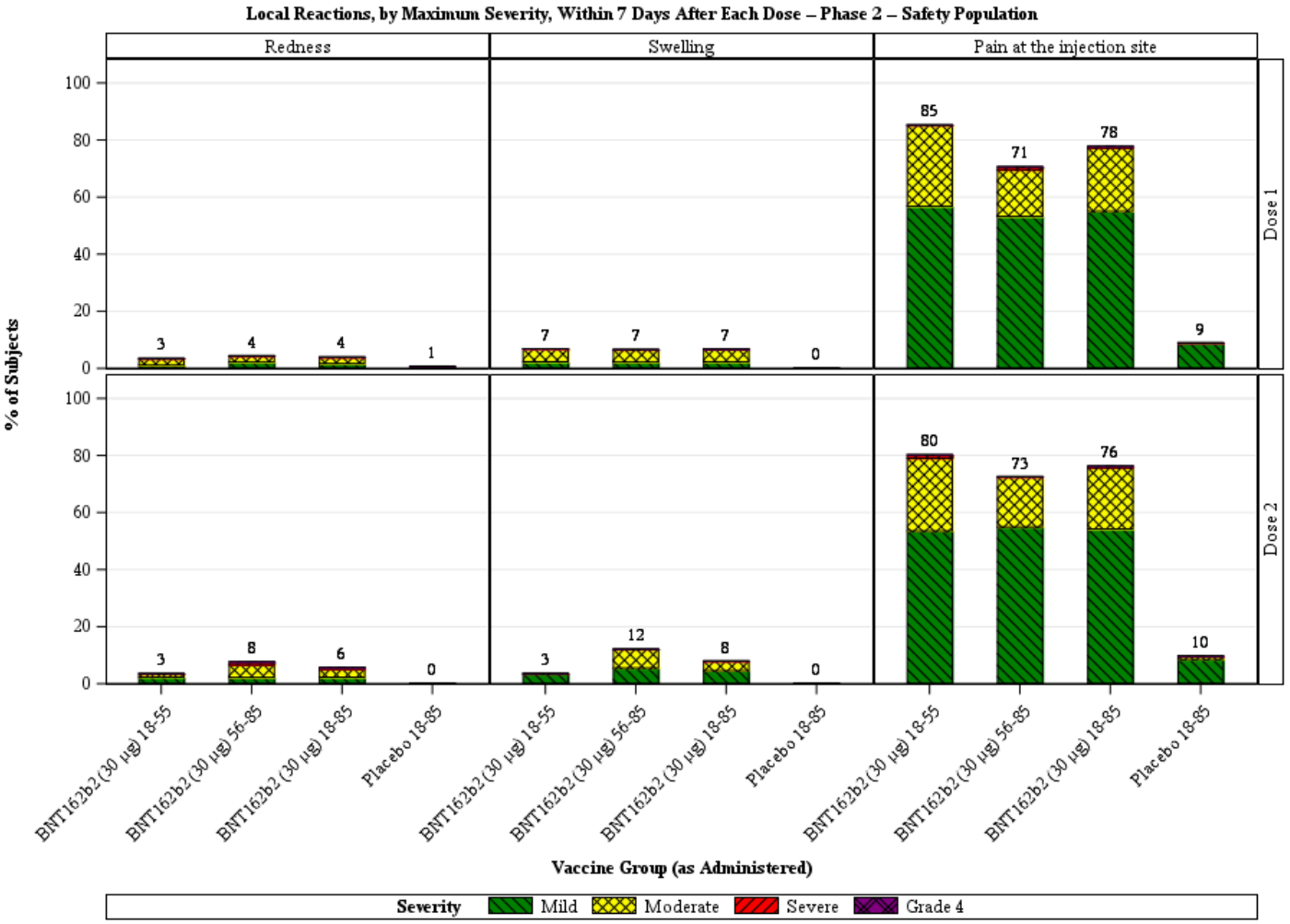
Abbreviations: LLOQ = lower limit of quantitation; NT90 = 90% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f003_sars_90_p2

14.24. Reverse Cumulative Distribution Curves, S1-Binding IgG Level Assay – Phase 2 – Dose 2 Evaluable Immunogenicity Population



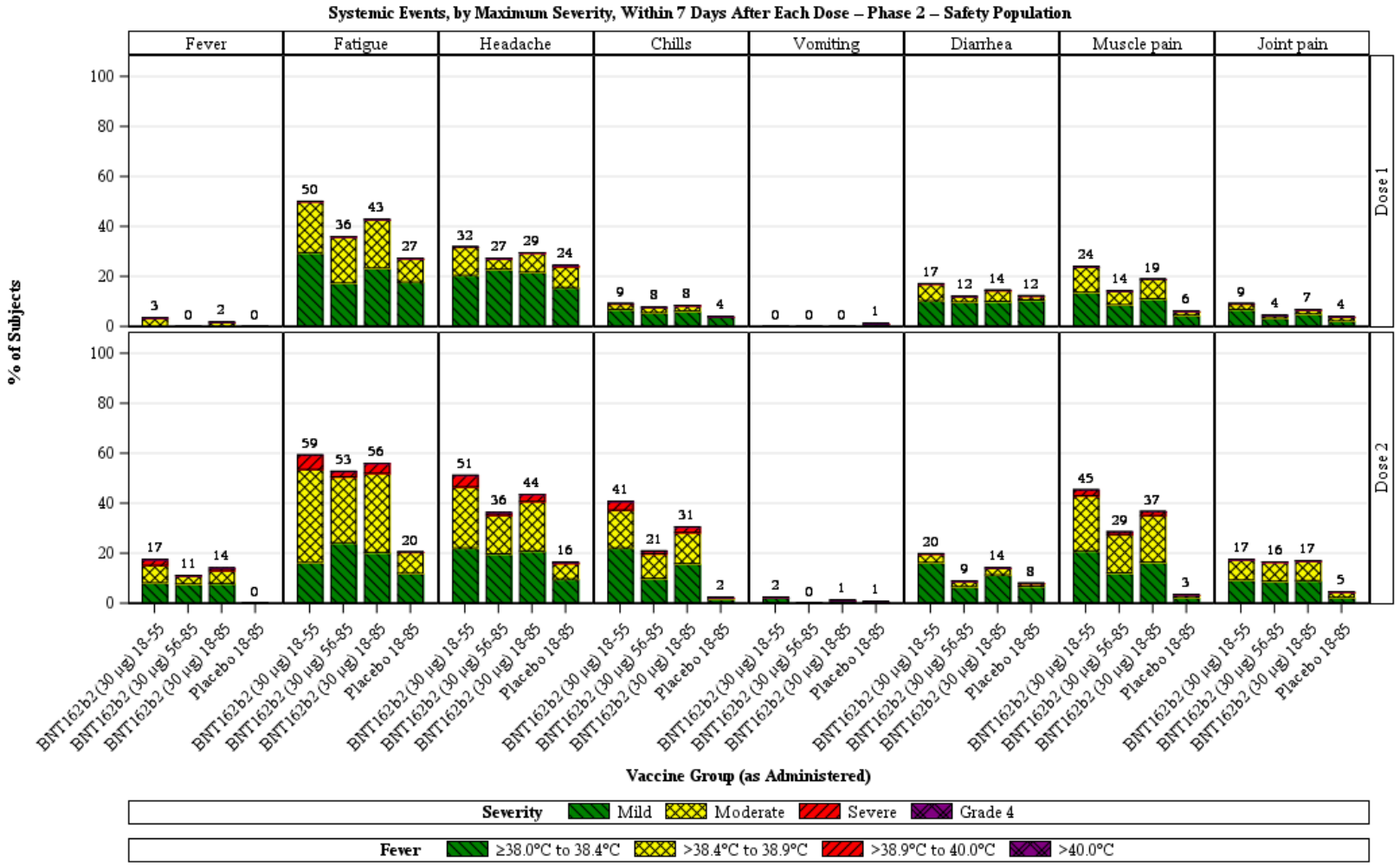
Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S1 = spike protein S1 subunit.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f003_s1_p2

14.25. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population



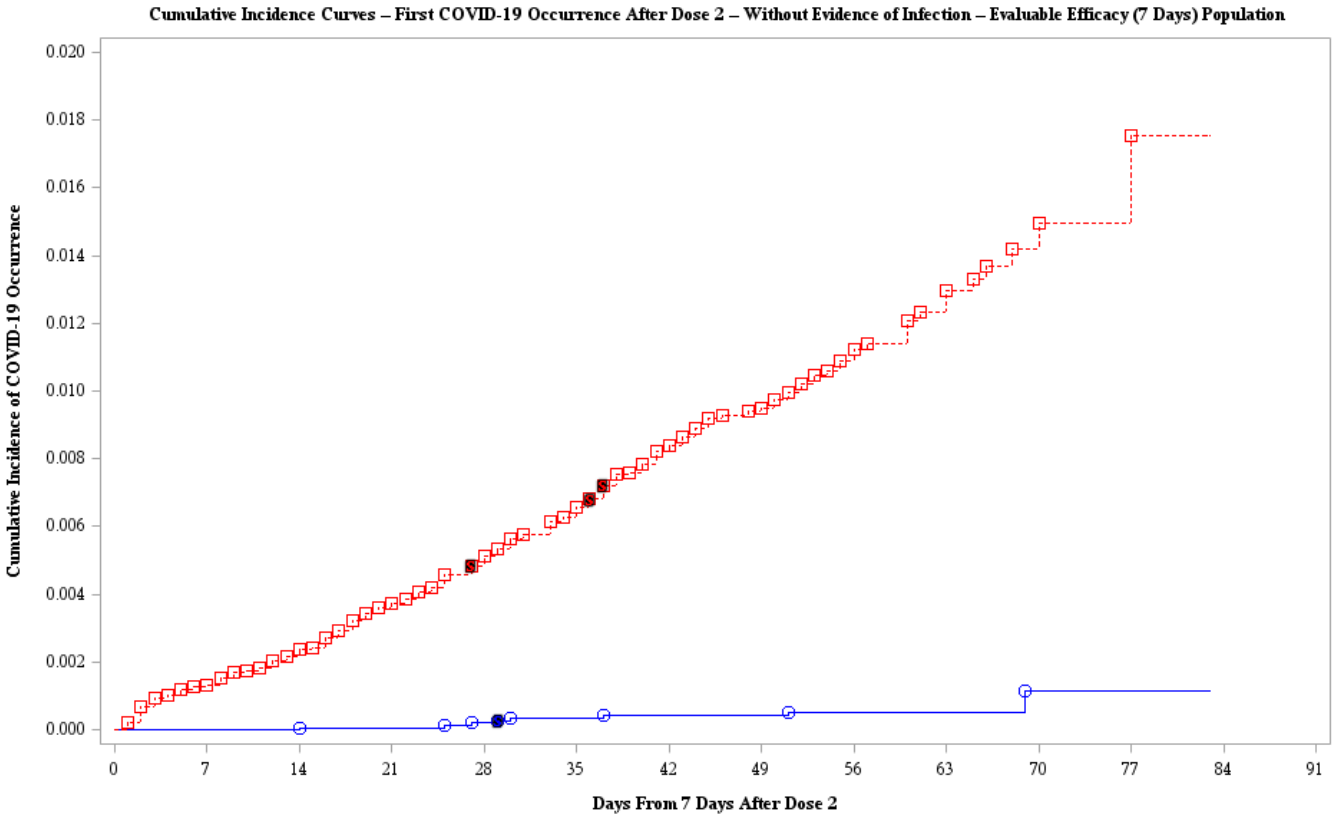
Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 11SEP2020 (17:39)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_f001_lr_maxsev_p2

14.26. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population



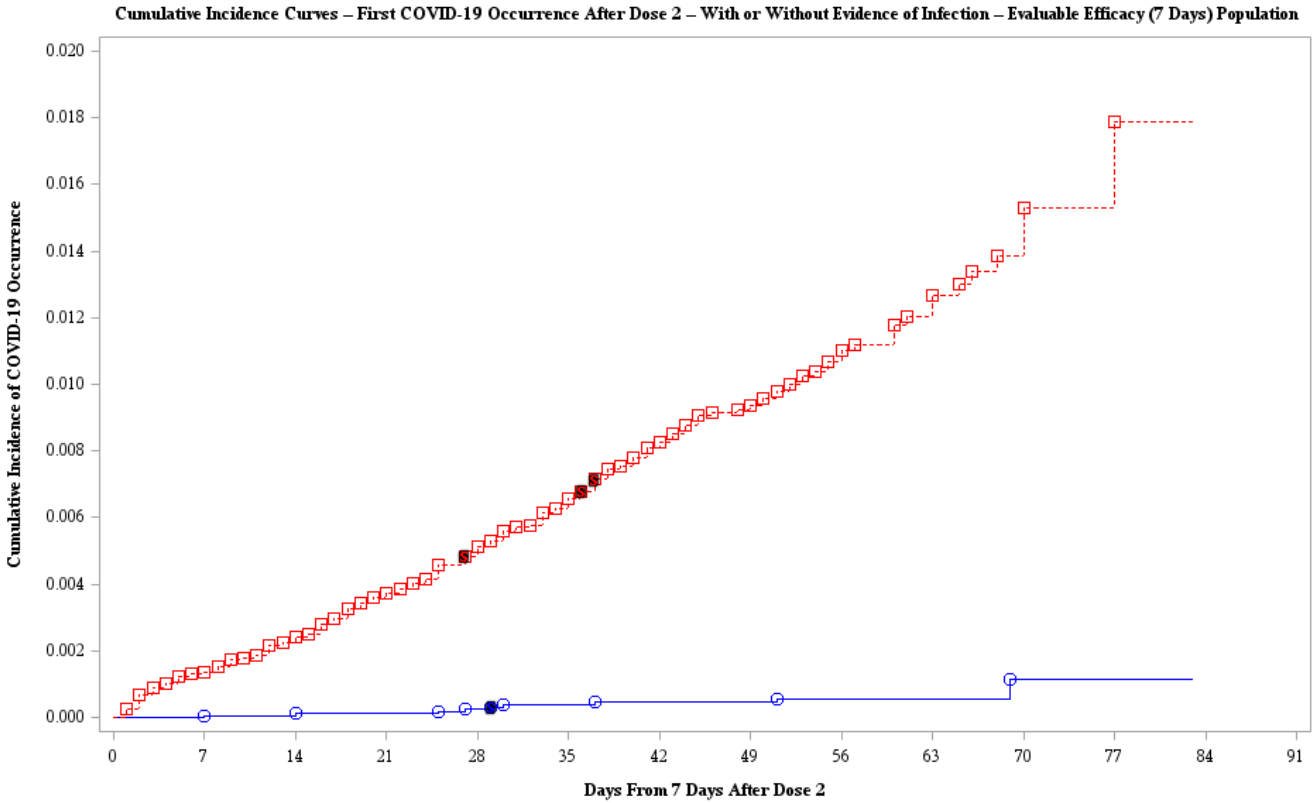
Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 11SEP2020 (17:39)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_f001_se_maxsev_p2

14.27. Cumulative Incidence Curves for the First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population



Note: "S" indicates subjects with severe COVID-19 or COVID-19 leading to hospitalization.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_f001_km_7d2_wo_eval

14.28. Cumulative Incidence Curves for the First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population



Note: "S" indicates subjects with severe COVID-19 or COVID-19 leading to hospitalization.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adc19ef Table Generation: 17NOV2020 (16:48)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: /nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_f001_km_7d2_eval

SUBJECT NARRATIVES

Primary Reason for Narrative	Subject Number
Death	Subject C4591001 1007 10071101
	Subject C4591001 1066 10661350
	Subject C4591001 1081 10811194
	Subject C4591001 1152 11521085
	Subject C4591001 1162 11621327
	Subject C4591001 1231 12313972
Related Serious Adverse Event	Subject C4591001 1015 10151047
	Subject C4591001 1018 10181159
	Subject C4591001 1142 11421247
	Subject C4591001 1178 11781107 (also Safety-Related Subject Withdrawal)
Safety-Related Subject Withdrawal	Subject C4591001 1005 10051214
	Subject C4591001 1006 10061020
	Subject C4591001 1011 10111181
	Subject C4591001 1012 10121163
	Subject C4591001 1015 10151134
	Subject C4591001 1016 10161087
	Subject C4591001 1027 10271105
	Subject C4591001 1037 10371252
	Subject C4591001 1054 10541186
	Subject C4591001 1055 10551145
	Subject C4591001 1071 10711023
	Subject C4591001 1071 10711169
	Subject C4591001 1079 10791004
	Subject C4591001 1083 10831029
	Subject C4591001 1083 10831060
	Subject C4591001 1087 10871121
	Subject C4591001 1087 10871228
	Subject C4591001 1087 10871557
	Subject C4591001 1090 10901415

Subject C4591001 1090 10901507
Subject C4591001 1093 10931058
Subject C4591001 1095 10951141
Subject C4591001 1095 10951173
Subject C4591001 1096 10961031
Subject C4591001 1109 11091503
Subject C4591001 1112 11121118
Subject C4591001 1112 11121255
Subject C4591001 1112 11121337
Subject C4591001 1117 11171186
Subject C4591001 1120 11201127
Subject C4591001 1120 11201408
Subject C4591001 1122 11221026
Subject C4591001 1127 11271022
Subject C4591001 1133 11331170
Subject C4591001 1134 11341153
Subject C4591001 1134 11341174
Subject C4591001 1140 11401035
Subject C4591001 1140 11401306
Subject C4591001 1142 11421111
Subject C4591001 1145 11451076
Subject C4591001 1152 11521359
Subject C4591001 1152 11521476
Subject C4591001 1152 11521497
Subject C4591001 1156 11561015
Subject C4591001 1163 11631059
Subject C4591001 1166 11661047
Subject C4591001 1205 12051028
Subject C4591001 1224 12241012
Subject C4591001 1224 12241065
Subject C4591001 1226 12261072
Subject C4591001 1230 12301045
Subject C4591001 1231 12311409
Subject C4591001 1231 12311926
Subject C4591001 1231 12312577
Subject C4591001 1231 12312982
Subject C4591001 1231 12315429
Subject C4591001 1231 12315441

Subject C4591001 1232 12321213
Subject C4591001 1232 12321293
Subject C4591001 1241 12411279
Subject C4591001 1241 12411766
Subject C4591001 1246 12461025
Subject C4591001 1247 12471121
Subject C4591001 1247 12471135
Subject C4591001 1248 12481218
Subject C4591001 1254 12541142
Subject C4591001 1270 12701057
Subject C4591001 4444 44441979

Other Serious Adverse Event

Subject C4591001 1003 10031065
Subject C4591001 1003 10031113
Subject C4591001 1003 10031149
Subject C4591001 1005 10051054
Subject C4591001 1005 10051069
Subject C4591001 1005 10051293
Subject C4591001 1006 10061098
Subject C4591001 1007 10071276
Subject C4591001 1007 10071347
Subject C4591001 1008 10081184
Subject C4591001 1008 10081603
Subject C4591001 1009 10091135
Subject C4591001 1011 10111029
Subject C4591001 1013 10131084
Subject C4591001 1013 10131176
Subject C4591001 1013 10131517
Subject C4591001 1016 10161277
Subject C4591001 1016 10161289
Subject C4591001 1018 10181132
Subject C4591001 1019 10191010
Subject C4591001 1019 10191037
Subject C4591001 1019 10191146
Subject C4591001 1019 10191229
Subject C4591001 1019 10191254
Subject C4591001 1021 10211190

Subject C4591001 1027 10271054
Subject C4591001 1028 10281059
Subject C4591001 1028 10281060
Subject C4591001 1038 10381101
Subject C4591001 1042 10421166
Subject C4591001 1044 10441093
Subject C4591001 1047 10471114
Subject C4591001 1054 10541173
Subject C4591001 1055 10551153
Subject C4591001 1055 10551176
Subject C4591001 1057 10571052
Subject C4591001 1057 10571137
Subject C4591001 1057 10571327
Subject C4591001 1072 10721007
Subject C4591001 1079 10791228
Subject C4591001 1079 10791246
Subject C4591001 1080 10801013
Subject C4591001 1080 10801152
Subject C4591001 1081 10811026
Subject C4591001 1081 10811036
Subject C4591001 1081 10811046
Subject C4591001 1081 10811110
Subject C4591001 1081 10811135
Subject C4591001 1082 10821076
Subject C4591001 1082 10821094
Subject C4591001 1083 10831194
Subject C4591001 1084 10841219
Subject C4591001 1084 10841317
Subject C4591001 1084 10841480
Subject C4591001 1085 10851216
Subject C4591001 1087 10871029
Subject C4591001 1087 10871070
Subject C4591001 1087 10871150
Subject C4591001 1088 10881220
Subject C4591001 1089 10891150
Subject C4591001 1089 10891182
Subject C4591001 1090 10901300
Subject C4591001 1091 10911197

Subject C4591001 1091 10911300
Subject C4591001 1092 10921015
Subject C4591001 1092 10921123
Subject C4591001 1092 10921187
Subject C4591001 1094 10941155
Subject C4591001 1095 10951101
Subject C4591001 1095 10951107
Subject C4591001 1095 10951180
Subject C4591001 1095 10951204
Subject C4591001 1095 10951228
Subject C4591001 1096 10961044
Subject C4591001 1096 10961062
Subject C4591001 1097 10971011
Subject C4591001 1097 10971017
Subject C4591001 1097 10971025
Subject C4591001 1097 10971061
Subject C4591001 1097 10971084
Subject C4591001 1098 10981024
Subject C4591001 1107 11071044
Subject C4591001 1107 11071065
Subject C4591001 1109 11091111
Subject C4591001 1109 11091164
Subject C4591001 1109 11091204
Subject C4591001 1109 11091276
Subject C4591001 1109 11091387
Subject C4591001 1109 11091448
Subject C4591001 1109 11091558
Subject C4591001 1110 11101031
Subject C4591001 1111 11111095
Subject C4591001 1111 11111109
Subject C4591001 1111 11111130
Subject C4591001 1111 11111193
Subject C4591001 1114 11141080
Subject C4591001 1116 11161045
Subject C4591001 1116 11161059
Subject C4591001 1117 11171036
Subject C4591001 1118 11181044
Subject C4591001 1118 11181057

Subject C4591001 1118 11181074
Subject C4591001 1124 11241106
Subject C4591001 1127 11271023
Subject C4591001 1128 11281014
Subject C4591001 1128 11281103
Subject C4591001 1129 11291074
Subject C4591001 1129 11291138
Subject C4591001 1131 11311145
Subject C4591001 1131 11311222
Subject C4591001 1133 11331006
Subject C4591001 1134 11341058
Subject C4591001 1134 11341250
Subject C4591001 1135 11351143
Subject C4591001 1140 11401002
Subject C4591001 1140 11401009
Subject C4591001 1140 11401078
Subject C4591001 1140 11401244
Subject C4591001 1142 11421032
Subject C4591001 1142 11421044
Subject C4591001 1142 11421084
Subject C4591001 1145 11451056
Subject C4591001 1145 11451063
Subject C4591001 1146 11461161
Subject C4591001 1146 11461200
Subject C4591001 1146 11461264
Subject C4591001 1147 11471239
Subject C4591001 1149 11491313
Subject C4591001 1150 11501001
Subject C4591001 1152 11521095
Subject C4591001 1152 11521260
Subject C4591001 1156 11561001
Subject C4591001 1156 11561006
Subject C4591001 1156 11561007
Subject C4591001 1157 11571134
Subject C4591001 1161 11611029
Subject C4591001 1162 11621059
Subject C4591001 1167 11671009
Subject C4591001 1167 11671085

Subject C4591001 1167 11671175
Subject C4591001 1170 11701217
Subject C4591001 1174 11741042
Subject C4591001 1178 11781015
Subject C4591001 1178 11781025
Subject C4591001 1178 11781048
Subject C4591001 1178 11781138
Subject C4591001 1178 11781167
Subject C4591001 1195 11951023
Subject C4591001 1221 12211007
Subject C4591001 1223 12231097
Subject C4591001 1223 12231159
Subject C4591001 1223 12231166
Subject C4591001 1223 12231182
Subject C4591001 1226 12261067
Subject C4591001 1226 12261137
Subject C4591001 1226 12261282
Subject C4591001 1226 12261300
Subject C4591001 1226 12261571
Subject C4591001 1226 12261745
Subject C4591001 1226 12261769
Subject C4591001 1226 12262089
Subject C4591001 1226 12262240
Subject C4591001 1230 12301025
Subject C4591001 1231 12311205
Subject C4591001 1231 12311281
Subject C4591001 1231 12311315
Subject C4591001 1231 12311352
Subject C4591001 1231 12311579
Subject C4591001 1231 12311711
Subject C4591001 1231 12311766
Subject C4591001 1231 12311834
Subject C4591001 1231 12311844
Subject C4591001 1231 12311946
Subject C4591001 1231 12312390
Subject C4591001 1231 12312576
Subject C4591001 1231 12312593
Subject C4591001 1231 12312854

Subject C4591001 1231 12312868
Subject C4591001 1231 12312914
Subject C4591001 1231 12313193
Subject C4591001 1231 12313621
Subject C4591001 1231 12313653
Subject C4591001 1231 12313674
Subject C4591001 1231 12313783
Subject C4591001 1231 12314001
Subject C4591001 1231 12314035
Subject C4591001 1231 12314216
Subject C4591001 1231 12314407
Subject C4591001 1231 12314833
Subject C4591001 1231 12314898
Subject C4591001 1231 12315291
Subject C4591001 1231 12315473
Subject C4591001 1231 12315632
Subject C4591001 1231 12315653
Subject C4591001 1241 12411206
Subject C4591001 1241 12411643
Subject C4591001 1241 12411825
Subject C4591001 1241 12412191
Subject C4591001 1246 12461035
Subject C4591001 1248 12481120
Subject C4591001 1248 12481163
Subject C4591001 1251 12511050
Subject C4591001 1260 12601037
Subject C4591001 1260 12601069
Subject C4591001 1261 12611006
Subject C4591001 1265 12651101
Subject C4591001 1270 12701069
Subject C4591001 4444 44441007
Subject C4591001 4444 44441249
Subject C4591001 4444 44441748

COVID-19 Case (Evaluable and/or Severe)

Subject C4591001 1003 10031122
Subject C4591001 1006 10061012

Subject C4591001 1006 10061066
Subject C4591001 1006 10061084
Subject C4591001 1006 10061091
Subject C4591001 1006 10061114
Subject C4591001 1008 10081011
Subject C4591001 1008 10081048
Subject C4591001 1008 10081130
Subject C4591001 1008 10081214
Subject C4591001 1008 10081319
Subject C4591001 1008 10081356
Subject C4591001 1009 10091128
Subject C4591001 1013 10131288
Subject C4591001 1013 10131475
Subject C4591001 1016 10161003
Subject C4591001 1016 10161004
Subject C4591001 1016 10161017
Subject C4591001 1016 10161035
Subject C4591001 1016 10161048
Subject C4591001 1016 10161183
Subject C4591001 1016 10161207
Subject C4591001 1018 10181198
Subject C4591001 1019 10191038
Subject C4591001 1019 10191184
Subject C4591001 1028 10281038
Subject C4591001 1028 10281100
Subject C4591001 1028 10281132
Subject C4591001 1028 10281138
Subject C4591001 1037 10371036
Subject C4591001 1037 10371280
Subject C4591001 1038 10381051
Subject C4591001 1039 10391025
Subject C4591001 1046 10461058
Subject C4591001 1047 10471024
Subject C4591001 1047 10471252
Subject C4591001 1068 10681082
Subject C4591001 1068 10681110
Subject C4591001 1071 10711022
Subject C4591001 1071 10711058

Subject C4591001 1072 10721057
Subject C4591001 1077 10771195
Subject C4591001 1079 10791046
Subject C4591001 1079 10791054
Subject C4591001 1081 10811151
Subject C4591001 1082 10821016
Subject C4591001 1085 10851293
Subject C4591001 1088 10881219
Subject C4591001 1088 10881233
Subject C4591001 1089 10891235
Subject C4591001 1090 10901121
Subject C4591001 1090 10901353
Subject C4591001 1091 10911203
Subject C4591001 1092 10921021
Subject C4591001 1092 10921130
Subject C4591001 1093 10931081
Subject C4591001 1095 10951238
Subject C4591001 1095 10951260
Subject C4591001 1096 10961172
Subject C4591001 1096 10961258
Subject C4591001 1098 10981062
Subject C4591001 1101 11011095
Subject C4591001 1107 11071171
Subject C4591001 1109 11091067
Subject C4591001 1109 11091092
Subject C4591001 1109 11091323
Subject C4591001 1109 11091416
Subject C4591001 1109 11091448
Subject C4591001 1109 11091482
Subject C4591001 1110 11101050
Subject C4591001 1110 11101136
Subject C4591001 1110 11101162
Subject C4591001 1111 11111010
Subject C4591001 1116 11161075
Subject C4591001 1116 11161253
Subject C4591001 1117 11171010
Subject C4591001 1118 11181088
Subject C4591001 1120 11201115

Subject C4591001 1122 11221025
Subject C4591001 1123 11231073
Subject C4591001 1123 11231086
Subject C4591001 1123 11231117
Subject C4591001 1123 11231214
Subject C4591001 1123 11231255
Subject C4591001 1123 11231256
Subject C4591001 1123 11231284
Subject C4591001 1125 11251006
Subject C4591001 1125 11251014
Subject C4591001 1125 11251023
Subject C4591001 1125 11251028
Subject C4591001 1125 11251049
Subject C4591001 1125 11251109
Subject C4591001 1125 11251114
Subject C4591001 1125 11251124
Subject C4591001 1125 11251215
Subject C4591001 1126 11261017
Subject C4591001 1128 11281165
Subject C4591001 1131 11311100
Subject C4591001 1131 11311138
Subject C4591001 1133 11331209
Subject C4591001 1134 11341022
Subject C4591001 1135 11351207
Subject C4591001 1141 11411088
Subject C4591001 1141 11411161
Subject C4591001 1141 11411162
Subject C4591001 1149 11491113
Subject C4591001 1152 11521363
Subject C4591001 1152 11521372
Subject C4591001 1156 11561044
Subject C4591001 1162 11621075
Subject C4591001 1163 11631113
Subject C4591001 1163 11631135
Subject C4591001 1167 11671152
Subject C4591001 1167 11671157
Subject C4591001 1168 11681004
Subject C4591001 1168 11681007

Subject C4591001 1168 11681008
Subject C4591001 1168 11681114
Subject C4591001 1168 11681117
Subject C4591001 1170 11701089
Subject C4591001 1178 11781065
Subject C4591001 1178 11781238
Subject C4591001 1178 11781280
Subject C4591001 1179 11791085
Subject C4591001 1221 12211002
Subject C4591001 1223 12231005
Subject C4591001 1223 12231096
Subject C4591001 1226 12261309
Subject C4591001 1226 12261363
Subject C4591001 1226 12261599
Subject C4591001 1226 12261624
Subject C4591001 1226 12261660
Subject C4591001 1226 12261964
Subject C4591001 1226 12262111
Subject C4591001 1231 12311043
Subject C4591001 1231 12311267
Subject C4591001 1231 12311407
Subject C4591001 1231 12311531
Subject C4591001 1231 12311556
Subject C4591001 1231 12311560
Subject C4591001 1231 12311651
Subject C4591001 1231 12311664
Subject C4591001 1231 12311754
Subject C4591001 1231 12311764
Subject C4591001 1231 12311982
Subject C4591001 1231 12312479
Subject C4591001 1231 12312507
Subject C4591001 1231 12312630
Subject C4591001 1231 12312635
Subject C4591001 1231 12312867
Subject C4591001 1231 12312914
Subject C4591001 1231 12313182
Subject C4591001 1231 12313296
Subject C4591001 1231 12313400

	Subject C4591001 1231 12313422
	Subject C4591001 1231 12313520
	Subject C4591001 1231 12313668
	Subject C4591001 1231 12313787
	Subject C4591001 1231 12313895
	Subject C4591001 1231 12314112
	Subject C4591001 1231 12314308
	Subject C4591001 1231 12314534
	Subject C4591001 1231 12314622
	Subject C4591001 1231 12315636
	Subject C4591001 1231 12315637
	Subject C4591001 1235 12351071
	Subject C4591001 1235 12351093
	Subject C4591001 1241 12412017
	Subject C4591001 1241 12412018
	Subject C4591001 1251 12511159
	Subject C4591001 4444 44441092
	Subject C4591001 4444 44441144
	Subject C4591001 4444 44441204
	Subject C4591001 4444 44441224
	Subject C4591001 4444 44441563
	Subject C4591001 4444 44442304
COVID-19 Case (Not Evaluable or Severe)	
	Subject C4591001 1005 10051341
	Subject C4591001 1005 10051403
	Subject C4591001 1007 10071407
	Subject C4591001 1007 10071409
	Subject C4591001 1008 10081338
	Subject C4591001 1008 10081529
	Subject C4591001 1008 10081580
	Subject C4591001 1008 10081639
	Subject C4591001 1008 10081721
	Subject C4591001 1009 10091211
	Subject C4591001 1009 10091257
	Subject C4591001 1011 10111174
	Subject C4591001 1013 10131670

Subject C4591001 1016 10161305
Subject C4591001 1016 10161316
Subject C4591001 1016 10161319
Subject C4591001 1016 10161341
Subject C4591001 1024 10241130
Subject C4591001 1028 10281193
Subject C4591001 1028 10281229
Subject C4591001 1028 10281250
Subject C4591001 1028 10281294
Subject C4591001 1036 10361078
Subject C4591001 1038 10381103
Subject C4591001 1039 10391021
Subject C4591001 1068 10681033
Subject C4591001 1071 10711216
Subject C4591001 1071 10711228
Subject C4591001 1072 10721051
Subject C4591001 1079 10791162
Subject C4591001 1083 10831029
Subject C4591001 1085 10851286
Subject C4591001 1087 10871089
Subject C4591001 1087 10871209
Subject C4591001 1089 10891217
Subject C4591001 1091 10911014
Subject C4591001 1091 10911387
Subject C4591001 1092 10921158
Subject C4591001 1092 10921268
Subject C4591001 1093 10931014
Subject C4591001 1093 10931050
Subject C4591001 1093 10931148
Subject C4591001 1096 10961388
Subject C4591001 1097 10971103
Subject C4591001 1097 10971104
Subject C4591001 1098 10981029
Subject C4591001 1101 11011024
Subject C4591001 1109 11091556
Subject C4591001 1110 11101006
Subject C4591001 1110 11101072
Subject C4591001 1116 11161322

Subject C4591001 1120 11201335
Subject C4591001 1121 11211105
Subject C4591001 1123 11231025
Subject C4591001 1123 11231085
Subject C4591001 1123 11231144
Subject C4591001 1123 11231234
Subject C4591001 1123 11231313
Subject C4591001 1123 11231386
Subject C4591001 1125 11251107
Subject C4591001 1125 11251148
Subject C4591001 1125 11251222
Subject C4591001 1125 11251238
Subject C4591001 1127 11271099
Subject C4591001 1133 11331512
Subject C4591001 1135 11351148
Subject C4591001 1141 11411020
Subject C4591001 1147 11471004
Subject C4591001 1147 11471035
Subject C4591001 1149 11491066
Subject C4591001 1156 11561006
Subject C4591001 1156 11561033
Subject C4591001 1156 11561064
Subject C4591001 1162 11621044
Subject C4591001 1169 11691007
Subject C4591001 1169 11691058
Subject C4591001 1171 11711269
Subject C4591001 1174 11741053
Subject C4591001 1178 11781276
Subject C4591001 1179 11791138
Subject C4591001 1194 11941061
Subject C4591001 1203 12031037
Subject C4591001 1207 12071024
Subject C4591001 1209 12091013
Subject C4591001 1226 12261360
Subject C4591001 1226 12261894
Subject C4591001 1226 12262189
Subject C4591001 1226 12262267
Subject C4591001 1231 12311054

Subject C4591001 1231 12311087
Subject C4591001 1231 12311147
Subject C4591001 1231 12311195
Subject C4591001 1231 12311356
Subject C4591001 1231 12311391
Subject C4591001 1231 12311431
Subject C4591001 1231 12311532
Subject C4591001 1231 12311549
Subject C4591001 1231 12311568
Subject C4591001 1231 12311641
Subject C4591001 1231 12311656
Subject C4591001 1231 12311911
Subject C4591001 1231 12312130
Subject C4591001 1231 12312320
Subject C4591001 1231 12312334
Subject C4591001 1231 12312339
Subject C4591001 1231 12312375
Subject C4591001 1231 12312571
Subject C4591001 1231 12312660
Subject C4591001 1231 12312679
Subject C4591001 1231 12312752
Subject C4591001 1231 12312763
Subject C4591001 1231 12312805
Subject C4591001 1231 12313006
Subject C4591001 1231 12313068
Subject C4591001 1231 12313069
Subject C4591001 1231 12313090
Subject C4591001 1231 12313103
Subject C4591001 1231 12313125
Subject C4591001 1231 12313225
Subject C4591001 1231 12313357
Subject C4591001 1231 12313395
Subject C4591001 1231 12313457
Subject C4591001 1231 12313510
Subject C4591001 1231 12313657
Subject C4591001 1231 12313662
Subject C4591001 1231 12313709
Subject C4591001 1231 12314301

Subject C4591001 1231 12314314
Subject C4591001 1231 12314477
Subject C4591001 1231 12314492
Subject C4591001 1231 12314700
Subject C4591001 1235 12351027
Subject C4591001 1235 12351187
Subject C4591001 1235 12351188
Subject C4591001 1241 12411260
Subject C4591001 1241 12411688
Subject C4591001 1241 12411695
Subject C4591001 1241 12411885
Subject C4591001 1241 12412215
Subject C4591001 1241 12412355
Subject C4591001 1241 12412568
Subject C4591001 1247 12471066
Subject C4591001 1247 12471085
Subject C4591001 1251 12511207
Subject C4591001 1251 12511209
Subject C4591001 4444 44441025
Subject C4591001 4444 44441044
Subject C4591001 4444 44441253
Subject C4591001 4444 44441560
Subject C4591001 4444 44441787
Subject C4591001 4444 44442188

15. REFERENCES

1. Virus Pathogen Resource (ViPR). Strain details for severe acute respiratory syndrome-related coronavirus strain Wuhan-Hu-1 [Internet]. Available from: https://www.viprbrc.org/brc/viprStrainDetails.spg?ncbiAccession=MN908947&decorator=corona. Accessed: 11 August 2020.
2. Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020;382(8):727-33.
3. World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19. [Internet]. Available from: https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Published: 11 March 2020. Accessed: 01 April 2020.
4. Johns Hopkins University & Medicine, Coronavirus Resource Center. COVID-19 dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU) [Internet]. Available from: https://coronavirus.jhu.edu/map.html. Accessed: 23 September 2020.
5. Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19): information for clinicians on investigational therapeutics for patients with COVID-19. [Internet]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html. Updated: 25 April 2020. Accessed: 26 June 2020.
6. Rauch S, Jasny E, Schmidt KE, et al. New vaccine technologies to combat outbreak situations. Front Immunol. 2018;9:1963.
7. Sahin U, Kariko K, Tureci O. mRNA-based therapeutics--developing a new class of drugs. Nat Rev Drug Discov. 2014;13(10):759-80.
8. BNT162 Investigator's Brochure. 12 August 2020.
9. Walsh EE, Frenck R, Falsey AR, et al. RNA-based COVID-19 vaccine BNT162b2 selected for a pivotal efficacy study. medRxiv. 2020;10.1101/2020.08.17.20176651.
10. Kranz LM, Diken M, Haas H, et al. Systemic RNA delivery to dendritic cells exploits antiviral defence for cancer immunotherapy. Nature. 2016;534(7607):396-401.
11. Kamphuis E, Junt T, Waibler Z, et al. Type I interferons directly regulate lymphocyte recirculation and cause transient blood lymphopenia. Blood. 2006;108(10):3253-61.
12. Walsh EE, Frenck RW, Falsey AR, et al. Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. 2020;10.1056/NEJMoa2027906.
13. Vogel AB, Kanevsky I, Che Y, et al. A prefusion SARS-CoV-2 spike RNA vaccine is highly immunogenic and prevents lung infection in non-human primates. 2020;10.1101/2020.09.08.280818 %J bioRxiv:2020.09.08.280818.