Analysis Data Reviewer Guide

BLA Analysis for Participants ≥16 Years of Age

BioNTech SE and PFIZER INC.

Study C4591001

ANALYSIS DATA REVIEWER GUIDE REVISION HISTORY

Version	Summary of Major Change(s) and Impact	Version Date
1.0	First approved version of Analysis Data Reviewer Guide	3-May-2021

Analysis Data Reviewer Guide

Contents

1. Introduction

1.1 Purpose

This document provides context for the analysis datasets and terminology that benefit from additional explanation beyond the Data Definition document (define.xml) for an individual study. In addition, this document provides a summary of ADaM conformance findings. This ADRG does not include asymptomatic surveillance, asymptomatic infection analysis, manufacturing process 1 process 2 lot analysis, Phase 1 booster analysis and Phase 2/3 booster and new variant strain analysis. This ADRG covers:

- Updated Efficacy analyses in blinded placebo-controlled follow-up evaluated duration of protection (data cutoff date: 13 March 2021).
- Immunogenicity analyses of adults (18 to 85 years of age) including data up to 1 month after Dose 2 in Phase 2, and up to 6 months after Dose 2 in Phase 1.
- Safety data presented for
  - Blinded placebo-controlled period: Dose 1 to 1 month after Dose 2 and to unblinding date:
    - Phase 1 participants randomized to BNT162b2 30µg
    - Phase 2/3 participants including HIV+ subset
  - Open-label observational period: from time of unblinding to data cutoff date:
    - Phase 2/3 participants originally randomized to BNT162b2 30µg
    - Phase 2/3 participants originally randomized to placebo who then received BNT162b2 30µg

Cumulative follow-up from Dose 1 to 6 months after Dose 2: Phase 2/3 participants originally randomized to BNT162b2 (inclusive of blinded data and open-label data), comprised of at least 3000 in each age group (16 to 55 years of age, >55 years of age)

1.2 Acronyms

Acronym	Translation
ADaM	Analysis Dataset Model
ADRG	Analysis Data Reviewer's Guide
AE	Adverse Event
BLA	Biologics License Application
COVID-19	Coronavirus Disease 2019
eCRF	Electronic Case Report Form
eDT	Electronic Data Transfer (e.g. central lab data, ECG vendor data, PK data, etc.)
EUA	Emergency Use Authorization
HIV	Human Immunodeficiency Virus
ICD	Informed Consent Document
IG	Implementation Guide
IWR	Interactive Web-based Response
LAR	Legally Acceptable Representative
LLOQ	Lower Limit of Quantification
MedDRA	Medical Dictionary for Regulatory Activities
modRNA	nucleoside-modified messenger ribonucleic acid
NA	Not Applicable
NAAT	nucleic acid amplification test
PI	principal investigator
SAP	Statistical Analysis Plan
SDTM	Study Data Tabulation Model
SoA	Schedule of Activities
TAUG	Therapeutic Area User Guide
WHO	World Health Organization
VE	Vaccine Efficacy
WHO DDE	WHO Drug Dictionary Enhanced
WOCBP	Women of childbearing potential

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	•SDTM v1.4 •SDTM-IG v3.2
SDTM Controlled Terminology	CDISC SDTM Controlled Terminology, 2020-03-27
ADaM	•ADaM v2.1 •ADaM-IG v1.1
ADaM Controlled Terminology	CDISC ADaM Controlled Terminology, 2020-03-27
Data Definitions	Define-XML v2.0
Medications Dictionary	WHO DDE v202003
Medical Events Dictionary	MedDRA v23.1
Pinnacle 21	Pinnacle 21 Enterprise 4.1.4

1.4 Source Data Used for Analysis Dataset Creation

For analysis, a data cutoff of 13Mar2021 was applied on SDTM data. Furthermore, any data related to the booster portion of the Phase 1 subjects was also programmatically excluded from SDTM data.

The ADaM datasets for this study were derived from the SDTM datasets.

External files used during ADaM dataset creation are listed in Appendix V.

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number: C4591001

Protocol Short Title: A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals.

Note: Protocol Amendment's 13, 14 and beyond mentioned elsewhere in the submission documentation are out of scope for this BLA and have not been included in this ADRG.

Protocol Versions:

Amendment 12: 2020-01-08

- Because of a formatting error in protocol amendment 11, exclusion criterion 4 was inadvertently added to exclusion criterion 3 and the subsequent criteria renumbered. This amendment corrects that error.

Amendment 11: 2020-01-04

- Added a potential intensive surveillance period for nasal swabbing, for assessment via NAAT:
  - Corresponding SoA and procedures added

Amendment 10: 2020-12-01

- Added the possibility of administering BNT162b2 to participants who originally received placebo, following any local or national recommendations.
- Added the possibility of administering BNT162b2 to participants who originally received placebo, following completion of the active safety surveillance period.

Amendment 9: 2020-10-29

- To better align with the natural history of SARS-CoV-2 infection, added Phase 2/3 secondary efficacy objectives, estimands, and endpoints to include COVID-19 cases that occur from 14 days after the second dose; also modified the existing secondary efficacy objectives, estimands, and endpoints to include COVID-19 cases that occur from 14 days, as well as 7 days, after the second dose;
    - Made corresponding changes to the study design, study assessments and procedures, and statistical analysis sections.
- Clarified that interim analyses will be conducted after accrual of at least 62, 92, and 120 cases.
- Included any participants 16 through 17 years of age enrolled under this amendment in the reactogenicity subset.
- Clarified that serology data after a postbaseline positive SARS-CoV-2 test result will not be included in the analysis based on the evaluable immunogenicity populations.

Amendment 8: 2020-10-15

- Clarified that for participants who are not in the reactogenicity subset, local reactions and systemic events following vaccination should be detected and reported as AEs.
- Clarified that premenarchal females are not WOCBP.

Amendment 7: 2020-10-06

- Reduced the lower age range to include adolescents 12 to 15 years of age and added corresponding objectives.
- Added that 2 periods of potential COVID-19 symptoms within 4 days will be considered as a single illness.

Amendment 6: 2020-09-08

- Removed exclusion criterion 2 (ie, known infection with HIV, HCV, or HBV) for Phase 3 and added criteria for HIV-positive participants.
- Decreased the lower age limit and removed the upper age limit for inclusion in Phase 2/3 in order to evaluate BNT162b2 30 μg in older adolescents and those over 85 years of age; updated the title and other references to adults to align with this change.
- Clarified that inclusion criterion 4 (ie, participants at higher risk for acquiring COVID-19) is applicable for Phase 2/3 only, and provided some examples

Amendment 5: 2020-07-24

- Clarified that a single vaccine candidate, administered as 2 doses 21 days apart, will be studied in Phase 2/3.
- Stated that the vaccine candidate selected for Phase 2/3 evaluation is BNT162b2 at a dose of 30 μg.
- Renamed Stage 1 to Phase 1, removed Stage 2, and renamed Stage 3 to Phase 2/3.

- Clarified which stopping rules apply to which phase of the study.
- Moved the immunogenicity objectives in Phase 2/3 to become exploratory.
- Modified exclusion criterion 5, so that participants with a previous clinical or microbiological diagnosis of COVID-19 are excluded from all phases of the study.

Amendment 4: 2020-06-30

- BNT162b3 candidate has been added to the protocol.
- Further nonclinical data are available to support the study of the BNT162b3 candidate in humans, and the candidate has been added to the protocol.
- The 6-month safety follow-up telephone contact has been changed to an in-person visit for Stage 3 participants, to allow collection of an immunogenicity blood sample.

Amendment 3: 2020-06-10

- 20-µg dose level is formally included for BNT162b1 and BNT162b2.
- In order to increase flexibility enrolling participants, an extended screening window (increased from 14 to 28 days) for sentinel participants in Stage 1 has been added. This is considered acceptable since eligible participants are expected to be either healthy or have stable medical conditions.

Amendment 2: 2020-05-27

- Added a 50-µg dose level for vaccine candidates based on the modRNA platform (ie, BNT162b1, BNT162b2, and BNT162b3).

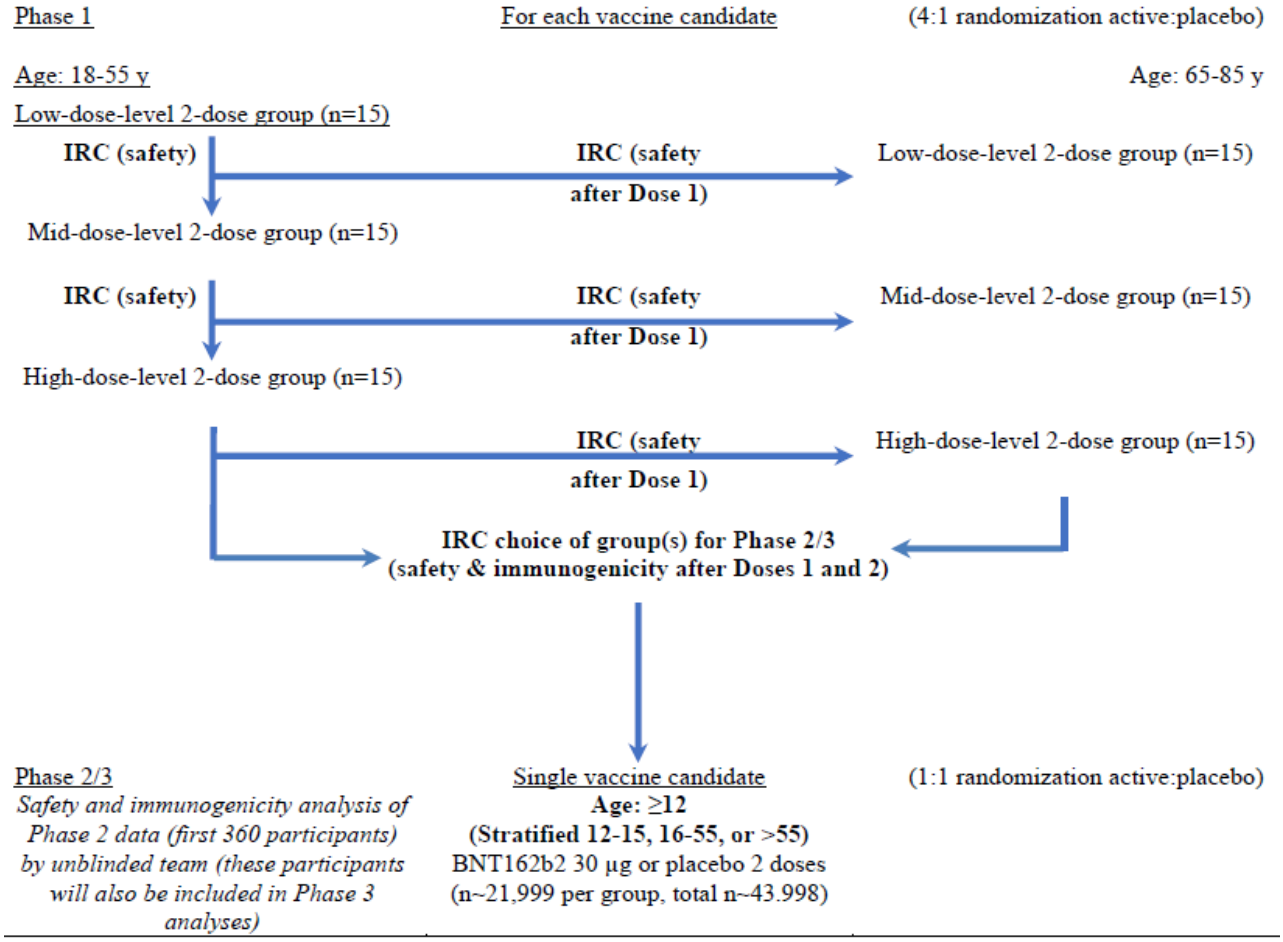
Amendment 1: 2020-05-13

- Decreased the dose levels for BNT162a1 and BNT162c2
- Modified exclusion criteria and prohibited inhaled/nebulized corticosteroids for sentinel participants in Stage 1.

Original Protocol 2020-04-15

2.2 Protocol Design in Relation to ADaM Concepts

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



Abbreviation: IRC = internal review committee.

Note: Participants who originally received placebo will be offered the opportunity to receive BNT162b2 at defined points as part of the study.

The study will evaluate the safety, tolerability, and immunogenicity of 3 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:

- As a 2-dose (separated by 21 days) schedule;
- At various dose levels in Phase 1;
- In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55, or >55 years of age]).

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

Phase 2/3 is event-driven. Under the assumption of a true VE rate of ≥60%, after the second dose of investigational product, a target of 164 primary-endpoint cases of confirmed COVID-19 due to SARS-CoV-2 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.

3. Analysis Considerations Related to Multiple Analysis Datasets

3.1 Study Populations and Core Variables

A description of the key analysis subject populations used in this study along with the subsetting criteria required to identify those subjects in each population from the ADaM datasets and the expected N associated with each analysis is described in detail in Appendix VIII Section 1.

Core variables are those that are represented across all/most analysis datasets.

Variable Type	Variable Name	Variable Description
Study/Site/ Subject ID variables	STUDYID	Study identifier used for this protocol
	USUBJID	Unique subject identifier
	SUBJID	Subject identifier for the study
	SITEID	Study site identifier
Demographics	AGE	Age at ICD
	AGETR01	Age at Dose 1
	AGEGR1	Pooled age group 1 (based on Age at Dose 1) Including following age categories: 12-15 Years; 16-55 Years; >55 Years for Phase 2/3 subjects. 18-55 Years; 65-85 Years for Phase 1 subjects.
	AGEGR1N	Pooled age group 1 (N): 1= 12-15 Years; 2= 16-55 Years; 3= 18-55 Years; 4= 65-85 Years; 5= >55 Years
	SEX	Sex: F=Female; M=Male
	ETHNIC	Ethnicity, Including HISPANIC OR LATINO; NOT HISPANIC OR LATINO; NOT REPORTED
	RACE	Race, including WHITE; BLACK OR AFRICAN AMERICAN; ASIAN; MULTIPLE; NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER; OTHER; NOT REPORTED
Baseline Status	COVBLST	Baseline SARS-CoV-2 status: Positive or Negative
	HIVFL	HIV positive subjects Flag
Treatment Variables	ARM	Description of Planned Arm
	ARMCD	Planned Arm Code
	ACTARM	Description of Actual Arm
	ACTARMCD	Actual Arm Code
	DOSALVL	Actual Dosing Level for Phase 1 subjects only
	DOSALVLN	Actual Dosing Level (N) for Phase 1 subjects only
	DOSPLVL	Planned Dosing Level for Phase 1 subjects only
	DOSPLVLN	Planned Dosing Level (N) for Phase 1 subjects only
	TRTSDTM	Datetime of first exposure to treatment
	TRTEDTM	Datetime of last exposure to treatment
	TR01SDTM	Datetime of first exposure to treatment for blinded placebo-controlled period
	TR01EDTM	Datetime of last exposure to treatment for blinded placebo-controlled period
	TR02SDTM	Datetime of first exposure to treatment for open label vaccination period
	TR02EDTM	Datetime of last exposure to treatment for open label vaccination period

Variable Type	Variable Name	Variable Description
	TRT01A	Actual Treatment for blinded placebo-controlled period
	TRT01AN	Actual Treatment for blinded placebo-controlled period (N)
	TRT01P	Planned Treatment for blinded placebo-controlled period
	TRT01PN	Planned Treatment for blinded placebo-controlled period (N)
	TRT02A	Actual Treatment for open label vaccination period
	TRT02AN	Actual Treatment for open label vaccination period (N)
	TRT02P	Planned Treatment for open label vaccination period
	TRT02PN	Planned Treatment for open label vaccination period (N)
	VAX101	Actual vaccination taken at Dose 1 for blinded placebo-controlled period
	VAX102	Actual vaccination taken at Dose 2 for blinded placebo-controlled period
	VAX10U	Actual vaccination taken at unplanned dose for blinded placebo-controlled period
	VAX201	Actual vaccination taken at Dose 1 for open label vaccination period
	VAX202	Actual vaccination taken at Dose 2 for open label vaccination period
	VAX20U	Actual vaccination taken at unplanned dose for open label vaccination period
	VAX101DT	Date of Dose 1 for blinded placebo-controlled period
	VAX102DT	Date of Dose 2 for blinded placebo-controlled period
	VAX10UDT	Date of unplanned dose for blinded placebo-controlled period
	VAX201DT	Date of Dose 1 for open label vaccination period
	VAX202DT	Date of Dose 2 for open label vaccination period
	VAX20UDT	Date of unplanned dose for open label vaccination period
Study Phase	PHASE	Study Phase "Phase 1" for subjects from Phase 1; "Phase 2_ds360/ds6000" for subjects from Phase 2; "Phase 3_ds6000" for subjects from Phase 3 and included in DS6000; "Phase 3" for other subjects from Phase 3 DS360 indicates the 360 Phase 2 subjects. DS6000 indicates first 6000 subjects from Phase 3 with 3000 subjects receiving actual treatment, and 3000 subjects receiving placebo.

Variable Type	Variable Name	Variable Description
		See more details in Appendix V
	PHASEN	Study phase (N). 1 = Phase 1; 2 = Phase 2_ds360/ds6000; 3 = Phase 3_ds6000; 4 = Phase 3
Date/Time variables	UNBLNDDT	Treatment unblinding date This is the start date of open-label follow up/vaccination period for subjects who were unblinded
	BDCSRDT	Censor date for blinded placebo-controlled follow up period. This date is the earliest date of the day before treatment unblinding date UNBLNDDT (if applicable), the day before first dose date of BNT162b2 at open label vaccination period (if applicable), end of study date (if applicable), complete of study date (if applicable) and the date of cutoff (13Mar2021). This date is used for AE incidence rate summary table (Exposure adjusted) for blinded placebo-controlled follow up period.
	X1CSRDT	Censor date for open label follow up period. This date is the earliest date of end of study date (if applicable), complete of study date (if applicable) and the date of cutoff (13Mar2021). This date is used for AE incidence rate summary table for open label follow up period.
Population Flags**	DS3KFL	Flag of phase2/3 subjects with at least 6 months of follow-up time after Dose 2 (28*6=168) days after Dose 2 by the date of cutoff) for subjects originally received BNT162b2. This flag is used to subset the subjects for AE summary tables with reporting period from Dose 1 to 6-month after Dose 2 regardless of unblinding or not. There are 12006 subjects in total from safety population by excluding the subjects with multiple sites.
	MULENRFL	Subjects with multiple sites are excluded from all analysis. Note: Subjects flagged as YES-POP4 in variable SUPPDV.QNAM = "CAPE" are the subjects with multiple sites and were excluded from all of summary analysis.
	REACTOFL	Population flag for subjects from reactogenicity subset
	PEDIMMFL	Population flag for 12-15/16-25 years of age subjects in immunogenicity subset (280 subjects from active group and 50 subjects from placebo group for each age group) These 660 subjects were randomly selected for immunobridging assessment.

Variable Type	Variable Name	Variable Description
	PEDREAFL	Population flag for 12-15/16-25 years of age reactogenicity subset
	EV1MD2FL	Population flag for subjects without evidence of infection up to 1 Month After Dose 2
	ENRLFL	Enrolled population flag defined as: All participants who have a signed ICD.
	RANDFL	Randomized population flag defined as: All participants who are assigned a randomization number in the IWR system.
	RAND1FL	Randomized population by excluding the subjects with multiple sites
	SAFFL	Safety population flag defined as: All randomized participants who receive at least 1 dose of the study intervention. Analyses of reactogenicity endpoints will be based on a subset of the safety population that includes participants with any e-diary data reported after vaccination Note: Subjects flagged as both YES-POP1 and YES-POP5 in variable SUPPDV.QNAM = "CAPE" were excluded from safety population for unreliable data due to lack of principal investigator oversight.
	SAF1FL	Safety population by excluding multiply enrolled subjects, HIV positive subjects and subjects with all doses indeterminate
	SAF2FL	Safety population by excluding multiply enrolled subjects and subjects with all doses indeterminate
	AAI01FL	Dose 1 all-available Immunogenicity Population Flag defined as: For Phase 1 only: all randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2.
	AAI02FL	Dose 2 all-available Immunogenicity Population Flag defined as: All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2. Note: Subjects flagged as YES-POP5 in variable SUPPDV.QNAM = "CAPE" were excluded from all-available immunogenicity population for unreliable data due to lack of principal investigator oversight.
	EVAL01FL	Dose 1 evaluable Immunogenicity Population Flag defined as: For Phase 1 only, all eligible randomized

Variable Type	Variable Name	Variable Description
		participants who receive the vaccine to which they are randomly assigned at the first dose, have 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 have no other important protocol deviations as determined by the clinician.
	EVAL02FL	Dose 2 evaluable Immunogenicity Population Flag defined as: All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, with Dose 2 received within the predefined window (within 19-42 days after Dose 1), have at least 1 valid and determinate immunogenicity result after Dose 2 from the blood collection within an appropriate window after Dose 2 (within 6-8 days after Dose 2 for Phase 1 and within 28-42 days after Dose 2 for Phase 2/3), and have no other important protocol deviations as determined by the clinician. Note: Subjects flagged as YES-POP3 in variable SUPPDV.QNAM = "CAPE" were excluded from evaluable immunogenicity population due to important protocol deviation identified by clinical.
	AAI1EFFL	Dose 1 all-available efficacy population flag defined as: All randomized participants who receive at least 1 vaccination. Used for efficacy analysis. Note: Subjects flagged as YES-POP5 in variable SUPPDV.QNAM = "CAPE" were excluded from all-available efficacy population for unreliable data due to lack of principal investigator oversight.
	AAI2EFFL	Dose 2 all-available efficacy population flag defined as: All randomized participants who complete 2 vaccination doses. Used for efficacy analysis. Note: Subjects flagged as YES-POP5 in variable SUPPDV.QNAM = "CAPE" were excluded from all-available efficacy population for unreliable data due to lack of principal investigator oversight.
	EVALEFFL	Evaluable efficacy population flag (7 days) defined as: All eligible randomized participants who receive all vaccination(s) as randomized, with Dose 2

Variable Type	Variable Name	Variable Description
		received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2. Used for efficacy analysis. Note: Subjects flagged as YES-POP2 in variable SUPPDV.QNAM = "CAPE" were excluded from evaluable efficacy population due to important protocol deviation identified by clinical.

**See Appendix VIII for additional variables used when subsetting data for each analysis.

3.2 Treatment Variable

ARM versus TRTxxP

Are the values of ARM equivalent in meaning to values of TRTxxP?

No, TRT01P is null when ARM equals to "NOT ASSIGNED" or "SCREEN FAILURE". ARM represents the planned arm for the blinded placebo-controlled period based on randomization file. TRT01P has the planned treatment for the blinded placebo-controlled period. TRT02P has the planned treatments of open label vaccination period for subjects who received placebo only in the blinded placebo-controlled period and become eligible for receipt of BNT162b2 after unblinding. See details in below table.

PHASE	ARM	TRT01P	TRT02P
Phase 1	BNT162b1 Phase 1 (10 mcg)	BNT162b1 Phase 1 (10 mcg)	-
	BNT162b1 Phase 1 (20 mcg)	BNT162b1 Phase 1 (20 mcg)	-
	BNT162b1 Phase 1 (30 mcg)	BNT162b1 Phase 1 (30 mcg)	-
	BNT162b1 Phase 1 (100/10 mcg)	BNT162b1 Phase 1 (100/10 mcg)	-
	BNT162b2 Phase 1 (10 mcg)	BNT162b2 Phase 1 (10 mcg)	-
	BNT162b2 Phase 1 (20 mcg)	BNT162b2 Phase 1 (20 mcg)	-
	BNT162b2 Phase 1 (30 mcg)	BNT162b2 Phase 1 (30 mcg)	-
	Placebo	Placebo	-
	Placebo	Placebo	BNT162b2 Phase 1 (30 mcg)
	NOT ASSIGNED	-	-
	SCREEN FAILURE	-	-
Phase 2/3	BNT162b2 Phase 2/3 (30 mcg)	BNT162b2 Phase 2/3 (30 mcg)	-
	Placebo	Placebo	-
	Placebo	Placebo	BNT162b2 Phase 2/3 (30 mcg)
	NOT ASSIGNED	-	-

PHASE	ARM	TRT01P	TRT02P
	SCREEN FAILURE	-	-

Note: Unit of dose 'mcg' was displayed as 'µg' in all of outputs.

ACTARM versus TRTxxA

If TRTxxA is used, then are the values of ACTARM equivalent in meaning to values of TRT01A?

No, ACTARM represents the actual arm for the blinded placebo-controlled period. TRT01A has the actual treatment for the blinded placebo-controlled period, TRT02A has the actual treatment of open label vaccination period for subjects who received placebo only in the blinded placebo-controlled period and received BNT162b2 after unblinding. See details in below table.

PHASE	ACTARM	TRT01A	TRT02A
Phase 1	BNT162b1 Phase 1 (10 mcg)	BNT162b1 Phase 1 (10 mcg)	-
	BNT162b1 Phase 1 (20 mcg)	BNT162b1 Phase 1 (20 mcg)	-
	BNT162b1 Phase 1 (30 mcg)	BNT162b1 Phase 1 (30 mcg)	-
	BNT162b1 Phase 1 (100/10 mcg)	BNT162b1 Phase 1 (100/10 mcg)	-
	BNT162b2 Phase 1 (10 mcg)	BNT162b2 Phase 1 (10 mcg)	-
	BNT162b2 Phase 1 (20 mcg)	BNT162b2 Phase 1 (20 mcg)	-
	BNT162b2 Phase 1 (30 mcg)	BNT162b2 Phase 1 (30 mcg)	-
	Placebo	Placebo	-
	Placebo	Placebo	BNT162b2 Phase 1 (30 mcg)
	NOT ASSIGNED	-	-
	SCREEN FAILURE	-	-
Phase 2/3	BNT162b2 Phase 2/3 (30 mcg)	BNT162b2 Phase 2/3 (30 mcg)	-
	Placebo	Placebo	-
	Placebo	Placebo	BNT162b2 Phase 2/3 (30 mcg)
	Not Treated	-	-
	NOT ASSIGNED	-	-
	SCREEN FAILURE	-	-

Note: Unit of dose 'mcg' was displayed as 'µg' in all of outputs.

Use of ADaM Treatment Variables in Analysis

Are both planned and actual treatment variables used in analyses?

Yes. Both actual treatment and planned treatment were used in the analysis. Planned treatment variable was used across efficacy analysis, immunogenicity analysis and disposition table. Actual treatment variable was used across safety analysis.

See details in below table.

Reporting Period	Analysis Population	Treatment Variables Used in Analysis	Applicable analysis
Blinded placebo-controlled period or Open label follow-up period	Safety	TRT01A	Conduct of study, Adverse Event, Medical History, Concomitant Medications/Vaccinations, Reactogenicity
	Randomized	TRT01P	Vaccine as Administered, Disposition, Immunogenicity, efficacy
Open label follow-up period (For subjects received placebo only in the blinded placebo-controlled period and then received BNT162b2 after unblinding)	Safety	TRT02A	Adverse Event

Note: Unit of dose 'mcg' was displayed as 'µg' in all of outputs.

Use of ADaM Treatment Grouping Variables in Analysis

Are both planned and actual treatment grouping variables used in analysis?

No. Neither planned nor actual treatment grouping variables are used in analysis

3.3 Subject Issues that Require Special Analysis Rules

- Subjects whose data is considered potentially unreliable due to lack of PI oversight identified as significant quality event were excluded from analysis populations.

- According to the Protocol, HIV-positive subjects in Phase 3 will not be included in analyses of the overall study objectives, with the exception of the specific exploratory objective for this group. In the BLA, Human immunodeficiency virus (HIV)-positive subjects are included in the analysis populations the summary of analysis populations and shown as part of the study demographics and study conduct tables but not included in the analyses of overall safety, immunogenicity and efficacy endpoints.

- Handling of Misallocation of Vaccine:
  - For AE summaries, demographics and all other tables by safety population, count the subjects in active treatment group as long as one of the doses is active vaccination BNT162b2.
  - For reactogenicity analyses by dose, subjects who received a different investigational product regimen from the regimen they were assigned will be included in the safety population for the summaries of individual vaccinations up until the point their regimen differs from the assigned regimen, at which point they would no longer be included.
  - Immediate AE and AEs post dose 1 and 2 were summarized by following the same rule

as reactogenicity for post dose 1 and post dose 2 summary.

The following table shows how subjects are assigned to treatment arms for safety related analyses under all possible vaccination scenarios:

	Vaccine Dose			Analysis					
Scenario	Actual Dose 1	Actual Dose 2	Actual Arm (Overall)	Reactoge-nicity Post Dose 1	Reactoge-nicity Post Dose 2	Reactoge-nicity post any Dose	AE Post Dose 1	AE Post Dose 2	Other*
1	Active	Active	Active	Active	Active	Active	Active	Active	Active
2	Placebo	Placebo	Placebo	Placebo	Placebo	Placebo	Placebo	Placebo	Placebo
3	Active		Active	Active	*Exclude*	Active	Active	*Exclude*	Active
4	Placebo		Placebo	Placebo	*Exclude*	Placebo	Placebo	*Exclude*	Placebo
5	Active	Placebo	Active	Active	*Exclude*	Active	Active	*Exclude*	Active
6	Placebo	Active	Active	Placebo	*Exclude*	Active	Placebo	*Exclude*	Active

* Other includes all other AE summary, demographic, and other study conduct tables by Safety Population (Follow Overall Actual Arm)

- 6 Subjects were enrolled into the study more than once. These subjects will not be included in any analyses and will only be included in separate listings (disposition listing, AE listing, local reaction listing and systemic events listing) created specifically for this subject. These subjects will be excluded from other outputs using the exclusion flag (MULENRFL) in ADSL.

Duplicated Subject #	SUBJID at 1st Site	SUBJID at 2nd site
1	10561101	11331382
2	11101123	11331405
3	11491117	12691090
4	12691070	11351357
5	11341006	10891112
6	11231105	10711213

- Subjects C4591001 1163 11631006, C4591001 1163 11631005, C4591001 1163 11631008, are vaccinated as per CRF, but due to lack of matching actual vaccination data, these are not assigned to any dosing group. In the analyses these subjects will be:

  For safety:
  a. Excluded from all table/figures.
  b. Included in all regular listings.

  For efficacy:
  a. Excluded from the evaluable population by the definition in the SAP, because it is not possible to confirm if they received the vaccination as randomized.
  b. Included in all tables/figures/listings based on all-available population.

3.4 Use of Visit Windowing, Unscheduled Visits, and Record Selection

Was windowing used in one or more analysis datasets?

Yes. windowing was considered during the derivation of ADAE.VPHASE. Please refer to Appendix II for more details.

Were unscheduled visits used in any analyses?

Yes. please refer to Section 5.2.7 and 5.2.9 for more details.

Based on protocol guidance, multiple unscheduled Covid illness visits that are less than four days apart are collapsed in ADSYMPT into their respective earlier visit/s and are considered as single unscheduled illness visit during the analysis.

3.5 Imputation/Derivation Methods

If date imputation was performed, were there rules that were used in multiple analysis datasets?

Yes, date imputations for partial or missing dates were performed for adverse events, medical history and concomitant medication described in Appendix III.

Was DTYPE used in one or more analysis datasets?

Yes, DTYPE was used in ADFACEVD and ADVA. For details on DTYPE, please refer to Section 5.2.7 and 5.2.11.

4. Analysis Data Creation and Processing Issues

4.1 Split Datasets

There are no split datasets.

4.2 Data Dependencies

All datasets pull core variable values from ADSL. ADC19EF also uses the ADSYMPT dataset as an input to create efficacy parameter variables.

4.3 Intermediate Datasets

No intermediate analysis datasets were created in this trial.

5. Analysis Dataset Descriptions

5.1 Overview

Are data for screen failures, including data for run-in screening (for example, SDTM values of ARMCD='SCRNFAIL', or 'NOTASSGN') included in ADaM datasets?

Yes. Subjects with 'NOTASSGN' 'SCRNFAIL' are included in ADSL, ADAE, ADCM, ADDS, ADDV, ADMH and ADVA

Are data taken from an ongoing study?

Yes. All data up through 13Mar2021 cutoff are included in the SDTM datasets and used for ADaM datasets and analyses. Furthermore, any data related to the booster portion of the Phase 1 subjects was also programmatically excluded from SDTM data.

Do the analysis datasets support all protocol- and statistical analysis plan-specified objectives?

No. Objectives on VE against asymptomatic infection and Phase 1 booster are not assessed. The booster and variant strain assessment in Protocol amendment 14 and SAP V5 are also not included.

Additional Content of Interest

No additional content of Interest.

5.2 Analysis Datasets

Dataset Label	Class	Efficacy	Safety	Baseline or other subject PK/PD	Primary	Structure
ADSL Subject-Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET			X		One record per subject
ADAE Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE		X		X	One record or multiple records per subject per adverse event per event start date
ADCEVD Diary and CRF Event Analysis Dataset	OCCURRENCE DATA STRUCTURE		X			One record or multiple records per subject per clinical event
ADFACEVD Diary and Non-event Analysis Dataset	BASIC DATA STRUCTURE		X		X	One record or multiple records per subject per analysis parameter per analysis timepoint
ADCM Concomitant Medications Analysis Dataset	OCCURRENCE DATA STRUCTURE		X			One record or multiple records per subject per recorded medication occurrence or constant-dosing interval
ADDS Disposition Analysis Dataset	OCCURRENCE DATA STRUCTURE			X		One record or multiple records per subject per disposition status or protocol milestone
ADDV Protocol Deviation Analysis Dataset	OCCURRENCE DATA STRUCTURE			X		One record or multiple records per subject per protocol deviation per event start date
ADMH Medical History Analysis Dataset	OCCURRENCE DATA STRUCTURE			X		One record or multiple records per subject per medical history event

Dataset Label	Class	Efficacy	Safety	Baseline or other subject PK/PD	Primary	Structure
ADC19EF Covid-19 Efficacy Analysis	BASIC DATA STRUCTURE	X			X	One record or multiple records per subject per analysis parameter per analysis timepoint
ADSYMPT Covid-19 Signs and Symptoms	BASIC DATA STRUCTURE	X			X	One record or multiple records per subject per analysis parameter per analysis timepoint
ADVA Immunogenicity Analysis Dataset	BASIC DATA STRUCTURE	X				One record or multiple records per subject per analysis parameter per analysis visit

5.2.1 ADSL – Subject-Level Analysis Dataset

ADSL included all subjects in the DM domain and contained relevant subject level information, treatment variables and analysis set flags. This dataset supported the creation of all other analysis datasets. ADSL also comprised the variables to support baseline characteristics and disposition analyses, and the classification variables used for subgroup analyses and used as covariates for statistical analyses.

ADSL includes the following information for each subject:

- Subject identifier
- Demographic information
- Planned treatment and actual treatment (details described in Section 3.1 Core Variables)
- Population flags (details described in Section 3.1 Core Variables)
- Key dates and datetime related to conduct of study (details described in Section 3.1 Core Variables)
- Variables to support subgroup analyses
    - Age group (details described in Section 3.1 Core Variables for Age group)
    - Sex (Female and Male)
    - Race (White, Black or African American and All Others)

      Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
    - Ethnicity (Hispanic/Latino, Non-Hispanic/Non-Latino and Not Reported)
    - Baseline SARS-CoV-2 Status (Positive and Negative)
    - Flag for Comorbidities (Y/N)
    - Obese Flag for Adolescent (Y/N)

5.2.2 ADCEVD – Diary and CRF Event Analysis Dataset

This dataset contains information on duration of local reactions (LR: redness, swelling, and pain

at the injection site) and systemic events (SE: fever, chills, diarrhea, fatigue, headache, joint pain, muscle pain and vomiting) and is used to generate the summaries of duration of these reactions or events.

Duration of each reaction or event is defined as the number of days from the start of the first reported event to the resolution of the last reported event (ADURN = AENDT – ASTDT+1), which is the sum of the duration of the reactogenicity event in the assessment period and beyond the assessment period if a reactogenicity event continued beyond the assessment interval. Those clinical assessments at unscheduled visits within 7 days after each dose were involved in the derivation of duration and summary analysis.

No imputation was carried out for partial or missing symptom resolved dates from investigator data collected on the CRF. Those events with the resolution date partial or missing (AENDT eq missing), were included in the "Unknown" category for any reporting. However, if a reaction is ongoing at the time of a subsequent vaccination, the end date/day for the ongoing reaction would be the date/day that the next vaccine is administered, which will be used for the duration computation. Participants with no reported reaction have no duration.

5.2.3 ADAE – Adverse Events Analysis Dataset

This is the main safety analysis dataset comprised of adverse events recorded on the CRF. For dictionary coding, MedDRA version 23.1 was used. Partial start dates or partial end dates of adverse events were imputed using rules described in Appendix III.

AE data is reported excluding the reactogenicity events [AECAT not in ("REACTOGENICITY")]. AE summaries were analyzed based on the specific reporting periods. The vaccine phase (VPHASE) was derived based on the start date of the AE and the phase date (ADSL.V01DT, ADSL.V02DT, ADSL.V02OBDT, ADSL.V03DT, ADSL.V04DT), please refer to Appendix II for more details, and was applied to select AEs for summaries based on different reporting period. See details in Appendix VIII.

5.2.4 ADCM – Concomitant Medications Analysis Dataset

The dataset contains information of nonstudy vaccines (CMCAT = "VACCINATIONS"), concomitant medications (CMCAT = "GENERAL CONCOMITANT MEDICATIONS") and prohibited concomitant medications (CMCAT in (' CONCOMITANT IMMUNOSUPPRESSIVE THERAPY',' CORTICOSTEROIDS',' IMMUNOGLOBULINS')). For dictionary coding, WHO DDE v202003 were used.

Partial start dates or partial end dates of nonstudy vaccines and concomitant medications were imputed using rules described in Appendix III.

5.2.5 ADDS – Disposition Analysis Dataset

This dataset contains information for various disposition events (DSCAT = "DISPOSITION EVENT") for each subject throughout the study. The phases in the disposition event are presented in the table below as DSPHASE. The subject's completion status or reason for discontinuation is identified in DSDECOD (Standardized Disposition Term).

Disposition phases included in this study are as follows:

DSCAT	DSPHASE
DISPOSITION EVENT	SCREENING
DISPOSITION EVENT	REPEAT SCREENING 1
DISPOSITION EVENT	VACCINATION
DISPOSITION EVENT	OPEN LABEL TREATMENT
DISPOSITION EVENT	FOLLOW-UP

5.2.6 ADDV – Protocol Deviation Analysis Dataset

This dataset contains information about protocol deviation events and causes for protocol deviations. Important protocol deviations were flagged as "Important" in variable DVCAT and the corresponding exclusion flag was capture in SUPPDV.QNAM='CAPE'.

5.2.7 ADFACEVD – Diary and Non-event Analysis Dataset

This is a primary analysis dataset for vaccine studies, including information of occurrence, severity level and maximum severity of reactogenicity assessments reported in the e-diary. Reactogenicity assessments cover 3 parts: local reactions, systemic events and use of antipyretic/pain medication which were assessed within 7 days after each dose.

ADFACEVD is a dataset using BDS structure, which contains one or multiple records per subject per analysis parameter (PARAM) per analysis timepoint (ATPT). Variables PARAM and PARAMCD were used to distinguish different measurements or findings. The detailed list of parameters included in this dataset are described in Appendix IV.

Unscheduled visits of clinical assessments within 7 days after each vaccination for reactogenicity from FACE and VS dataset were considered for summary analysis.

Reactogenicity assessments reported in the e-diary on or after the date of treatment unblinding (ADSL.UNBLNDDT) were excluded from onset and maximum severity summary analysis. However, events with onset before unblinding that continue after the date of unblinding were used in duration calculation. The events reported on the same day of unblinding were flagged as 'Y' in variable CUTUNBFL in ADFACEVD.

Maximum severity records were created in this dataset with DTYPE equal to "MAXIMUM". For all subjects, each local reaction or systemic event was targeted to have 7 assessments from Day 1 to Day 7. The maximum severity value reported during the interval was stored in an additional record with DTYPE equaled "MAXIMUM" (see the table as below) which is then used to summarize the maximum severity of these events.

PARAM	DTYPE
Redness maximum severity	MAXIMUM
Redness maximum diameter	MAXIMUM
Swelling maximum severity	MAXIMUM
Swelling maximum diameter	MAXIMUM
Pain at injection site maximum severity	MAXIMUM
Chills maximum severity	MAXIMUM
Diarrhea maximum severity	MAXIMUM
Fatigue maximum severity	MAXIMUM
Fever maximum temperature	MAXIMUM

PARAM	DTYPE
Headache maximum severity	MAXIMUM
Joint pain maximum severity	MAXIMUM
Muscle pain maximum severity	MAXIMUM
Vomiting maximum severity	MAXIMUM

ADFACEVD includes the following key flags to support reactogenicity analyses:

- KNOWVFL – Y for that reaction or event if a subject had at least one record reported from day 1 to day 7 after each dose for a given reaction or event. This was derived per subject per dose per parameter(/event).
- EVENTFL – Y for that reaction or event if a subject had at least one record where the event occurred (where diameter>2.0 cm for redness and swelling or 38 °C<=temperature<=42 °C for fever or presence=yes for other symptoms) from day 1 to day 7 after each dose for a given reaction or event. This was derived per subject per dose per parameter(/event).
- KNOWVDFL – Y for a valid record (where the event was reported regardless if it occurred or not) at that day from day 1 to day 7 after each dose for a given reaction or event. This was derived per subject per dose per parameter(/event) per day.
- EVENTDFL – Y for a record where the event occurred (where diameter>2.0 cm for redness and swelling or 38 °C<=temperature<=42 °C for fever or with any valid severity/intensity or presence=yes for other symptoms) at that day from day 1 to day 7 after each dose. This was derived per subject per dose per parameter(/event) per day.

- Category variables FTEMCATN / FTEMCAT were used for fever summary analyses:

FTEMCATN	FTEMCAT
.	Missing
0	<38.0°C
1	≥38.0°C to 38.4°C
2	>38.4°C to 38.9°C
3	>38.9°C to 40.0°C
4	>40.0°C

- AVALCA1N / AVALCAT1 was derived based on diameter value and for parameters "Redness maximum severity" and "Swelling maximum severity" the maximum severity was derived per below table.

AVALCA1N	AVALCAT1	SEVERITY
0	>0-2.0	NONE
1	>2.0-5.0	MILD
2	>5.0-10.0	MODERATE
3	>10.0	SEVERE

5.2.8 ADMH – Medical History Analysis Dataset

This dataset contains all medical histories (MHCAT = "GENERAL MEDICAL HISTORY") collected on the CRF. MedDRA version 23.1 was used for dictionary coding of medical histories. Partial start dates or partial end dates medical histories were imputed using rules described in Appendix III.

5.2.9 ADSYMPT – Covid-19 Signs and Symptoms

The purpose of this dataset is to gather all signs/symptoms/conditions/laboratory results

associated with SARS-CoV-2 from unscheduled Covid illness visits which will then be used to create the efficacy endpoint dataset ADC19EF. The main SDTM domains that were used to create the ADSYMPT dataset were CE, CM, DD, DS, HO, FA, IS, LB, MB, MH, PR, VS and the analysis dataset ADSL. Some of the important variables that make up this dataset are PARAMCD, PARAM, PARAMN, PARCAT1, PARCAT2, AVAL, AVALC, ADT, ASTDT, AENDT, VSSTRESU, MBMETHOD and ISMETHOD. Algorithms used to create each of these variables are included in the define.xml.

Protocol defined symptoms include "Chills, Diarrhea, Fever, New loss of taste or smell, New or increased cough, New or increased muscle pain, New or increased sore threat, Vomiting, Loss of taste/smell".

These data were identified and captured in the ADSYMPT dataset as follows:

- From FA all records with FACAT = "EFFICACY" and FASCAT = "RESPIRATORY ILLNESS" provides the COVID-19 signs and symptoms.
- Subjects with local lab swab samples are identified using MB.MBTESTCD= "SARSCOV2" and MB.MBMETHOD = "IMMUNOCHROMATOGRAPHY".
- Subjects with central swab samples are identified using MB.MBTESTCD = "RTCOV2NS" and MB.MBMETHOD = "REVERSE TRANSCRIPTASE PCR".
- For the severe COVID-19 data from vital signs, subjects with admission to ICU, deaths, lab oxygenation data, ECG/oxygen therapy/intubation, etc., please refer to SAP Appendix 3 for more details

All COVID-19 signs, symptoms and conditions were defined as shown in the table below.

PARAMN	PARAMCD	PARAM	Derivation
1	CHILLS	CHILLS	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "CHILLS" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
2	DIARRHEA	DIARRHEA	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "DIARRHEA" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
3	FEVER	FEVER	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "FEVER" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
4	NLTSTSML	NEW LOSS OF TASTE OR SMELL	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "NEW LOSS OF TASTE OR SMELL" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
5	NCOUG	NEW OR INCREASED COUGH	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "NEW OR INCREASED COUGH" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".

PARAMN	PARAMCD	PARAM	Derivation
6	NMUSPN	NEW OR INCREASED MUSCLE PAIN	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "NEW OR INCREASED MUSCLE PAIN" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
7	NSTBRTH	NEW OR INCREASED SHORTNESS OF BREATH	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "NEW OR INCREASED SHORTNESS OF BREATH" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
8	NSRTHROT	NEW OR INCREASED SORE THROAT	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "NEW OR INCREASED SORE THROAT" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
9	VOMIT	VOMITING	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "VOMITING" and FA.FACAT = "EFFICACY" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
11	NNSLCONG	NEW OR INCREASED NASAL CONGESTION	Set to "NEW OR INCREASED NASAL CONGESTION" when upcase(FA.FAOBJ) = "NEW OR INCREASED NASAL CONGESTION" or "NASAL CONGESTION" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
14	WHEEZ	NEW OR INCREASED WHEEZING	Set to "NEW OR INCREASED WHEEZING" when upcase(FA.FAOBJ) = "NEW OR INCREASED WHEEZING" or upcase(FA.FAOBJ) = "WHEEZING" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
15	FATIGUE	FATIGUE	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "FATIGUE" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
16	HEADACHE	HEADACHE	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "HEADACHE" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
17	RIHNRA	RHINORRHOEA	Set to "RHINORRHOEA" when upcase(FA.FAOBJ) contains "RUNNY NOSE" or upcase(FA.FAOBJ) = "RHINORRHOEA" and FA.FAOBJ ^= "NEW OR INCREASED NASAL DISCHARGE" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".
18	NAUSEA	NAUSEA	Set to FA.FAOBJ when upcase(FA.FAOBJ) = "NAUSEA" and FA.FACAT = "EFFICACY" and FA.FASCAT = "RESPIRATORY ILLNESS".

PARAMN	PARAMCD	PARAM	Derivation
25	SARDFN	SIGNIFICANT ACUTE RENAL DYSFUNCTION	Set to CE.CESCAT when CE.CESCAT = "SIGNIFICANT ACUTE RENAL DYSFUNCTION".
30	SAHDFN	SIGNIFICANT ACUTE HEPATIC DYSFUNCTION	Set to CE.CESCAT when CE.CESCAT = "SIGNIFICANT ACUTE HEPATIC DYSFUNCTION".
35	SANDFN	SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION	Set to CE.CESCAT when CE.CESCAT = "SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION".
40	SARSCOV2	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Set to MB.MBTEST when upcase(MB.MBTESTCD) = "SARSCOV2" and MB.MBMETHOD = "IMMUNOCHROMATOGRAPHY".
41	RTCOV2NS	CEPHEID RT-PCR ASSAY FOR SARS-COV-2	Set to MB.MBTEST when upcase(MB.MBTESTCD) = "RTCOV2NS" and MB.MBMETHOD = "REVERSE TRANSCRIPTASE PCR".
50	RESP	RESPIRATORY RATE	Set to VS.VSTEST when VS.VSTESTCD = "RESP".
51	HR	HEART RATE	Set to VS.VSTEST when VS.VSTESTCD = "HR".
52	OXYSAT	OXYGEN SATURATION	Set to VS.VSTEST when VS.VSTESTCD = "OXYSAT"
53	DIABP	DIASTOLIC BLOOD PRESSURE	Set to VS.VSTEST when VS.VSTESTCD = "DIABP".
54	SYSBP	SYSTOLIC BLOOD PRESSURE	Set to VS.VSTEST when VS.VSTESTCD = "SYSBP".
60	PO2FIO2	PP ARTERIAL O2/FRACTION INSPIRED O2	Set to LB.LBTEST when LB.LBTEST = "PP Arterial O2/Fraction Inspired O2".
71	NIPPV	NON-INVASIVE POSITIVE PRESSURE VENTILATION	Set to PR.PRTRT when upcase(PR.PRTRT) = "NON-INVASIVE POSITIVE PRESSURE VENTILATION".
74	MCHVENT	MECHANICAL VENTILATION	Set to PR.PRTRT when upcase(PR.PRTRT) = "MECHANICAL VENTILATION".
76	HFOXTHRP	HIGH FLOW OXYGEN	Set to PR.PRTRT when upcase(PR.PRTRT) = "HIGH FLOW OXYGEN THERAPY".
80	VSOPRES	VASOPRESSORS AGENTS	Set to CM.CMSCAT when CM.CMCAT = "GENERAL CONCOMITANT MEDICATIONS" and CM.CMSCAT = "VASOPRESSORS AGENTS". Keep only one record per subject per CM.CMSTDTC where CM.CMTRT is not missing.
90	C19NIG	N-BINDING ANTIBODY	Set to IS.ISTEST when IS.ISTESTCD = "C19NIG"
91	HCUICU	SUBJECT IN ICU DUE TO POTENTIAL COVID-19 ILLNESS	Set to "SUBJECT IN ICU DUE TO POTENTIAL COVID-19 ILLNESS" when HOTERM = "ICU' or (SUPPHO.QNAM = "HCUICU" and SUPPHO.QVAL = "Y").

PARAMN	PARAMCD	PARAM	Derivation
92	HCUHSP	HOSPITALIZED DUE TO COVID-19 ILLNESS?	Set to "HOSPITALIZED DUE TO COVID-19 ILLNESS" when SUPPHO.QNAM = "HCUHSP" and SUPPHO.QVAL = "Y"
95	PRCDTH	PRIMARY CAUSE OF DEATH	Set to "PRIMARY CAUSE OF DEATH" when DD.DDTESTCD = "PRCDTH"
96	SECDTH	SECONDARY CAUSE OF DEATH	Set to DD.DDTEST when DD.DDTESTCD = "SECDTH"
99	DEATH	DEATH	Set to DS.DSDECOD when DS.DSDECOD = "DEATH".

5.2.10 ADC19EF – Covid-19 Efficacy Analysis

The purpose of this dataset is to gather all signs/symptoms/conditions associated with SARS-COV-2 and derive case onset, severe illness onset, and surveillance time for various end point analyses. This dataset contains all derivations to account for surveillance times during blinded placebo-controlled follow-up period, and variables to support the first primary end point and secondary endpoints as defined in the Statistical Analysis Plan. Details around the derivation of surveillance times and the flow charts for identification of first and secondary primary end points are available in Appendix VI and Appendix VII respectively. Detailed algorithms for each parameter are included in the define.xml.

Variables used to identify the primary end points as well the other endpoints of special interest are listed in the table below:

PARAMN	PARAMCD	PARAM
40	SARSCOV2	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
41	RTCOV2NS	CEPHEID RT-PCR ASSAY OF SARS-COV-2
90	C19NIG	N-BINDING ANTIBODY
91	HCUICU	SUBJECT IN ICU DUE TO POTENTIAL COVID-19 ILLNESS
92	HCUHSP	HOSPITALIZED DUE TO COVID-19 ILLNESS?
95	PRCDTH	PRIMARY CAUSE OF DEATH
96	SECDTH	SECONDARY CAUSE OF DEATH
100	DTHODC19	DEATH OCCURRED DUE TO COVID-19 ILLNESS?
101	PRPDSAD	PRESENCE OF PROTOCOL DEFINED SYMPTOMS AFTER DOSE
102	PRCDCSAD	PRESENCE OF CDC DEFINED SYMPTOMS AFTER DOSE
103	SEVCVS	SEVERE COVID-19 SYMPTOMS - VITAL SIGNS
104	SEVCRF	SEVERE COVID-19 SYMPTOMS - RESPIRATORY FAILURE
105	SEVCVSPR	SEVERE COVID-19 SYMPTOMS - USE OF
106	SEVCRHN	SEVERE COVID-19 SYMPTOMS - SIGNIFICANT ACUTE RENAL, HEPATIC, OR NEUROLOGIC DYSFUNCTION
107	PRSVCSAD	PRESENCE OF PROTOCOL DEFINED SEVERE COVID-19 SYMPTOMS AFTER DOSE
108	PRSCDCAD	PRESENCE OF CDC DEFINED SEVERE COVID-19 SYMPTOMS AFTER DOSE
110	NAATRAD	COVID-19 NAAT RESULT AFTER DOSE
120	C19ONST	PROTOCOL DEFINED COVID-19 ILLNESS ONSET
125	CDCONST	CDC DEFINED COVID-19 ILLNESS ONSET

PARAMN	PARAMCD	PARAM
130	SEVCONST	SEVERE COVID-19 ILLNESS ONSET
135	CDCSONST	CDC DEFINED SEVERE COVID-19 ILLNESS ONSET
141	ST1PD	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR PROTOCOL DEFINED SYMPTOMS
142	ST17PD	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS
143	ST2PD	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS
144	ST27PD	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS
145	ST214PD	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS
151	ST1CD	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS
152	ST17CD	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS
153	ST2CD	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS
154	ST27CD	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS
155	ST214CD	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS
161	ST1SE	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS
162	ST17SE	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS
163	ST2SE	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS
164	ST27SE	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS
165	ST214SE	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS
171	STC1SE	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS
172	STC17SE	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS
173	STC2SE	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS
174	STC27SE	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS
175	STC214SE	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS
201	ST1PDA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
202	ST17PDA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
203	ST2PDA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
204	ST27PDA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE

PARAMN	PARAMCD	PARAM
205	ST214PDA	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
211	ST1CDA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
212	ST17CDA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
213	ST2CDA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
214	ST27CDA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
215	ST214CDA	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS - ALL AVAILABLE
221	ST1SEA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
222	ST17SEA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
223	ST2SEA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
224	ST27SEA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
225	ST214SEA	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
231	STC1SA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
232	STC17SA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
233	STC2SA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
234	STC27SA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
235	STC214SA	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL AVAILABLE
301	ST1PDX	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - CROSSOVER
331	STC1SX	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - CROSSOVER

5.2.11 ADVA – Immunogenicity Analysis Dataset

This dataset contains immunogenicity assessments for subjects for Phase 1, Phase 2 and pediatric analysis (12-15 years age group and randomly selected subjects from 16-25 years age group). Due to additional follow-up as well as ongoing data cleaning, there may be minor differences due to difference in database snapshots and cutoff dates applied to SDTM and ADaM in this case. Subjects excluded from the evaluable immunogenicity populations were identified programmatically for samples outside the visit window, not receiving correct vaccination as randomized, no valid assay result; exclusion due to important deviations were provided in SUPPDV dataset.

For Phase 1 for BNT162b2 30 mcg and equivalent Placebo subjects (30 subjects in total), visits 'V1_DAY1_VAX1_S',' V4_WEEK3_VAX2_S' and 'V7_MONTH1_S' were retested by lab. And for these retested visits (flagged as 'REPEAT TEST' in ISTSTDTL), only the retested values were used for analysis.

Assay results collected within a dose-specified sample collection window, either Dose 1 or Dose 2, that were not distinguished by the dose-specified immunogenicity population flags (EVIMMFL for evaluable immunogenicity population, AAIMMFL for all-available immunogenicity population), were excluded from analysis of the corresponding immunogenicity population.

Flags (ABLFL/APSBLFL/ABLPBLFL) used for identifying baseline and post baseline records are also available for each parameter. The ratio from post-baseline to baseline (R2BASE) was calculated as AVAL/BASE for fold rise summaries.

Assay results collected at COVID convalescent visit within 28-42 days after Dose 2, were used for the 1-month post Dose 2 analysis for subjects without a Visit 3 serology assay collected.

Assay results below the corresponding LLOQ were set to 0.5 × LLOQ and missing assay results were not imputed. DTYPE was set to "LLOQIMP" for parameters that needed imputation for LLOQ. All analysis parameters are presented in below table.
Note: When determinate subjects achieved 4-fold rise post baseline, assay results at baseline below the corresponding LLOQ were set to LLOQ.

PARCAT1	PARAMCD	PARAMN	PARAM	ISLLOQ
SEROLOGY	C2NGNT50	1	SARS-CoV-2 serum neutralizing titer 50 (titer) - Virus Neutralization Assay	20
SEROLOGY	C2NGNT90	2	SARS-CoV-2 serum neutralizing titer 90 (titer) - Virus Neutralization Assay	20
SEROLOGY	C19S1IGG	3	COVID-19 S1 IgG (U/mL) - Luminex Immunoassay	1.2665
SEROLOGY	C19RBDIG	4	COVID-19 RBD IgG (U/mL) - Luminex Immunoassay	1.1505
SEROLOGY	C19NIG	5	N-binding antibody - N-binding Antibody Assay	NA
SEROLOGY	NT50_S1	11	SARS-CoV-2 serum neutralizing titer 50 to COVID-19 S1 IgG	NA
SEROLOGY	NT90_S1	12	SARS-CoV-2 serum neutralizing titer 90 to COVID-19 S1 IgG	NA

6. Data Conformance Summary

6.1 Conformance Inputs

Specify the software name and version for the analysis datasets

Pinnacle 21 Enterprise 4.1.4., Validation Engine version 1907.2
Pinnacle Validation Engine FDA 2010.1 was also used to evaluate the data. And there's no significant change identified.

Specify the version of the validation rules (i.e. CDISC, FDA) for the analysis datasets

CDISC ADaM-CT 2020-03-27

Specify the software name and version for the define.xml

Pinnacle 21 Enterprise 4.1.4.

Specify the version of the validation rules (i.e. CDISC, FDA) for the define.xml

CDISC ADaM CT 2020-03-27

6.2 Issues Summary (Pinnacle 21 Enterprise Validation Report)

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
AD0018	Variable label mismatch between dataset and ADaM standard	Error	ADVA	3 (4.00%)	On Page 21 of ADaM IG 1.1 descriptive text is allowed at the end of the labels of variables whose names contain indexes "y" or "zz"; Therefore, all labels for variables that contain indexes will throw false positive error messages.
AD0034	PDRMUPFL value is not Y or null	Error	ADC19EF	2089175 (97.22%)	PDRMUPFL is not defined as parameter level flags. It is subject level flags based on series of events therefore having values of Y/N are acceptable.
AD0034	CDRMUPFL value is not Y or null	Error	ADC19EF	2085470 (97.04%)	CDRMUPFL is not defined as parameter level flags. It is subject level flags based on series of events therefore having values of Y/N are acceptable.
AD0099	ASTDY is greater than AENDY	Error	ADC19EF	7579 (0.39%)	ASTDT is greater than AENDT in some cases, as surveillance time could start at various time points for some subjects. For example, a subject's surveillance time could be prior to the start of event due to positive COVID case or other criteria as noted in the define.xml leading to ASTDT >AEDNT and ASTDY > AENDY.
AD0124	Inconsistent value for PARCAT1 within a unique PARAMCD	Error	ADSYMPT	17 (< 0.1%)	Observations for PARAMCD="HCUICU" are included when we have ICU observations from either SDTM HO or from HCUICU observations in SUPPHO. The PARCAT1 differs based on the different categories (HOCAT) picked from the SDTM. Therefore, the different PARCAT1 values for PARAMCD="HCUICU" are acceptable.
AD0253	Record key from SDTM AE is not traceable to ADaM ADAE (not enough ADAE recs)	Error	AE	2192 (5.55%)	AECAT="REACTOGENICITY" records (from ediary) was not kept in ADAE (Based on CDISC Vaccine TAUG flat model).
AD0361	Value of ASTDT is greater than value of AENDT	Error	ADC19EF	7579 (0.39%)	ASTDT is greater than AENDT in some cases, as surveillance time could start at various time points for some subjects. For example, a subject's surveillance time could be prior to the start of event due to positive COVID case or other criteria as noted in the define.xml leading to ASTDT >AEDNT and ASTDY > AENDY.

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
AD1012	Secondary custom variable is present but its primary variable is not present	Warning	ADDS	1 (7.14%)	AD1012 check is limited to "standard" ADaM variables explicitly defined in ADaM IG documents. M1P2EXC is the variable to capture the necessary information. Any new custom variables added to analysis data are out-of-scope for AD1012 check.
AD1012	Secondary custom variable is present but its primary variable is not present	Warning	ADFACEVD	1 (7.14%)	AD1012 check is limited to "standard" ADaM variables explicitly defined in ADaM IG documents. EVENTOCC stands for Occurrences of Event. Any new custom variables added to analysis data are out-of-scope for AD1012 check.
AD1012	Secondary custom variable is present but its primary variable is not present	Warning	ADSL	5 (22.73%)	AD1012 check is limited to "standard" ADaM variables explicitly defined in ADaM IG documents. FUP1CA1N/SCREEN/FUP2CA1N/FPX1CA1N/FUP2CA2N are the variable to capture the necessary information. Any new custom variables added to analysis data are out-of-scope for AD1012 check.
AD1012	Secondary custom variable is present but its primary variable is not present	Warning	ADVA	2 (16.67%)	AD1012 check is limited to "standard" ADaM variables explicitly defined in ADaM IG documents. BSSEROC/BSSERON stands for baseline sero status. Any new custom variables added to analysis data are out-of-scope for AD1012 check.
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADC19EF	52998 (2.47%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADCEVD	6921 (2.55%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADCM	230 (1.15%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADDS	2915 (2.37%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADDV	828 (2.23%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADFACEVD	58677 (2.60%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADMH	2854 (1.45%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADSL	1166 (2.42%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADSYMPT	9090 (2.77%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	DTYPE value not found in 'Derivation Type' extensible codelist	Warning	ADVA	12084 (10.57%)	New terms were added to extensible codelist DTYPE for the study protocol needs: LLOQIMP and Derived
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADVA	2716 (2.37%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple

7. Submission of Programs

All programs for analysis datasets as well as primary safety and efficacy results are submitted as shown below. All programs were created on a SAS platform using 9.4. ADSL.sas (adsl-sas.txt) must be run first before any other ADaM datasets; all other programs are dependent on ADSL output. ADC19EF program is dependent on ADSYMPT. Annotated Mock Tables for each output are also included for reference in Appendix I.

7.1 ADaM Programs

Program Name	Output	Input	Macro Used
adsl-sas.txt	adsl.xpt	dm suppdm ex suppex ds suppds is co lb cm ie dv suppdv vs sv mb suppmb mh pr face ce ho suppho	NA
adds-sas.txt	adds.xpt	ds suppds sv adsl	NA
adae-sas.txt	adae.xpt	ae suppae ex adsl	NA
addv-sas.txt	addv.xpt	dv suppdv adsl	NA
adcm-sas.txt	adcm.xpt	cm suppcm adsl	NA
adcevd-sas.txt	adcevd.xpt	ce face vs ex suppce suppface suppvs adsl	NA
adfacevd-sas.txt	adfacevd.xpt	face vs ex suppface suppvs adsl	NA
admh-sas.txt	admh.xpt	mh suppmh adsl	NA
adva-sas.txt	adva.xpt	is suppis adsl	NA
adc19ef-sas.txt	adc19ef.xpt	adsympt adsl	NA
adsympt-sas.txt	adsympt.xpt	ce cm dd ds face ho suppho is mb mh lb pr vs adsl	NA

7.2 Analysis Output Programs

Below is the list of outputs for which SAS programs have been provided to replicate the results in the tables. For the more complex outputs, a detailed annotated mock table is also included as a reference (see the link to the individual mocks shown in the table below) to give additional details for each output in Appendix I.

Table	Program Name	Output Name	Title	Input	Population Subset used
1	adsl-s005-demo-all-p3-saf-sas.txt	adsl_s005_demo_all_p3_saf html	Demographic Characteristics – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL	ADSL.SAFFL eq "Y" and ADSL.PHASEN > 1 and ADSL.AGEGR1N > 1 and

Table	Program Name	Output Name	Title	Input	Population Subset used
					ADSL.MULENRFL ne "Y" and ADSL.TRT01A ne ""
2	adds-s002-all-p3-rand-sas.txt	adds_s002_all_p3_rand.html	Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age	ADSL ADDS	ADSL.RANDFL eq 'Y' and ADSL.PHASEN ne 1 and ADSL.AGEGR1N >1 and ADSL.MULENRFL ne "Y"
3	adsl-fu-d2-p3-saf-sas.txt	adsl_fu_d2_p3_saf.html	Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL	ADSL.SAFFL eq "Y" and ADSL.PHASEN > 1 and ADSL.AGEGR1N > 1 and ADSL.MULENRFL ne "Y" and ADSL.TRT01A ne ""
4	adce-s010-lr-p3-saf-sas.txt	adce_s010_lr_p3_saf.html	Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL ADFACEVD	ADSL.SAFFL="Y" and ADSL.HIVFL="N" and ADSL.PHASEN > 1 and ADSL.AGEGR1N > 1 and ADSL.MULENRFL ne 'Y' and ADFACEVD.TRTA ne "" and ADFACEVD.FAOBJ in ("PAIN AT INJECTION SITE" "SWELLING" "REDNESS") and ADFACEVD.KNOWVFL="Y" and ADFACEVD.CUTUNBFL ne "Y"
5	adce-s020-se-p3-saf-sas.txt	adce_s020_se_p3_saf.html	Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL ADFACEVD	ADSL.SAFFL="Y" and ADSL.HIVFL='N' and ADSL.PHASEN > 1 and ADSL.AGEGR1N > 1 and ADSL.MULENRFL ne 'Y' and ADFACEVD.TRTA ne "" and ADFACEVD.FAOBJ not in ("PAIN AT INJECTION SITE" "SWELLING" "REDNESS") and index(upcase(ADFACEVD.FAOBJ),"HOSPI")=0 and ADFACEVD.KNOWVFL="Y" and ADFACEVD.CUTUNBFL ne "Y"
6	adae-s091-all-pd2-p3-saf1-sas.txt	adae_s091_all_pd2_p3_saf1.html	Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL ADAE	ADSL.SAFFL="Y" and ADSL.PHASEN > 1 and ADSL.AGEGR1N > 1 and ADSL.MULENRFL ne "Y" and ADSL.HIVFL ne 'Y' and NOT (ADSL.VAX101='' and ADSL.VAX102='')

Table	Program Name	Output Name	Title	Input	Population Subset used
7	adae-s092-all-unb-p3-saf-sas.txt	adae-s092-all-unb-p3-saf.html	Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL ADAE	ADSL.SAFFL='Y' and ADSL.PHASEN in (2,3,4) and ADSL.AGETR01 >=16 and ADSL.MULENRFL ne 'Y' and ADSL.HIVFL ne 'Y' and (ADSL.VAX101DT ne . and ADSL.BDCSRDT ne .) and ADSL.TRT01A ne ""
8	adae-vax-tier2-p3-saf-sas.txt	adae_vax_tier2_p3_saf.html	Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL ADAE	ADSL.SAFFL = "Y" and ADSL.PHASEN > 1 and ADSL.AGEGR1N > 1 and ADSL.MULENRFL ne "Y" and ADSL.HIVFL ne "Y" and ADSL.TRT01A ne ""
9	adae-s091-all-pd2-p3-saf2-sas.txt	adae_s091_all_pd2_p3_saf2.html	Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population	ADSL ADAE	ADSL.SAFFL="Y" and ADSL.PHASEN > 1 and ADSL.AGEGR1N > 1 and ADSL.MULENRFL ne "Y" and ADSL.HIVFL ne 'Y' and ADSL.TRT01AN = 8 and ADSL.DS3KFL='Y'
10	adae-s092-cr-cut-p3x-saf-sas.txt	adae-s092-cr-cut-p3x-saf.html	Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population	ADSL ADAE	ADSL.SAFFL='Y' and ADSL.PHASEN > 1 and ADSL.AGETR01 ge 16 and ADSL.MULENRFL ne 'Y' and ADSL.HIVFL ne 'Y' and ADSL.ARM='Placebo' and ADSL.VAX201DT>. and ADSL.X1CSRDT>.
11	adc19ef-ve-cov-7pd2-wo-eval-sas.txt	adc19ef_ve_cov_7pd2_wo_eval.html	Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL='Y' and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N' and ADC19EF.PDP27FL='Y'
12	adc19ef-ve-cov-	adc19ef_ve_cov_7p	Vaccine Efficacy – First COVID-19	ADSL	ADSL.EVALEFFL='Y' and ADSL.MULENRFL

Table	Program Name	Output Name	Title	Input	Population Subset used
	7pd2-eval-sas.txt	d2_eval.html	Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADC19EF ADSYMPT	ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N'
13	adc19ef-ve-cov-7pd2-wo-sg-eval-sas.txt	adc19ef_ve_cov_7pd2_wo_sg_eval html	Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL='Y' and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N' and ADC19EF.PDP27FL='Y'
14	adc19ef-ve-cov-7pd2-sg-eval-sas.txt	adc19ef_ve_cov_7pd2_sg_eval html	Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL='Y' and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N'
15	adc19ef-ve-sev-cov-7pd2-wo-eval-sas.txt	adc19ef_ve_sev_cov_7pd2_wo_eval html	Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL='Y' and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N' and ADC19EF.PDP27FL='Y'
16	adc19ef-ve-sev-cov-7pd2-eval-sas.txt	adc19ef_ve_sev_cov_7pd2_eval html	Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL='Y' and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N'
17	adc19ef-ve-sev-cov-pd1-aai-	adc19ef_ve_sev_cov_pd1_aai html	Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-	ADSL ADC19EF	ADSL.AAI1EFFL='Y' and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL

Table	Program Name	Output Name	Title	Input	Population Subset used
	sas.txt		Controlled Follow-up Period – Dose 1 All-Available Efficacy Population	ADSYMPT	= 'N'
18	adsl-demo-7d-eval-eff-sas.txt	adsl_demo_7d_eval_eff.html	Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADC19EF.PDP27FL='Y'
19	adsl-demo-7d-wwo-eval-eff-sas.txt	adsl_demo_7d_wwo_eval_eff.html	Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADC19EF.PDP27FL in ('Y' 'N')

8. Appendix

Appendix I: Annotated Mocks for Key Tables

General note: Each row subsetting is based on N criteria plus additional criteria annotated on the mocks.

Disposition of All Randomized Subjects – Phase 2/3 Subjects ⩾16 Years of Age

ADSL.TRT01P

ADSL.RANDFL eq 'Y' and ADSL.PHASEN ne 1 and ADSL.AGEGR3N ne . and ADSL.MULENRFL ne "Y"

ADSL.RANDFL eq 'Y'

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=xx) n[b] (%)	Placebo (N[a]=xx) n[b] (%)	Total (N[a]=xx) n[b] (%)
Randomized		xx (xxx.x)	xx (xxx.x)
Not vaccinated		xx (xxx.x)	xx (xxx.x)
Original blinded placebo-controlled follow-up period			
Vaccinated			xx (xxx.x)
Dose 1			xx (xxx.x)
Dose 2			xx (xxx.x)
Discontinued from original blinded placebo-controlled follow-up vaccination period[c]			
Reason for discontinuation			
Adverse event			
Withdrawal by subject			
Physician decision			
Death			xx (xxx.x)
Pregnancy			xx (xxx.x)
Other			
Unblinded before 1-month post–Dose 2 visit			
Completed 1-month post–Dose 2 visit	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)

ADSL.RANDFL eq 'Y' and (ADSL.VAX101DT eq . and ADSL.VAX102DT eq . and ADSL.VAX10UDT=. and ADSL.VAX201DT eq . and ADSL.VAX202DT eq .)

ADSL.RANDFL eq 'Y' and (ADSL.VAX101DT ne . or ADSL.VAX102DT ne .)

ADSL.RANDFL eq 'Y' and ADSL.VAX101DT ne .

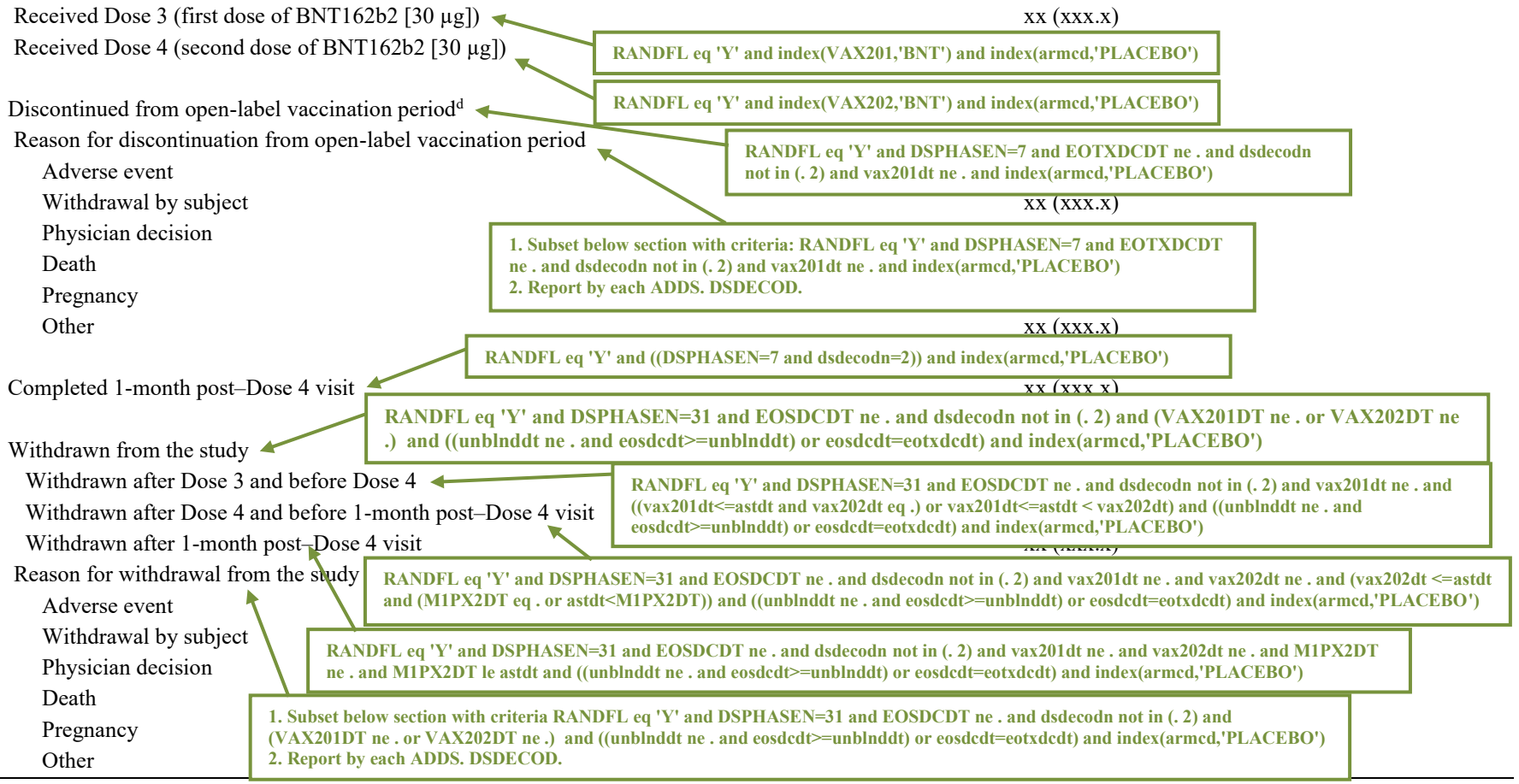
ADSL.RANDFL eq 'Y' and ADSL.VAX102DT ne . and (ADSL.VAX102DT< ADSL.UNBLNDDT or ADSL.UNBLNDDT=.)

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=26 and ADSL.EOTDCDT ne . and ADDS.dsdecodn not in (. 2) and (ADSL.VAX101DT ne . or ADSL.VAX102DT ne .) and (ADSL.unblnddt=. or ADSL.eotdcdt< ADSL.unblnddt)

1. Subset below section with criteria: ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=26 and ADSL.EOTDCDT ne . and ADDS.dsdecodn not in (. 2) and (ADSL.VAX101DT ne . or ADSL.VAX102DT ne .) and (ADSL.unblnddt=. or ADSL.eotdcdt< ADSL.unblnddt)
2. Report by each ADDS. DSDECOD.

ADSL.RANDFL eq 'Y' and ADSL.UNBLNDDT ne . and (ADSL.UNBLNDDT<= ADDS.M1PD2DT or ADDS.M1PD2DT=.)

ADSL.RANDFL eq 'Y' and ((ADDS.DSPHASEN=26 and ADDS.dsdecodn=2)) and (ADSL.unblnddt=. or ADDS.astdt< ADSL.unblnddt)



Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
Note: Subjects randomized but did not sign informed consent or had a significant quality event due to lack of PI oversight are not included in any analysis population
Note: Because of a dosing error, Subject[s] C4591001 xxxx xxxxx [and C4591001 xxxx xxxxxx] received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving 1 dose of BNT162b2 (30 µg) and 1 dose of placebo.

a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Original blinded placebo-controlled vaccination period is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).

PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM)
(Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

ADSL.SAFFL eq "Y" and ADSL.PHASEN ne 1 and ADSL.AGEGR1N not in (. 1) and ADSL.MULENRFL ne "Y"

Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=xx) n[b] (%)	Placebo (N[a]=xx) n[b] (%)	Total (N[a]=xx) n[b] (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled vaccination period			
<2 Months		xx (xx.x)	xx (xx.x)
⩾2 Months to <4 months		xx (xx.x)	xx (xx.x)
⩾4 Months to <6 months		xx (xx.x)	xx (xx.x)
⩾6 Months	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total exposure from Dose 2 to cutoff date			
<2 Months			
⩾2 Months to <4 months			
⩾4 Months to <6 months		xx (xx.x)	
⩾6 Months	xx (xx.x)		

ADSL.TRT01A

ADSL.FUP2CA2N in (1,2)

ADSL.FUP2CA2N in (3,4)

ADSL.FUP2CA2N in (5,6)

ADSL.FUP2CA2N >6

ADSL.FUP2CA1N in (1,2)

ADSL.FUP2CA1N in (3,4)

ADSL.FUP2CA1N in (5,6)

ADSL.FUP2CA1N >6

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.

b. n = Number of subjects with the specified characteristic.

PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: abcdefgh Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

ADFACEVD.ATPTREF

ADFACEVD.TRTA

ADSL.AGEGR1

ADFACEVD.FAOBJ

			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			x, xx.x)		xx.x)	(xx.x, xx.x)
		Mild			, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Moderate			x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Severe			x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Grade 4			x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Swelling[d]						
		Any			x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Mild			x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Moderate			x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Pain at the injection site[e]						
		Any	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Mild	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)

ADFACEVD.FATESTCD ='MAXSEV' and AVALC ne '' and EVENTF='Y'

ADSL.SAFFL="Y" and ADSL.HIVFL="N" and ADFACEVD.FAOBJ in ("PAIN AT INJECTION SITE" "SWELLING" "REDNESS") and ADSL.KNOWVFL="Y" and ADFACEVD.TRTA ne "" and ADSL.PHASEN ne 1 and ADSL.AGEGR1N^=1 and ADSL.MULENRFL^='Y' and ADSL.CUTUNBFL ne "Y"

For Dose ne "Any Dose":
if ADFACEVD.ATPTREF = "VACCINATION 2" and ADSL.VAX101 ne ADSL.VAX102 then delete;

		Any local reaction[f]	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
	2	<Repeat for Dose 2>						
	Any dose	<Repeat for any dose>						
<Repeat for each age group>								

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM)
(Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

ADSL.AGEGR1 | ADFACEVD.ATPTREF | ADFACEVD.TRTA | ADFACEVD.FAOBJ

Age Group	Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)			Placebo		
			N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
16-55 Years	1	Fever						
		≥38.0℃						(xx.x, xx.x)
		≥38.0℃ to 38.4℃						(xx.x, xx.x)
		>38.4℃ to 38.9℃						(xx.x, xx.x)
		>38.9℃ to 40.0℃				NN	nn (xx.x)	(xx.x, xx.x)
		>40.0℃				NN	nn (xx.x)	(xx.x, xx.x)
		Fatigue[d]						
		Any				NN	nn (xx.x)	(xx.x, xx.x)
		Mild				NN	nn (xx.x)	(xx.x, xx.x)
		Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Headache[d]						
		Any	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Mild	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Chills[d]						

ADSL.SAFFL="Y" and ADFACEVD.TRTA ne "" and ADFACEVD.FAOBJ not in ("PAIN AT INJECTION SITE" "SWELLING" "REDNESS") and index(upcase(ADFACEVD.FAOBJ),"HOSPI")=0 and ADSL.KNOWVFL="Y" and ADSL.PHASEN ne 1 and ADSL.AGEGR1N^=1 and ADSL.MULENRFL^='Y' and ADSL.HIVFL='N' and ADSL.CUTUNBFL ne "Y"

For Dose ne "Any Dose":
if ADFACEVD.ATPTREF= "VACCINATION 2" and ADSL.VAX101 ne ADSL.VAX102 then delete;

FATESTCD in ("MAXSEV" "MAXTEMP" "MEDTFVPN") and EVENTFL="Y" and AVALC ne ""

Any	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Mild	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Vomiting[e]						
Any	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Mild	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Diarrhea[f]						
Any	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Mild	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
New or worsened muscle pain[d]						
Any	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Mild	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
New or worsened joint pain[d]						

		Any	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Mild	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Moderate	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Severe	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
		Grade 4	NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
	Any systemic event[g]		NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
	Use of antipyretic or pain medication[h]		NN	nn (xx.x)	(xx.x, xx.x)	NN	nn (xx.x)	(xx.x, xx.x)
2	<Repeat for Dose 2>							
Any dose	<Repeat for any dose>							
<Repeat for each age group>								

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.

a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of subjects with the specified characteristic.

c. Exact 2-sided CI based on the Clopper and Pearson method.

d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe 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℃, 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: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

AECAT='ADVERSE EVENT' and ADSL.SAFFL='Y' and ADAE.VPHASEN in (1,2,3) and ADSL.PHASEN ne 1 and ADSL.AGEGR1N ne 1 and ADSL.HIVFL ne 'Y' and ADSL.MULENRFL ne "Y" and ADSL.V01DT >= ADAE.ASTDT

ADSL.SAFFL="Y" and ADSL.PHASEN ne 1 and ADSL.AGEGR1N ne 1 and ADSL.MULENRFL ne "Y" and ADSL.HIVFL ne 'Y' and NOT (ADSL.VAX101='' and ADSL.VAX102='')

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

ADSL.TRT01A

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=xx)	Placebo (N[a]=xx)
Adverse Event	**n[b] (%)**	**n[b] (%)**
Any event	xx (xx.x)	xx (xx.x)
Related[c]	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Life-threatening	xx (xx.x)	xx (xx.x)
Any serious adverse event	xx (xx.x)	xx (xx.x)
Related[c]	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Life-threatening	xx (xx.x)	xx (xx.x)
Any adverse event leading to withdrawal	xx (xx.x)	xx (xx.x)
Related[c]	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Life-threatening	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)

upcase(ADAE.AREL)="RELATED"

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADAE.AESER="Y"

index (upcase(ADAE.AEACN),'DRUG WITHDRAWN') > 0 or ADAE.AESUBJDC='Y')

ADAE.AESDTH='Y' or ADAE.AEOUT='FATAL'

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

ADAE.AECAT = 'ADVERSE EVENT' and ADSL. SAFFL='Y' and ADSL.AGETR01 >=16 and ADSL.PHASEN in (2,3,4) and ADAE.VPHASEN>0 and ADSL.MULENRFL ne 'Y' and ADSL.HIVFL ne 'Y' and (.<ADSL.VAX101DT<=ADAE.ASTDT<=ADSL.BDCSRDT)

ADSL.SAFFL='Y' and ADSL.AGETR01 >=16 and ADSL.PHASEN in (2,3,4) and ADSL.MULENRFL ne 'Y' and ADSL.HIVFL ne 'Y' and (ADSL.VAX101DT ne . and ADSL.BDCSRDT ne .)

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

ADSL.TRT01A

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=xxx, TE[b] =xxx)			Placebo (N[a]=xxx, TE[b] =xxx)		
Adverse Event	**n**	**IR (/100 PY)[d]**	**(95% CI[e])**	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**
Any event	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Related[f]	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Severe	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Life-threatening	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Any serious adverse event	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Related[f]	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Severe	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Life-threatening	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Any adverse event leading to withdrawal	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Related[f]	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Severe	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Life-threatening	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Death	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)

upcase(ADAE.AREL)="RELATED"

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADAE.AESER="Y"

upcase(ADAE.AEACN)='DRUG WITHDRAWN' or ADAE.AESUBJDC='Y'

upcase(ADAE.AEOUT)='FATAL'

SUM(ADSL. FUP1UNB)/(365.25*100)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = the number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

ADAE.AEBODSYS

ADAE.AEDECOD

ADSL.TRT01A

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg)		Placebo			
	(N[a]=xx)		(N[a]=xx)		Difference	
System Organ Class						
Preferred Term	**n[b] (%)**	**(95% CI[c])**	**n[b] (%)**	**(95% CI[c])**	**%[d]**	**(95% CI[e])**
<System organ class>						
<Preferred term>				(xx.x, xx.x)	xx.x	(xx.x, xx.x)
<Preferred term>				(xx.x, xx.x)	xx.x	(xx.x, xx.x)
<System organ class>						
<Preferred term>	xx (xx.x)	(xx.x, xx.x)	xx			
<Preferred term>	xx (xx.x)	(xx.x, xx.x)	xx			

ADAE.AECAT = 'ADVERSE EVENT' and ADAE.VPHASEN in (1,2) and ADAE.V01DT >= ADAE.ASTDT and (ADAE.UNBLNDDT = . or ADAE.UNBLNDDT > ADAE.ASTDT) and ADSl.AGEGR1N ne 1 and ADSL.MULENRFL ne "Y" and ADSL.HIVFL ne "Y"

Method Used:

```
proc binomial data=XXXX out=XXXX1 max_time=120 alpha=0.95 ;
  by _event;
  RISKDIFF / AS ONE STD;
  popl _trt_id;
  outcome _exist;
run;
```

Note: MedDRA (v23.1) coding dictionary applied.
Note: Tier 2 events are "common" adverse events with an incidence rate ⩾1.0% in any vacc
at this stage for this program.
Note: The 95% confidence interval quantifies the precision of the risk difference estimate. C
only be used to identify potentially important adverse events.

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (BNT162b2 [30 µg] – placebo).
e. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.

PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMYYY (HH:MM)
(Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

ADAE.SAFFL="Y" and ADSL.HIVFL ne 'Y' and ADSL.PHASEN ne 1 and ADSL.AGEGR1N ne 1 and MULENRFL ne "Y" and TRT01AN = 8 and DS3KFL='Y'

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

ADSL.TRT01A

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=xx)	Placebo (N[a]=xx)
Adverse Event	**n[b] (%)**	**n[b] (%)**
Any event	xx (xx.x)	xx (xx.x)
upcase(ADAE.AREL)="RELATED"		
Related[c]	xx (xx.x)	xx (xx.x)
ADAE.ATOXGRN=3		
Severe	xx (xx.x)	xx (xx.x)
ADAE.ATOXGRN=4		
Life-threatening	xx (xx.x)	xx (xx.x)
Any serious adverse event	xx (xx.x)	xx (xx.x)
Related[c]	xx (xx.x)	xx (xx.x)
ADAE.AESER="Y"		
Severe	xx (xx.x)	xx (xx.x)
Life-threatening		xx (xx.x)
index (upcase(ADAE.AEACN),'DRUG WITHDRAWN') > 0 or ADAE.AESUBJDC='Y')		
Any adverse event leading to withdrawal		xx (xx.x)
Related[c]	xx (xx.x)	xx (xx.x)
Severe	xx (xx.x)	xx (xx.x)
Life-threatening	x (xx.x)	xx (xx.x)
ADAE.AESDTH='Y' or ADAE.AEOUT='FATAL'		
Death	x (xx.x)	xx (xx.x)

a. N = number of subjects in the specified 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: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

ADAE.AECAT='ADVERSE EVENT' and ADSL.SAFFL='Y' and ADAE.VPHASEN >=5 and ADAE.VPHASEN ne 99 and ADSL.PHASEN ne 1 and ADSL.AGETR01 ge 16 and ADSL.MULENRFL ne "Y" and ADSL.HIVFL ne 'Y' and ADSL.ARM='Placebo' and .<ADSL.VAX201DT <= ADAE.ASTDT<=ADSL.X1CSRDT

ADSL.SAFFL='Y' and ADSL.HIVFL ne 'Y' and ADSL.PHASEN ne 1 and ADSL.AGETR01 ge 16 and ADSL.MULENRFL ne 'Y' and ADSL.ARM='Placebo' and ADSL.VAX201DT>. and ADSL.X1CSRDT>.

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

ADSL.TRT02A

upcase(ADAE.AREL)="RELATED"

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADAE.AESER="Y"

index (upcase(ADAE.AEACN),'DRUG WITHDRAWN') > 0 or ADAE.AESUBJDC='Y')

upcase(ADAE.AEOUT)='FATAL'

SUM(ADSL. FPX1CUT)/(365.25*100)

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=xxx, TE[b] =xxx)			Placebo (N[a]=xxx, TE[b] =xxx)		
Adverse Event	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**
Any event	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Related[f]	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Severe	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Life-threatening	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Any serious adverse event	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Related[f]	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Severe	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Life-threatening	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Any adverse event leading to withdrawal	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Related[f]	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Severe	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Life-threatening	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)
Death	xx	x.x	(xx.x, xx.x)	xx	x.x	(xx.x, xx.x)

Note: Dose 3 = First dose of BNT162b2 (30 ug).

a. N = number of subjects in the specified group.

b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.

c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = the number of subjects reporting at least 1 occurrence of any event.

d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.

e. 2-sided CI based on Poisson distribution.

f. Assessed by the investigator as related to investigational product.

PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM)

(Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

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

ADSL.RANDFL="Y"

ADSL.EVALEFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N'

ADSL.EVALEFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N' and ADC19EF. PDP27FL = "Y"

ADSL.TRT01P

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=nn)		Placebo (N[a]=nn)				
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	nnn	xxx (nnn)	nnn	xxx (nnn)	xx.x	(xx.x, xx.x)	x.xxxx

ADSL.EVALEFFL="Y" and ADC19EF.PARAMCD="C19ONST" and index(upcase(ADC19EF.AVALC), "POS")>0 and ADC19EF.PDRMUPFL="N" and ADC19EF.ILD27FL="Y" and ADC19EF.FILOCRFL="Y" and ADC19EF.PDP27FL="Y" and ((not missing(ADSL.DVSTDT) and ADC19EF.ADT <= ADSL.DVSTDT) or missing(ADSL.DVSTDT)).

ADC19EF.PDRMUPFL = "N" AND ADC19EF.PDP27FL = "Y" AND ADC19EF.PARAMCD IN ("ST27PD") AND ADC19EF.AVAL > 0

Sum of ADC19EF.AVAL where ADC19EF.PARAMCD IN ("ST27PD")

AT = nucleic acid amplification test; SARS CoV-2 = severe acute respiratory syndrome

7 days after receipt of t

asal swab] at Visits 1 a

prior to 7 days after Dose 2 were included in the analysis.

a. N = number of subjects in the specified group.

b. n1 = Number of subjects meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of subjects at risk for the endpoint.

e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.

PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: abcdefgh Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

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

- **Follow the same annotations as above mock, except do not use PDP27FL="Y" subset condition as this table is for subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2**

ADSL.EVALEFFL="Y" and ADC19EF.PARAMCD="C19ONST" and index(upcase(ADC19EF.AVALC), "POS")>0 and ADC19EF.PDRMUPFL="N" and ADC19EF.ILD27FL="Y" and ADC19EF.FILOCRFL="Y" and ADC19EF.PDP27FL="Y" and ((not missing(ADSL.DVSTDT) and ADC19EF.ADT <= ADSL.DVSTDT) or missing(ADSL.DVSTDT)).

ADSL.EVALEFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N'

ADSL.TRT01P

ADSL.RANDFL="Y"

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

ADSL.EVALEFFL ="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N' and ADC19EF. PDP27FL = "Y"

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=nnn)		Placebo (N[a]=nnn)			
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	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Age group (years)						
12 to 15	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
16 to 55	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
>55	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
⩾65	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
16 to 17	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
16 to 25	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
16 to 64	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
18 to 64	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
55 to 64	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
65 to 74	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
⩾75	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
75 to 85	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
>85	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Sex						
Male	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Female	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Race						

Sum of ADC19EF.AVAL where ADC19EF.PARAMCD IN ("ST27PD")

ADC19EF.PDRMUPFL = "N" AND ADC19EF.PDP27FL = "Y" AND ADC19EF.PARAMCD IN ("ST27PD") AND ADC19EF.AVAL > 0

ADSL.AGETR01
12<=AGETR01<=15 for 12 to 15
16<=AGETR01<=55 for 16 to 55
AGETR01>55 for >55
AGETR01>=65 for ≥65
16<=AGETR01<=17 for 16 to 17
16<=AGETR01<=25 for 16 to 25
16<=AGETR01<=64 for 16 to 64
18<=AGETR01<=64 for 18 to 64
55<=AGETR01<=64 for 55 to 64
65<=AGETR01<=74 for 65 to 74
AGETR01>=75 for ≥75
75<=AGETR01<=85 for 75 to 85
AGETR01>85 for >85

ADSL.SEX

ADSL.ARACE

White	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Black or African American	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
American Indian or Alaska Native	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Asian	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Native Hawaiian or other Pacific Islander	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Multiracial	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Not reported	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
All others[f]	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Racial designation						
Japanese	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Ethnicity						
Hispanic/Latino	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Non-Hispanic/non-Latino	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Not reported	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Country						
Argentina	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Brazil	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Germany	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
South Africa	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
			xx	xxx (xx)	xx.x	(xx.x, xx.x)
			xx	xxx (xx)	xx.x	(xx.x, xx.x)
Prior SARS-CoV-2 status						
Positive at baseline[g]						
Positive N-binding only						
Positive NAAT only						
Positive NAAT and N-binding						
Negative at baseline but positive prior to 7 days after Dose 2[h]						
Negative prior to 7 days after Dose 2[i]						x, xx.x)
Unknown						x, xx.x)

ADSL.RACIALDN=5

ADSL.ETHNIC

ADSL.COUNTRY

ADC19EF.VRBLNGFL='N' or ADC19EF.CRD1NGFL='N' or ADC19EF.C19ILHFL="Y" or IE.IESTRESC='Y'

ADC19EF.VRBLNGFL='N' or ADC19EF.CRD1NGFL='N' or ADC19EF.C19ILHFL="Y" or IE.IESTRESC='Y' and (ADSL.NIGV1FL = "N" and ADSL.NAATNFL ne "N")

ADC19EF.VRBLNGFL='N' or ADC19EF.CRD1NGFL='N' or ADC19EF.C19ILHFL="Y" or IE.IESTRESC='Y' and (ADSL.NIGV1FL ne "N" and ADSL.NAATNFL = "N")

ADC19EF.VRBLNGFL='N' or ADC19EF.CRD1NGFL='N' or ADC19EF.C19ILHFL="Y" or IE.IESTRESC='Y' and (ADSL.NIGV1FL = "N" and ADSL.NAATNFL = "N")

ADC19EF.VRBLNGFL='Y' and ADC19EF.CRD1NGFL='Y' and (ADC19EF.CRD2NGFL="N" or ADC19EF.PARAMCD in ("NAATRAD", "RTCOV2NS", "C19ONST") and ADC19EF.AVALC="POS" and ADC19EF.VAX101DT ^= . and ADC19EF.VAX102DT ^= . and ADC19EF.VAX101DT < ADC19EF.ADT < sum(ADC19EF.VAX102DT,7))

ADC19EF.PDP27FL="Y"

Abbreviations: N le ndrome 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.
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: DDMMMYYYY (HH:MM) Source Data: abcdefgh Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

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

- **Follow the same annotations as above mock, except do not use PDP27FL="Y" subset condition as this table is for subject With or Without Evidence of Infection Prior to 7 Days After Dose 2**

ADSL.TRT01P

ADSL.RANDFL="Y"

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

ADSL.EVALEFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N' and ADC19EF. PDP27FL =

ADSL.EVALEFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N'

Efficacy Endpoint	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=nnn) n1[b]	Surveillance Time[c] (n2[d])	Placebo (N[a]=nnn) 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	nnn	xxx (nnn)	nnn	xxx (nnn)	xx.x	(xx.x, xx.x)	xx.xx%

ADSL.EVALEFFL="Y" and ADC19EF.PARAMCD="SEVCONST" and index(upcase(ADC19EF.AVALC), "POS")>0 and ADC19EF.PDRMUPFL="N" and ADC19EF.ILD27FL="Y" and ADC19EF.FILOCRFL="Y" and ADC19EF.PDP27FL="Y" and ((not missing(ADSL.DVSTDT) and ADC19EF.ADT <= ADSL.DVSTDT) or missing(ADSL.DVSTDT)).

ADC19EF.PDRMUPFL = "N" AND ADC19EF.PDP27FL = "Y" AND ADC19EF.PARAMCD IN ("ST27SE") AND ADC19EF.AVAL > 0

Sum of ADC19EF.AVAL where ADC19EF.PARAMCD IN ("ST27SE")

AT = nucleic acid amplification test; SAR- -COV-2 = severe acute respiratory syndrome coron virus

7 days after receipt of the last dos

b] at Visits 1 and 2), and had nega

b. n1 = Number of subjects meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endp Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance per

d. n2 = Number of subjects at risk for the endpoint.

e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.

PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: abcdefgh Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

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

- **Follow the same annotations as above mock, except do not use PDP27FL="Y" subset condition as this table is for subject With or Without Evidence of Infection Prior to 7 Days After Dose 2**

ADSL.AAI1EFFL="Y" and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1 and ADSL.HIVFL = 'N'

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

ADSL.AAI1EFFL="Y" and ADC19EF.PARAMCD="SEVCONST" and find(ADC19EF.AVALC, 'POS' , 'i') and ADC19EF.PDRMUPFL="N" and ADC19EF.ADT >= ADC19EF.VAX101DT and upcase(ADC19EF.FILOCRFL) = "Y".

ADSL.RANDFL="Y

ADSL.TRT01P

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=xx) n1[b]	Surveillance Time[c] (n2[d])	Placebo (N[a]=xx) n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First Severe COVID-19 occurrence after Dose 1	x	xx (xx)	x			
After Dose 1 to before Dose 2	x	xx (xx)	x			
Dose 2 to 7 days after Dose 2	x		x			
≥7 days after Dose 2	x	xx (xx)	x	xx(xx)	xx	(xx, xx)

Sum of ADC19EF.AVAL where ADC19EF.PARAMCD IN ("ST1SEA")

ADC19EF.PDRMUPFL = "N" AND ADC19EF.PARAMCD IN ("ST1SEA") AND ADC19EF.AVAL > 0

(not missing(ADC19EF.VAX101DT) and not missing(ADC19EF.VAX102DT) and ADC19EF.VAX101DT <= ADC19EF.ADT < ADC19EF.VAX102DT) or ((not missing(ADC19EF.VAX101DT) and missing(ADC19EF.VAX102DT) and ADC19EF.VAX101DT <= ADC19EF.ADT).

not missing(ADC19EF.VAX102DT) and ADC19EF.ADT >= ADC19EF.VAX102DT + 7.

not missing(ADC19EF.VAX102DT) and ADC19EF.VAX102DT <= ADC19EF.ADT < ADC19EF.VAX102DT + 7.

Abbreviations: VE = vaccine efficacy.

d group.

ndpoint definition.

-years for the given en

riod 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

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_wo_sg_eval

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

ADSL.EVALEFFL="Y" and ADC19EF. PDP27FL='Y' and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=xx) n[b] (%)	Placebo (N[a]=xx) n[b] (%)	Total (N[a]=xx) n[b] (%)
Sex			
Male (ADSL.SEX="M", ADSL.TRT01P)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Female (ADSL.SEX="F")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Race			
White (ADSL.ARACE="WHITE")			xx (xxx.x)
Black or African American (ADSL.ARACE="BLACK OR AFRICAN AMERICAN")			xx (xxx.x)
American Indian or Alaska Native (ADSL.ARACE="AMERICAN INDIAN OR ALASKA NATIVE")			xx (xxx.x)
Asian (ADSL.ARACE="ASIAN")			(xxx.x)
Native Hawaiian or other Pacific Islander (ADSL.ARACE="NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Multiracial (ADSL.ARACE="MULTIRACIAL")	x (xxx.x)	xx (xxx.x)	xx (xxx.x)
Not reported (ADSL.ARACE="NOT REPORTED")	x (xxx.x)	xx (xxx.x)	xx (xxx.x)
All others[c] (ADSL.ARACE not in ("WHITE" "BLACK OR AFRICAN AMERICAN"))	x (xxx.x)	xx (xxx.x)	xx (xxx.x)
Racial designation			
Japanese (ADSL. RACIALDN=5)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Ethnicity			
Hispanic/Latino (ADSL.ETHNIC="HISPANIC OR LATINO")		xx (xxx.x)	xx (xxx.x)
Non-Hispanic/non-Latino (ADSL.ETHNIC="NOT HISPANIC OR LATINO")		xx (xxx.x)	xx (xxx.x)
Not reported (ADSL.ETHNIC="NOT REPORTED")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Country			
Argentina (ADSL.COUNTRY="ARG")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)

Brazil (ADSL.COUNTRY="BRA")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Germany (ADSL.COUNTRY="DEU")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
South Africa (ADSL.COUNTRY="ZAF")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Turkey (ADSL.COUNTRY="TUR")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
USA (ADSL.COUNTRY="USA")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Age group (years) (ADSL.12<= AGETR01<=15)			
12 to 15	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
16 to 55 (ADSL. 16<=AGETR01<=55)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
≥55 (ADSL. AGETR01>=55)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
≥65 (ADSL.AGETR01>=65)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
16 to 17 (ADSL.16<= AGETR01<=17)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
16 to 25 (ADSL.16<= AGETR01<=25)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
16 to 64 (ADSL.16<= AGETR01<=64)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
18 to 64 (ADSL.18<= AGETR01<=64)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
55 to 64 (ADSL.55<= AGETR01>=64)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
65 to 64 (ADSL.65<= AGETR01<=64)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
≥75 (AGETR01>=75)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
75 to 85 (ADSL.75<= AGETR01<=85)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
>85 (ADSL. AGETR01>85)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Comorbidities[d] (ADSL.COMBODFL="Y" or (BMICATN = 4 and AGETR01 >=16) or OBESEFL="Y" then COMORBIDITIES = Yes else COMORBIDITIES = No)			
Yes	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
No	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Baseline SARS-CoV-2 status (ADSL.COVBLST="POS")			
Positive[e]	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Negative[f] (ADSL.COVBLST="NEG")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Unknown (ADSL.COVBLST not in ("NEG" "POS"))	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Age at vaccination (years) (ADSL.AGETR01)			
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)

Median	xx.x	xx.x	xx.x
Min, max	(xx, xx)	(xx, xx)	(xx, xx)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a . N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
f. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: abcdefgh Table Generation: DDMMMYYYY (HH:MM) (Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

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

- **Follow the same annotations as above mock, change subset condition , as below**

ADSL.EVALEFFL="Y" and ADC19EF. PDP27FLin ("Y" "N") and ADSL.MULENRFL ne "Y" and ADSL.PHASEN ne 1

Appendix II: Analysis plan AE windowing logic

AEs that occurred on the same day of a dose and without detailed AE start time are considered as occurring after dose but not considered as immediate AEs. An immediate AE is defined as an AE that occurred within 30 minutes (including 30 minutes) after dose.

AEs without start time and started on the same day of Dose x or AEs (with start time) started on or after the timepoint of dose x are included in 'AE's from dose x to 7 days after dose x', 'AE's from dose x to 1 months after dose x' and 'AE's from dose x to 6 months after dose x' window. Dose x could be Dose 1, Dose 2, Dose 3 or Dose 4 .

ADAE.VPHASE is derived based on AE window per the table below:

VPHASE		Comments
Pre-Vaccination	Event start before Dose 1	Blinded placebo-controlled period
Vaccination 1	Event start on or after Dose 1 and before Dose 2	Blinded placebo-controlled period
Vaccination 2	Event started on or after Dose 2 and before or on the day of 1 month follow up visit after Dose 2 (ADSL.V01DT) See details in below section for ADSL.V01DT	Blinded placebo-controlled period
Follow Up 1	Event start after the day of 1 month follow up visit after Dose 2 (ADSL.V01DT) and before or on the day of 6 months follow up visit after Dose 2 (ADSL.V02DT) See details in below section for ADSL.V02DT	Blinded placebo-controlled period
Follow Up 2	Event start after the day of 6 months follow up visit after Dose 2 (ADSL.V02DT) and before unblinding	Blinded placebo-controlled period
After unblinding and before Vaccination 3	Event start on or after unblinding and Dose 3 is missing	Open label follow-up period
	Event start on or after unblinding and before Dose 3	Open label follow-up period
Vaccination 3	Event start on or after Dose 3 and before Dose 4	Open label follow-up period
Vaccination 4	Event start on or after Dose 4 and before or on 1 month follow up visit after Dose 4 (ADSL.V03DT) See details in below section for ADSL.V03DT	Open label follow-up period
Follow Up 3	Event start after 1 month follow up visit after Dose 4 and before or on the day of 6 months follow up visit after Dose 4 (ADSL.V04DT) See details in below section for ADSL.V04DT	Open label follow-up period

VPHASE		Comments
Follow Up 4	Event start after the day of 6 months follow up visit after Dose 4 (ADSL.V04DT)	Open label follow-up period

For Phase 1 for BNT162b2 30 mcg and Equivalent Placebo Subjects:

For AE's from Dose 1 to 1 month after Dose 2 (Blinded placebo-controlled period):

- Dose 1 start date <= ae start date <= 1 month follow up date or the day before unblinding which one is earlier (ADSL.V01DT)
  V01DT is the blood sample collected date from visit 7.
  If visit 7 blood sample collection date is not available from CO dataset, then use the date of visit 7 from SV dataset.
  Else if date of visit 7 is not available, then use date of Dose 2 + 35 days
  Else if date of Dose 2 is not available, then use date of Dose 1 + 35 + 23 days

Note: if a subject was unblinded before visit 7 (V01DT), then ADSL.V01DT was reset to the day before unblinding. ADSL.V01DT=min (V01DT, ADSL.UNBLNDDT-1).

For AE's from Dose 1 to 6 months after Dose 2 (Blinded placebo-controlled period):

- Dose 1 start date <= ae start date < = 6 months follow up date or the day before unblinding which one is earlier (ADSL.V02DT)
  V02DT is the blood sample collected date from visit 8.
  If visit 8 blood sample collection date is not available from CO dataset, then use the date of visit 8 from SV dataset.
  Else if date of visit 8 from SV dataset is not available, then use date of Dose 2 + 189 days
  Else if date of Dose 2 is not available, then use date of Dose 1 + 189 + 23 days

Note: if a subject was unblinded before visit 8 (V02DT), then ADSL.V02DT was reset to the day before unblinding. ADSL.V02DT=min (V02DT, ADSL.UNBLNDDT-1).

For AE's from Dose 1 to 6 months after Dose 2 (Whole study period without considering unblinding):

- Dose 1 start date <= ae start date < = 6 months follow up date (ADSL.V02OBDT)
  V02OBDT is the blood sample collected date from visit 8.
  If visit 8 blood sample collection date is not available from CO dataset, then use the date of visit 8 from SV dataset.
  Else if date of visit 8 from SV dataset is not available, then use date of Dose 2 + 189 days
  Else if date of Dose 2 is not available, then use date of Dose 1 + 189 + 23 days

ADSL.V03DT is the date of visit 103 (1-month post dose 4 for follow up vaccination period) from SV after unblinding.
If date of visit 103 from SV dataset is not available, then use date of Dose 4 + 35 days
Else if date of Dose 4 is not available, then use date of Dose 3 + 35 + 23 days

ADSL.V04DT is the date of visit 104 (6-months post dose 4 for follow up period) from SV after unblinding.
If date of visit 104 from SV dataset is not available, then use date of Dose 4 + 189 days
Else if date of Dose 4 is not available, then use date of Dose 3 + 189 + 23 days

For Phase 2/3:

For AE's from Dose 1 to 1 month after Dose 2 (Blinded placebo-controlled period):

- Dose 1 start date <= ae start date <= 1 month follow up date or the day before unblinding which one is earlier (ADSL.V01DT)
  V01DT is the blood sample collected date from visit 3.
  If visit 3 blood sample collection date is not available from CO dataset, then use the date of visit 3 from SV dataset.
  Else if date of visit 3 is not available, then use date of Dose 2 + 35 days
  Else if date of Dose 2 is not available, then use date of Dose 1+ 35 + 23 days

Note: if a subject was unblinded before visit 3 (V01DT), then ADSL.V01DT was reset to the day before unblinding. ADSL.V01DT=min (V01DT, ADSL.UNBLNDDT-1).

For AE's from Dose 1 to 6 months after Dose 2 (Blinded placebo-controlled period):

- Dose 1 start date <= ae start date <= 6 months follow up date or the day before unblinding which one is earlier (ADSL.V02DT)
  V02DT is the blood sample collected date from visit 4.

  If visit 4 blood sample collection date is not available from CO dataset, then use the date of visit 4 from SV dataset.
  Else if date of visit 4 from SV dataset is not available, then use date of Dose 2 + 189 days
  Else if date of Dose 2 is not available, then use date of Dose 1+ 189 + 23 days

Note: if a subject was unblinded before visit 4 (V02DT), then ADSL.V02DT was reset to the day before unblinding. ADSL.V02DT=min (V02DT, ADSL.UNBLNDDT-1).

For AE's from Dose 1 to 6 months after Dose 2 (Whole study period without considering unblinding):

- Dose 1 start date <= ae start date <= 6 months follow up date (ADSL.V02OBDT)
  V02OBDT is the blood sample collected date from visit 4.
  If visit 4 blood sample collection date is not available from CO dataset, then use the date of visit 4 from SV dataset.
  Else if date of visit 4 from SV dataset is not available, then use date of Dose 2 + 189 days
  Else if date of Dose 2 is not available, then use date of Dose 1 + 189 + 23 days

Note: if a subject took Dose 3 in open label vaccination period before V02OBDT, then ADSL.V02OBDT was reset to the day before Dose 3. ADSL.V02OBDT=min (V02OBDT, ADSL.VAX201DT-1).

ADSL.V03DT is the date of visit 103 (1-month post dose 4 for follow up vaccination period) from SV after unblinding.
If date of visit 103 from SV dataset is not available, then use date of Dose 4 + 35 days
Else if date of Dose 4 is not available, then use date of Dose 3 + 35 + 23 days

ADSL.V04DT is the date of visit 104 (6-months post dose 4 for follow up period) from SV after unblinding.

If date of visit 104 from SV dataset is not available, then use date of Dose 4 + 189 days
Else if date of Dose 4 is not available, then use date of Dose 3 + 189 + 23 days

Appendix III: Handling of Incomplete Dates

Adverse events

Incomplete AE start and stop dates were imputed as follows:

Imputation only applied to partial AE start dates (missing day, missing both month and day). The purpose of imputation was only for allocating analysis interval on AE summary, the original partial date format was recorded or kept in the data and listings. No imputation on Diary data from subjects or symptom resolved date from Investigator collected as partial date. No imputation is carried out for completely missing AE start dates. No imputation is carried out for partial or completely missing AE stop dates. All information on AE stop date was used for imputation logic check as part of the imputation rules for partial AE start date.

Pfizer imputation rule applied:

Rules	Programming Logic
General rules	Imputation only applies to partial AE start dates (missing day, missing both month and day). The purpose of imputation is only for allocating analysis interval on AE summary, the original partial date format should be recorded or kept in the data and listings. No imputation on Diary data from subjects or symptom resolved date from Investigator collected as partial date. General Pfizer imputation rule applied: For Start date: - For missing Day: impute Day = first day of the month (01), e.g. November 1990 is treated as 01NOV1990 - For missing Month and Day: impute Month = first month of the year (JAN), impute Day = first day of the month (01), e.g. 1990 is treated as 01JAN1990 For Stop date: - For missing Day: impute Day = last day of the month (30 or 31), e.g. November 1990 is treated as 30NOV1990 - For missing Month and Day: impute Month = first month of the year (DEC), impute Day = last day of the month (31), e.g. 1990 is treated as 31DEC1990

Rules	Programming Logic
completely missing start dates	No imputation
completely missing stop dates	No imputation
partial stop dates	No imputation
the day portion of ASTDTM was initially missing	• Apply general imputation first, after general Pfizer imputation rule is applied, compare the month of the AE start date (ASTDTM) with the month of subsequent doses/vaccinations (EXSTDTC) • If the start date MONTH and YEAR of (ASTDTM) and any of the subsequent dose dates MONTH and YEAR of (EXSTDTC) are equal, and the stop date (AENDTM) is later than the dose date (EXSTDTC), whether the stop date (AENDTM) comes from partial or complete dates, or AE stop date is missing then reset ASTDTM to numeric value of first EXSTDTC of that month. • Otherwise if the AE start date MONTH and YEAR of (ASTDTM) do not match any month of subsequent doses/vaccination (EXSTDTC) MONTH and YEAR, or the stop date (AENDTM) comes from partial or complete dates is earlier than corresponding EXSTDTC, don't do the second imputation and retain the first imputation
day and month portion of ASTDTM were initially missing	• Apply general imputation first, compare the imputed AE start date (ASTDTM) with the dosing dates (EXSTDTC) in the same calendar year and the AE stop date (AENDTM). If the stop date is earlier than the earliest dosing date in the same calendar year, the AE start date will remain the first day of the calendar year. Otherwise, the AE start date (ASTDTM) will be imputed to the earliest dosing date (EXSTDTC) in that calendar year that is less than the AE stop date (AENDTM).

Concomitant medications/medical histories

Incomplete CM/MH start and stop dates were imputed as follows:

Imputation applied to partial CM/MH start dates and stop dates (missing day, missing both month and day). For partial start dates, if missing start day, the first day of the month was used; if missing start month and day, the first month of the year was used. For partial stop dates, if

missing stop day, the last day of the month was used; if missing stop month and day, the last month of the year was used.

Appendix IV: ADFACEVD Analysis Parameters

PARCAT1	PARCAT2	PARAM	PARAMCD
REACTOGENICITY	ADMINISTRATION SITE	Hospitalized for injection site pain occurrence indicator	OCHIS
REACTOGENICITY	ADMINISTRATION SITE	Pain at injection site maximum severity	MSPIS
REACTOGENICITY	ADMINISTRATION SITE	Pain at injection site occurrence indicator	OCPIS
REACTOGENICITY	ADMINISTRATION SITE	Pain at injection site severity/intensity	SEVPIS
REACTOGENICITY	ADMINISTRATION SITE	Redness diameter cm	DIARE
REACTOGENICITY	ADMINISTRATION SITE	Redness grade 4 criteria met	G4CRR
REACTOGENICITY	ADMINISTRATION SITE	Redness maximum diameter	MDIRE
REACTOGENICITY	ADMINISTRATION SITE	Redness maximum diameter cm	MADRE
REACTOGENICITY	ADMINISTRATION SITE	Redness maximum severity	MSERE
REACTOGENICITY	ADMINISTRATION SITE	Redness minimum diameter cm	MIDRE
REACTOGENICITY	ADMINISTRATION SITE	Redness occurrence indicator	OCISR
REACTOGENICITY	ADMINISTRATION SITE	Redness severity/intensity	SEVREDN
REACTOGENICITY	ADMINISTRATION SITE	Swelling diameter cm	DIASW
REACTOGENICITY	ADMINISTRATION SITE	Swelling grade 4 criteria met	G4CRS
REACTOGENICITY	ADMINISTRATION SITE	Swelling maximum diameter	MDISW
REACTOGENICITY	ADMINISTRATION SITE	Swelling maximum diameter cm	MADSW
REACTOGENICITY	ADMINISTRATION SITE	Swelling maximum severity	MSESW
REACTOGENICITY	ADMINISTRATION SITE	Swelling minimum diameter cm	MIDSW
REACTOGENICITY	ADMINISTRATION SITE	Swelling occurrence indicator	OCINS
REACTOGENICITY	ADMINISTRATION SITE	Swelling severity/intensity	SEVSWEL
REACTOGENICITY	MEDICATIONS GIVEN	Medications duration	MEDDUR
REACTOGENICITY	MEDICATIONS GIVEN	Medications medication to treat fever or pain	MEDTFVPN
REACTOGENICITY	MEDICATIONS GIVEN	Medications stop date meds given to trt/pnt symptoms	STPDMEDP
REACTOGENICITY	SYSTEMIC	Chills maximum severity	MAXCHIL
REACTOGENICITY	SYSTEMIC	Chills occurrence indicator	OCCHILLS
REACTOGENICITY	SYSTEMIC	Chills severity/intensity	SEVCHIL
REACTOGENICITY	SYSTEMIC	Diarrhea maximum severity	MAXDIAR
REACTOGENICITY	SYSTEMIC	Diarrhea occurrence indicator	OCDIAR
REACTOGENICITY	SYSTEMIC	Diarrhea severity/intensity	SEVDIAR
REACTOGENICITY	SYSTEMIC	Fatigue maximum severity	MAXSFAT
REACTOGENICITY	SYSTEMIC	Fatigue occurrence indicator	OCFATIG
REACTOGENICITY	SYSTEMIC	Fatigue severity/intensity	SEVFATI
REACTOGENICITY	SYSTEMIC	Fever maximum temperature	MAXTEMP
REACTOGENICITY	SYSTEMIC	Fever occurrence indicator	OCFEVER

PARCAT1	PARCAT2	PARAM	PARAMCD
REACTOGENICITY	SYSTEMIC	Headache maximum severity	MAXSHEA
REACTOGENICITY	SYSTEMIC	Headache occurrence indicator	OCHEAD
REACTOGENICITY	SYSTEMIC	Headache severity/intensity	SEVHEAD
REACTOGENICITY	SYSTEMIC	Hospitalized for chills occurrence indicator	OCHOCHIL
REACTOGENICITY	SYSTEMIC	Hospitalized for diarrhea occurrence indicator	OCHODI
REACTOGENICITY	SYSTEMIC	Hospitalized for headache occurrence indicator	OCHOHE
REACTOGENICITY	SYSTEMIC	Hospitalized for joint pain occurrence indicator	OCHOJP
REACTOGENICITY	SYSTEMIC	Hospitalized for muscle pain occurrence indicator	OCHOMP
REACTOGENICITY	SYSTEMIC	Hospitalized for tiredness (fatigue) occurrence indicator	OCHOFA
REACTOGENICITY	SYSTEMIC	Hospitalized for vomiting occurrence indicator	OCHOVO
REACTOGENICITY	SYSTEMIC	Joint pain maximum severity	MAXSJP
REACTOGENICITY	SYSTEMIC	Joint pain occurrence indicator	OCJOPAIN
REACTOGENICITY	SYSTEMIC	Joint pain severity/intensity	SEVJOIN
REACTOGENICITY	SYSTEMIC	Muscle pain maximum severity	MAXSMP
REACTOGENICITY	SYSTEMIC	Muscle pain occurrence indicator	OCMPNIS
REACTOGENICITY	SYSTEMIC	Muscle pain severity/intensity	SEVMUSP
REACTOGENICITY	SYSTEMIC	Vomiting maximum severity	MAXSVOM
REACTOGENICITY	SYSTEMIC	Vomiting occurrence indicator	OCVOMI
REACTOGENICITY	SYSTEMIC	Vomiting severity/intensity	SEVVOMI

Appendix V: External files used during ADaM dataset creation

The following files were used in the creation of specific ADaM datasets to identify specific subsets of subjects (e.g., Phase 1, Phase 2, Phase 3) as well as categories of medical history data used as comorbidities. Along with the xlsx files, pdf versions of the same files have been included.

ID	File Name	Comments
Rheumatic	report-cci-rheumatic.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Renal	report-cci-renal.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)

ID	File Name	Comments
Pulmonary	report-cci-pulmonary.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Periph vasc	report-cci-periph-vasc.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Peptic ulcer	report-cci-peptic-ulcer.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Mod sev liver	report-cci-mod-sev-liver.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Mild liver	report-cci-mild-liver.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
MI	report-cci-mi.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Metastatic tumour	report-cci-metastatic-tumour.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Lymphoma	report-cci-lymphoma.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)

ID	File Name	Comments
Leukemia	report-cci-leukemia.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Hemiplegia	report-cci-hemiplegia.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Diabetes without comp	report-cci-diabetes-without-comp.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Diabetes with comp	report-cci-diabetes-with-comp.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Dementia	report-cci-dementia.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
CHF	report-cci-chf.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Cerebrovascular	report-cci-cerebrovascular.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
Any malignancy	report-cci-any-malignancy.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)
AIDS HIV	report-cci-aids-hiv.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level) Used for ADSL creation to flag the subject with comorbidities (subject level)

ID	File Name	Comments
Comorbidity Categories	comorbidity-categories.xlsx	Used for ADMH creation to derive the Charlson Comorbidity Index categories by record level. One MH term may meet multiple Charlson Comorbidity Index categories.
Phase1	c4591001-phase-1-subjects-from dmw.xlsx	Used for ADSL creation to flag the subjects from Phase 1
Phase2	first-c4591001-360-participants-enrolled-v1-13aug20-update.xlsx	Used for ADSL creation to flag the subjects from Phase 2 DS360 subset
Phase3 DS6000	newlist-c4591001-6k-participants-enrolled-v3-17sep2020.csv	Used for ADSL creation to flag the subjects from Phase 3 DS6000 subset
HIV PT	201114-hiv-preferred-terms.xlsx	Used for ADSL creation to flag the HIV Positive
EUA 12-25 Age group	c4591001-subject-list-for-12-25-immuno-analysis-27jan2021.xlsx	Used for ADSL creation to flag the subjects from EUA 12-25 subset
BMI scale	bmi-12-15-scale.xlsx	Used for ADSL creation to flag the obese subjects for 12-15 years age group

Appendix VI: Surveillance Times

Start-of-surveillance time:

For all VE-related endpoints in this study, the start-of-surveillance times are summarized as follows:

Endpoint's Associated Participant-Level Population	Start-of-Surveillance Time
Evaluable Efficacy (7 days)	Dose 2 + 7 days (Day 8 relative to Dose 2)
Dose 2 All-available Efficacy	Dose 2 + 7 days (Day 8 relative to Dose 2)
Dose 1 All-available Efficacy	Dose 1 (Day 1 relative to Dose 1)

End-of-surveillance time:

The end of surveillance time is then determined considering the following events:

1. When the first COVID-19 case occurs.
2. When the participant's end of the study occurs due to, e.g. withdrawal or death or trial completion etc.
3. When the participant has first important protocol violation.
4. When the participant is unblinded at the time of being eligible for receipt of BNT162b2 or other reasons.

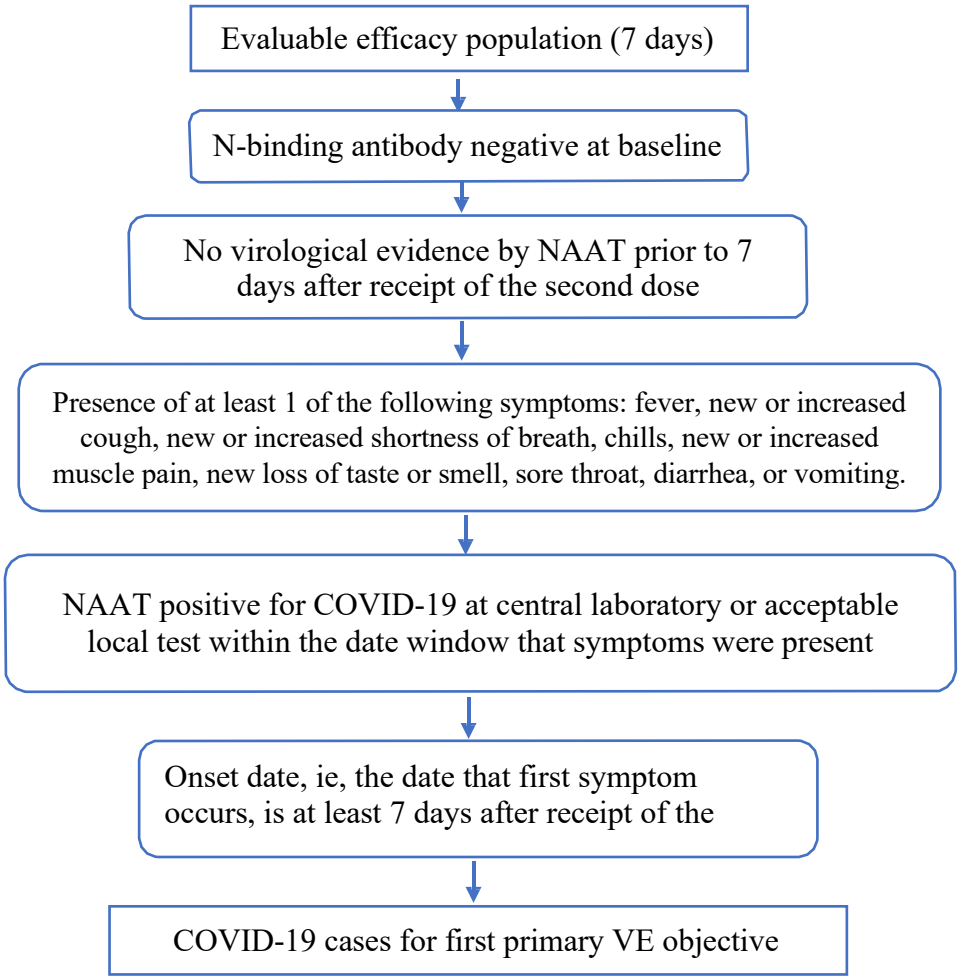
For all VE-related endpoints in this study, the end of a surveillance period for each participant is summarized below:

Endpoint's Associated Participant-Level Population	End-of-Surveillance Time
Evaluable Efficacy	Earliest of event (1), (2), (3) and (4)
Dose 2 All-available Efficacy	Earliest of event (1) and (2) and (4)
Dose 1 All-available Efficacy	Earliest of event (1) and (2) and (4)

Using the above start and stop times for surveillance time, the overall surveillance time is derived as: End-of-surveillance time – Start-of-surveillance time + 1

Appendix VII: Efficacy Flow Charts

1. The flowchart for deriving the COVID-19 cases included below for the first primary endpoints in evaluable efficacy participants with no serological or virological evidence of past SARS-CoV-2 infection:



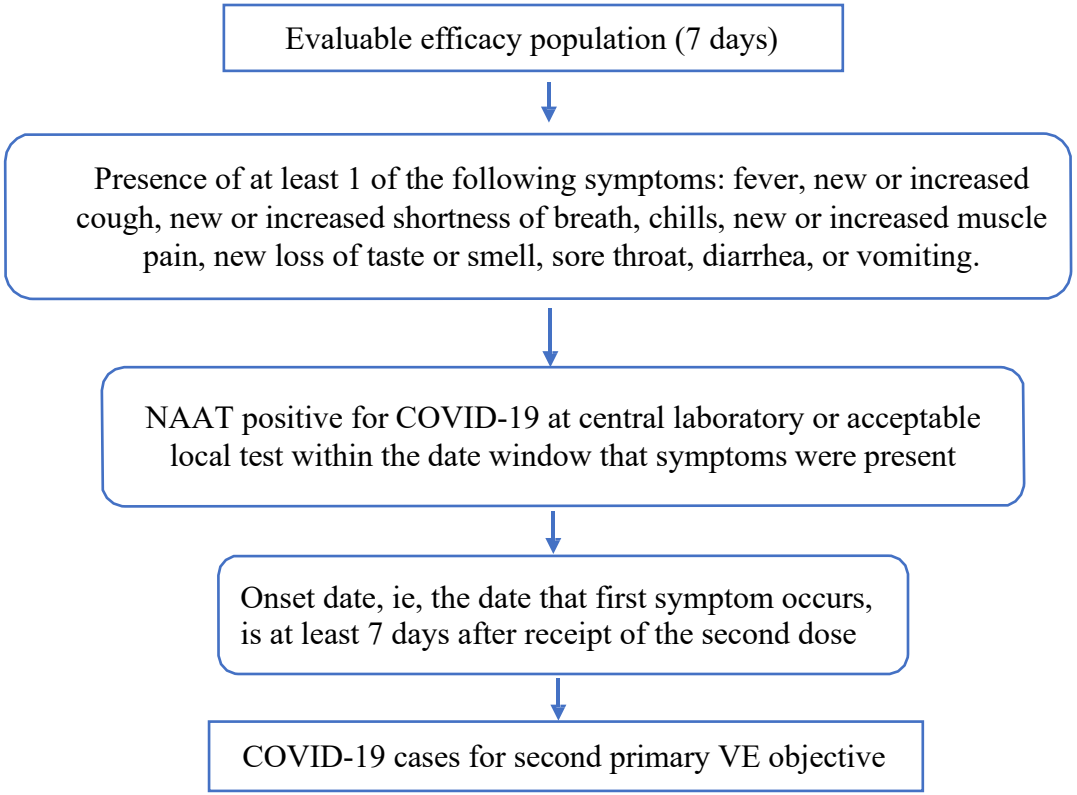
The central laboratory NAAT result will be used for the case definition, unless no result is available from the central laboratory, in which case a local NAAT result may be used if it was obtained using 1 of the following assays:

a. Cepheid Xpert Xpress SARS-CoV-2

b. Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)

c. Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001)

2. The flowchart for deriving the COVID-19 cases included below for the second primary endpoints in evaluable efficacy participants:



Appendix VIII: Detailed subsetting for Analysis:

1. Key Analysis Population Subsetting:

1.1 BLA Phase 2/3 Safety Analysis

Table Category	Analysis Population	Total Number of Subjects (N)			Subset Condition for Total N
		16-55 Years	>55 Years	Total	
Conduct of Study	Randomized	26236	17929	44165	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.RANDFL ="Y" and ADSL.MULENRFL ^= "Y"
	Safety	26164	17883	44047	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.TRT01A^=""
Adverse Events	Safety population for AEs reporting from Dose 1 to the specified reporting window	26021	17826	43847	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.HIVFL^="Y" and ADSL.TRT01A^=""
	Safety population for AEs reporting from Dose 1 to 6 month after Dose 2 for subjects originally received BNT162b2. Including all of AEs within 6-month after Dose 2 regardless of unblinding or not.	6666	5340	12006	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.HIVFL^="Y" and ADSL.TRT01A^="" and DS3KFL="Y"
	Safety population for AEs reporting from Dose 2 to the specified reporting window	25484	17636	43120	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.HIVFL^="Y" and ADSL.VAX102DT>. and ADSL.VAX101=ADSL.VAX102 and (ADSL.VAX102DT<ADSL.UNBLNDDT or ADSL.UNBLNDDT=.)
	Safety population for AEs reporting from Dose 3 to the specified reporting window	11346	8179	19525	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.HIVFL^="Y" and ADSL.VAX201DT>. and ADSL.TRT02A ^=""

Table Category	Analysis Population		Total Number of Subjects (N)			Subset Condition for Total N
			16-55 Years	>55 Years	Total	
	Safety population for AEs reporting from Dose 4 to the specified reporting window		8534	7377	15911	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.HIVFL^="Y" and ADSL.VAX202DT>. and ADSL.VAX201=ADSL.VAX202
	Safety population for AEs reporting from unblinding date to the date of cutoff for subjects originally received BNT162b2		11786	8523	20309	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.HIVFL^="Y" and ADSL.UNBLNDDT ^= . and ADSL.TRT01A="BNT162b2 Phase 2/3 (30 mcg)"
Reactogenicity[a]	Safety (Reactogenicity subset)	Dose 1	5979	4086	10065	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL. SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.VAX101 ^="" and ADSL.REACTOFL="Y"
		Dose 2	5847	4051	9898	ADSL.PHASEN>1 and ADSL.AGEGR1N>1 and ADSL. SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.VAX102 ^="" and ADSL.REACTOFL="Y" and ADSL.VAX102DT ^= .

a. For reactogenicity, the N listed here is the number of subjects in reactogenicity subset relative for the specified dose (Including HIV positive and not transmitted e-diary subjects). And the numbers match with the number of subjects in e-diary transmission table (number of subjects vaccinated at Dose 1/Dose2). The N in the maximum severity tables are the number of HIV negative subjects reporting at least 1 yes or no response before unblinding for the specified reaction/events after the specified dose which is less than the N specified in this table. For the detailed algorithm, please refer to Appendix I.

1.2 BLA Phase 2/3 Efficacy Analysis

Table Category	Analysis Population		Total Number of Subjects (N) (BNT162b2)				Subset Condition for Total N
		Sub-Category	12-15 Years	16-55 Years	>55 Years	Total	
Efficacy	Dose 1 All-Available Efficacy		1132	13059	8949	23140	Refer to Appendix I for more details. ADSL.PHASEN>1 and ADSL.MULENRFL ^= 'Y' and ADSL.AAI1EFFL = 'Y'
	Evaluable Efficacy	Subjects without evidence of	1006	11752	8311	21069	Refer to Appendix I for more details. ADSL.EVALEFFL="Y"

Table Category	Analysis Population		Total Number of Subjects (N) (BNT162b2)				Subset Condition for Total N
		Sub-Category	12-15 Years	16-55 Years	>55 Years	Total	
		infection prior to 7 days after Dose 2					and ADC19EF.PDP27FL='Y' and ADSL.PHASEN ne 1 and ADSL.MULENRFL ne "Y".
	Evaluable Efficacy	Subjects with or without evidence of infection prior to 7 days after Dose 2	1120	12489	8646	22255	Refer to Appendix I for more details ADSL.EVALEFFL="Y" and ADC19EF.PDP27FL in ('Y', 'N') and ADSL.PHASEN ne 1 and ADSL.MULENRFL ne "Y".

1.3 BLA Phase 1 Safety and Immunogenicity Analysis for BNT162b2 30 mcg and Equivalent Placebo Subjects

Table Category	Analysis Population	Total Number of Subjects (N)			Subset Condition for Total N
		18-55 Years	65-85 Years	Total	
Disposition	Randomized	15	15	30	ADSL.PHASEN=1 and ADSL.COHORTN in (1.18, 1.38) and ADSL.RANDFL="Y" and ADSL.MULENRFL ^="Y"
Adverse Events	Safety population for AEs reporting from Dose 1	15	15	30	ADSL.PHASEN=1 and ADSL.COHORTN in (1.18, 1.38) and ADSL.SAFFL="Y" and ADSL.MULENRFL^="Y" and ADSL.HIVFL^="Y"
Immunogenicity	Dose 1 all-available	15	15	30	ADSL.PHASEN=1 and ADSL.COHORTN in (1.18, 1.38) and ADSL.AAI01FL="Y"
	Dose 2 all-available	15	15	30	ADSL.PHASEN=1 and ADSL.COHORTN in (1.18, 1.38) and ADSL.AAI02FL="Y"
	Dose 1 evaluable	14	14	28	ADSL.PHASEN=1 and ADSL.COHORTN in (1.18, 1.38) and ADSL.EVAL01FL="Y"
	Dose 2 evaluable	13	14	27	ADSL.PHASEN=1 and ADSL.COHORTN in (1.18, 1.38) and ADSL.EVAL02FL="Y"

2. Adverse Event Analysis Reporting Period Subsetting:

Reporting Period		Subset condition to determine the AEs within corresponding reporting period. (Note: Additional subset for analysis population is needed)
Blinded Placebo-Controlled Follow-up Period	Immediate adverse event after Dose 1	ADAE.AECAT='ADVERSE EVENT' and ADAE.AEIMMFL='Y' and ADAE.VPHASEN=1
	Immediate adverse event after Dose 2	ADAE.AECAT='ADVERSE EVENT' and ADAE.AEIMMFL='Y' and ADAE.VPHASEN=2
	From Dose 1 to 7 days after Dose 1	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN=1 and ADSL.VAX101DT<=ADAE.ASTDT <=ADSL.VAX101DT+7
	From Dose 2 to 7 days after Dose 2	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN=2 and ADSL.VAX102DT<=ADAE.ASTDT <=ADSL.VAX102DT+7
	From Dose 1 to 1 month after Dose 2	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN in (1,2)
	From Dose 1 to unblinding (the day before unblinding)	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN in (1,2,3,99)
Blinded Placebo-Controlled Follow-up Period + Open-label follow up period for subjects who originally received BNT162b2	From Dose 1 to 6 Month after Dose 2 Note: This is for subjects originally received BNT162b2 and with at least 6 months of follow up time after Dose 2 (28*6 days after Dose 2), Including all of the AEs within 6-month after Dose 2 regardless of unblinding or not	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN>=1 and . <ADAE.ASTDT<=ADSL.V02OBDT
Open label follow-up period for subjects who received placebo and then received BNT162b2 After unblinding	Immediate adverse event after Dose 3 (1st dose of BNT162b2 after unblinding)/Dose 4 (2nd dose of BNT162b2 after unblinding)	ADAE.AECAT='ADVERSE EVENT' and ADAE.AEIMMFL='Y' and ADAE.VPHASEN in (5, 6)
	From Dose 3 (1st dose of BNT162b2 after unblinding) to 7 days after Dose 3	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN=5 and ADSL.VAX201DT<=ADAE.ASTDT <=ADSL.VAX201DT+7
	From Dose 4 (2nd dose of BNT162b2 after unblinding) to 7 days after Dose 4	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN=6 and ADSL.VAX202DT<=ADAE.ASTDT <=ADSL.VAX202DT+7
	From Dose 3 (1st dose of BNT162b2 after unblinding) to the date of cutoff	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN>=5 and ADAE.VPHASEN ne 99 and .<ADAE.ASTDT<=ADSL.X1CSRDT
Open label follow-up period for subjects who originally received BNT162b2	From unblinding date to the date of cutoff	ADAE.AECAT='ADVERSE EVENT' and ADAE.VPHASEN>=4 and ADAE.VPHASEN ne 99 and .<ADAE.ASTDT<=ADSL. X1CSRDT

Immediate AEs were those events occurring within the first 30 minutes after each dose, which were flagged as "Y" in ADAE.AEIMMFL.