Analysis Data Reviewer's Guide

sBLA Analysis for Participants 12-15 Years of Age

BioNTech SE and PFIZER INC.

Study C4591001

ADRG Template Version 2019-07-23

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	06-Dec-2021

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 covers

- Updated efficacy analyses in blinded placebo-controlled follow-up evaluated duration of protection (data cutoff date: 02Sep2021).
- Updated sequencing analysis for SARS-CoV-2 Variants of Concern or Variants of Interest.
- Safety data presented for
  - Blinded placebo-controlled period: Dose 1 to unblinding date.
  - Open-label observational period: from time of unblinding to data cutoff date:
    - Phase 3 12-15 years of age participants originally randomized to BNT162b2 30µg
    - Phase 3 12-15 years of age participants originally randomized to placebo who then received BNT162b2 30µg
  - Cumulative follow-up from Dose 1 to 6 months after Dose 2 for participants originally randomized to BNT162b2 30µg (inclusive of data from blinded and open-label periods)
  - New or updated Adverse events reported after EUA snapshot over both blinded and open-label time periods.

1.2 Acronyms

Acronym	Translation
COVID-19	Coronavirus Disease 2019
IWR	Interactive Web-based Response
LAR	Legally Acceptable Representative
modRNA	nucleoside-modified messenger ribonucleic acid
NA	Not Applicable
NAAT	nucleic acid amplification test
SoA	Schedule of Activities
VE	Vaccine Efficacy
WHO DDG	WHO Drug Dictionary Global
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	WHODD GLOBALB3Mar2021
Medical Events Dictionary	MedDRA v24.0

1.4 Source Data Used for Analysis Dataset Creation

This study is currently ongoing, and analysis data up to cut-off date: 02Sep2021 are included. Data cut-off is applied during SDTM creation.

The ADaM datasets for this study were derived from the SDTM datasets. SDTM datasets were prepared according to SDTM-IG version 3.2.

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

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 analysis and have not been included in this ADRG.

Protocol Versions:

Amendment 12: 2021-01-14

- 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: 2021-01-04

- 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 (Germany-specific): 2020-09-23

- According to regulatory request, inclusion criterion 1 now specifies that participants less than 18 years of age will not be enrolled in the EU.

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).

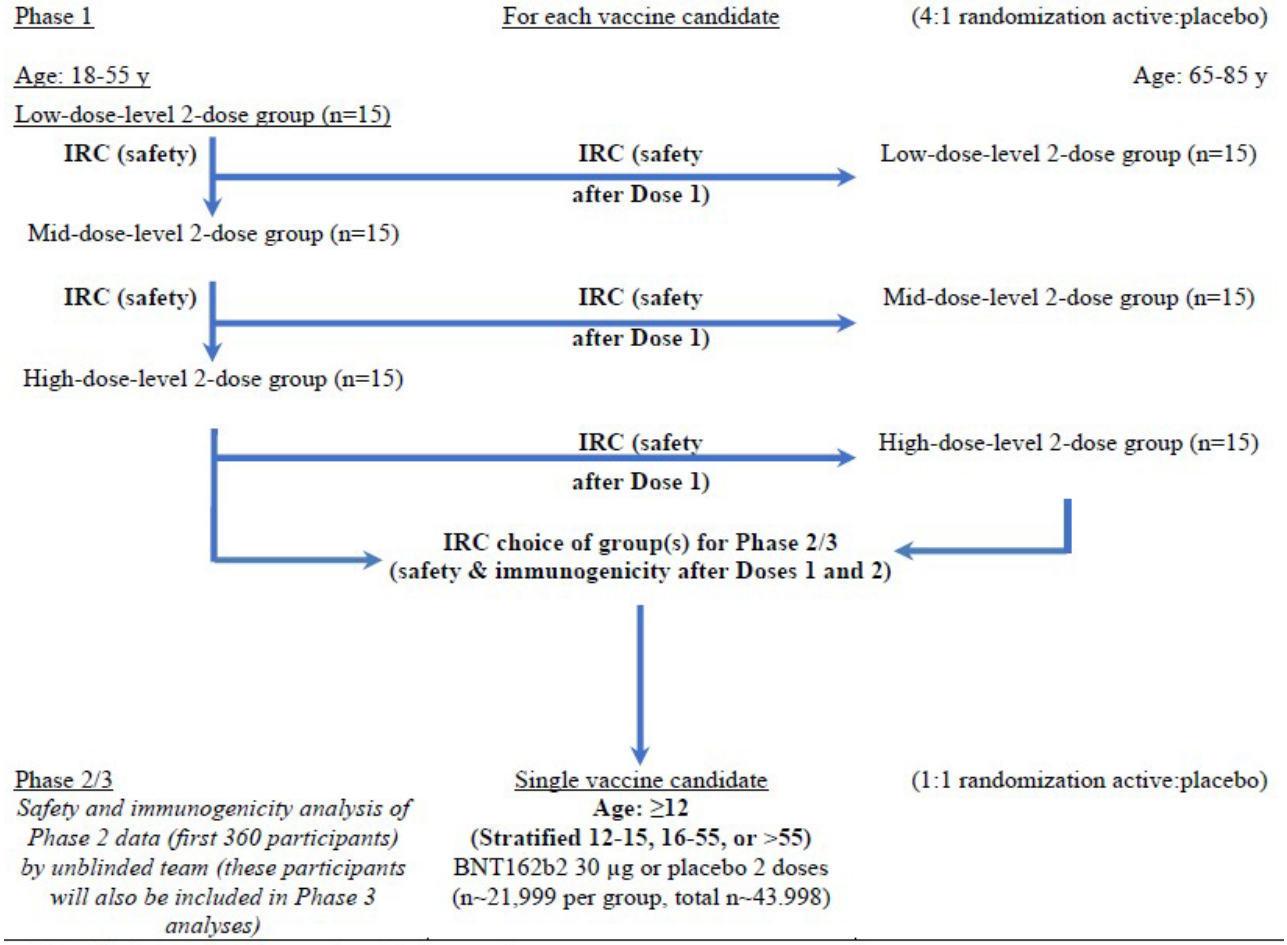
Amendment 1: 2020-05-13

- 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.

The study will evaluate the safety, tolerability, and immunogenicity of 2 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 different 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]).

Dependent upon safety and/or immunogenicity data generated during the course of this study, or the BioNTech study conducted in Germany (BNT162-01), it is possible that groups in Phase 1 may be started at the next highest dose, groups may not be started, groups may be terminated early, and/or groups may be added with dose levels below the lowest stated dose or intermediate between the lowest and highest stated doses.

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

To facilitate rapid review of data in real time, sponsor staff will be unblinded to vaccine allocation for the participants in Phase 1.

2.2.1 Phase 1

Each group (vaccine candidate/dose level/age group) will comprise 15 participants; 12 participants will be randomized to receive active vaccine and 3 to receive placebo.

For each vaccine candidate/dose level/age group, the following apply:

- Additional safety assessments (see protocol, Section 8.2)
- Controlled enrollment (required only for the first candidate and/or dose level studied):
    - No more than 5 participants (4 active, 1 placebo) can be vaccinated on the first day
    - The first 5 participants must be observed by blinded site staff for at least 4 hours after vaccination for any acute reactions
    - Vaccination of the remaining participants will commence no sooner than 24 hours after the fifth participant received his or her vaccination
- Application of stopping rules
- IRC review of safety data to determine escalation to the next dose level in the 18- to 55-year age cohort:
    - Escalation between dose levels will be based on IRC review of at least 7-day post–Dose 1 safety data in this study and/or the BioNTech study conducted in Germany (BNT162-01)
    - Note that, since both candidates are based upon the same RNA platform, dose escalation for the second candidate studied may be based upon the safety profile of the first candidate studied being deemed acceptable at the same, or a higher, dose level by the IRC

Groups of participants 65 to 85 years of age will not be started until safety data for the RNA platform have been deemed acceptable at the same, or a higher, dose level in the 18- to 55-year age cohort by the IRC.

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

The IRC will select 1 vaccine candidate that, in Phase 1, has an established dose level per age group based on induction of a post–Dose 2 immune response, including neutralizing antibodies, which is expected to be associated with protection against COVID-19, for progression into Phase 2/3.

Participants who originally received placebo and become eligible for receipt of BNT162b2 or another COVID-19 vaccine according to local or national recommendations (detailed separately, and available in the electronic study reference portal) will have the opportunity to receive BNT162b2 as part of the study. The investigator will ensure the participant meets at least 1 of the recommendation criteria. Any Phase 1 placebo recipient who has not already been offered the opportunity to receive BNT162b2 will be given this opportunity at the approximate time participants in Phase 2/3 reach Visit 4. Any participant who originally received placebo but then goes on to receive BNT162b2 will move to a new visit schedule (Protocol Section 1.3.3).

2.2.2 Phase 2/3

On the basis of safety and/or immunogenicity data generated during the course of this study, and/or the BioNTech study conducted in Germany (BNT162-01), 1 vaccine candidate was selected to proceed into Phase 2/3. Participants in this phase will be ≥12 years of age, stratified as follows: 12 to 15 years, 16 to 55 years, or >55 years. The 12- to 15-year stratum will comprise up to approximately 2000 participants enrolled at selected investigational sites. It is intended that a minimum of 40% of participants will be in the >55-year stratum. Commencement of each age stratum will be based upon satisfactory post–Dose 2 safety and immunogenicity data from the 18- to 55-year and 65- to 85-year age groups in Phase 1, respectively. 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.

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

The first 360 participants enrolled (180 to active vaccine and 180 to placebo, stratified equally between 18 to 55 years and >55 to 85 years) will comprise the "Phase 2" portion. Safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from these 360 participants will be analyzed by the unblinded statistical team, reviewed by the DMC, and submitted to appropriate regulatory authorities for review. Enrollment may continue during this period and these participants would be included in the efficacy evaluation in the "Phase 3" portion of the study.

In Phase 3, up to approximately 2000 participants, enrolled at selected sites, are anticipated to be 12 to 15 years of age. Noninferiority of immune response to prophylactic BNT162b2 in participants 12 to 15 years of age to response in participants 16 to 25 years of age will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin. A sample size of 225 evaluable participants (or 280 vaccine recipients) per age group will provide a power of 90.8% to declare the noninferiority in terms of GMR (lower limit of 95% CI for GMR >0.67). A random sample of 280 participants from each of the 2 age groups (12 to 15 years and 16 to 25 years) will be selected as an immunogenicity subset for the noninferiority assessment.

The initial BNT162b2 was manufactured using "Process 1"; however, "Process 2" was developed to support an increased scale of manufacture. In the study, each lot of "Process 2"-manufactured BNT162b2 will be administered to approximately 250 participants 16 to 55 years of age. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with "Process 1" and each lot of "Process 2" study intervention will be described. A random sample of 250 participants from those vaccinated with study intervention produced by manufacturing "Process 1" will be selected for this descriptive analysis.

Participants are expected to participate for up to a maximum of approximately 26 months. The duration of study follow-up may be shorter among participants enrolled in Phase 1 dosing arms that are not evaluated in Phase 2/3.

Participants ≥ 16 years of age who originally received placebo and become eligible for receipt of BNT162b2 or another COVID-19 vaccine according to local or national recommendations (detailed separately, and available in the electronic study reference portal) will have the opportunity to receive BNT162b2 as part of the study. The investigator will ensure the participant meets at least 1 of the recommendation criteria.

Any Phase 2/3 placebo recipient ≥16 years of age who has not already been offered the opportunity to receive BNT162b2 will be given this opportunity from 6 months after Vaccination 2 (at the time of the originally planned Visit 4).

Any participant who originally received placebo but then goes on to receive BNT162b2 will move to a new visit schedule (Protocol Section 1.3.3).

An intensive period of surveillance to evaluate the efficacy of BNT162b2 against asymptomatic SARS-CoV-2 infection may be conducted at selected sites among Phase 2/3 participants following approval of protocol amendment 11. After an initial in-person visit where a blood sample will be collected and a nasal (midturbinate) swab obtained, nasal (midturbinate) swabs will be obtained from consented participants every 2 weeks until Visit 4, or a sufficient number of cases of SARS-CoV-2 infection have accrued to evaluate this objective, whichever is sooner, per the SoA. The swabs will be tested at a central laboratory using NAAT to detect SARS-CoV-2. Participants who originally received placebo and become eligible for receipt of BNT162b2 according to local or national recommendations and then receive BNT162b2 as part of the study will not participate in surveillance for asymptomatic SARS-CoV-2 infection; if they become eligible during the surveillance period, the swabbing every 2 weeks will cease.

3. Analysis Considerations Related to Multiple Analysis Datasets

3.1 Core Variables

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

Variable Type	Variable Name	Variable Description
	AGEGR4	Pooled age group 4 (based on Age at Dose 1) Including following age categories: 12-15 Years; Note: There is one subject who is 15 years of age at ICD and 16 years of age at dose 1 in SDTM datasets, this subject was excluded from all ADAM datasets.
	AGEGR4N	Pooled age group 4 (N): 1= 12-15 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; AMERICAN INDIAN OR ALASKA NATIVE; ASIAN; MULTIPLE; NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER; NOT REPORTED
Baseline Status	COVBLST	Baseline SARS-CoV-2 status: Positive, Negative or Missing
	HIVFL	HIV positive subjects Flag Note: No HIV positive subjects from the 12-15 years of age.
Treatment Variables	ARM	Description of Planned Arm
	ARMCD	Planned Arm Code
	ACTARM	Description of Actual Arm
	ACTARMCD	Actual Arm Code
	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
	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

Variable Type	Variable Name	Variable Description
		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
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 (02Sep2021). 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 (02Sep2021). This date is used for AE incidence rate summary table for open-label follow-up period.
Population Flags**	DS3KFL	Flag of subjects with at least 6 months of follow-up time after dose 2 (28*6=168) days after dose 2

Variable Type	Variable Name	Variable Description
		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 1113 subjects in total from safety population for subjects from 12 to 15 years of age at dose 1.
	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.
	SAFFL	Safety population flag defined as: All randomized participants who receive at least 1 dose of the study intervention.
	AAI1EFFL	Dose 1 all-available efficacy population flag defined as: All randomized participants who receive at least 1 vaccination.
	AAI2EFFL	Dose 2 all-available efficacy population flag defined as: All randomized participants who complete 2 vaccination doses.
	EVALEFFL	Evaluable efficacy population flag (7 days) defined as: All eligible randomized participants who receive all vaccination(s) as randomized, with Dose 2 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. Note: Subjects unblinded or took an unplanned dose within 7 days post dose 2 were excluded from this evaluable efficacy populations. 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 VII 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, 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 2/3	BNT162b2 Phase 2/3 (30 mcg)	BNT162b2 Phase 2/3 (30 mcg)	-
	Placebo	Placebo	-
	Placebo	Placebo	BNT162b2 Phase 2/3 (30 mcg)

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 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	-	-

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 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	Safety	TRT01A	Conduct of study, Adverse Event, Medical History, Concomitant Medications/Vaccinations

Reporting Period	Analysis Population	Treatment Variables Used in Analysis	Applicable analysis
Open-label follow-up period	Randomized	TRT01P	Vaccine as Administered, Disposition, Efficacy, Sequencing
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 not used in analysis

3.3 Subject Issues that Require Special Analysis Rules

NA

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 for more details.

Based on protocol guidance, multiple unscheduled Covid illness visits that are less than 4 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?

No.

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?

No. Subjects with 'NOTASSGN' 'SCRNFAIL' are not included.

Are data taken from an ongoing study?

Yes. All data up through 02Sep2021 cutoff are included in the SDTM datasets and used for ADaM datasets and analyses.

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

No.

Additional Content of Interest

No additional content of Interest.

5.2 Analysis Datasets

Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	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 each adverse event per event start date
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 Deviations 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
ADC19EF Covid-19 Efficacy Analysis Dataset	BASIC DATA STRUCTURE	X				X	One record or multiple records per subject per analysis parameter per analysis timepoint
ADSYMPT Covid-19 Signs and Symptoms Analysis Dataset	BASIC DATA STRUCTURE	X				X	One record or multiple records per subject per analysis parameter per analysis timepoint
ADXB Sequencing Analysis Dataset	BASIC DATA STRUCTURE	X					One record per subject per analysis parameter per analysis timepoint

5.2.1 ADSL – Subject-Level Analysis Dataset

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
    - 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 and Non-Hispanic/Non-Latino)
    - Baseline SARS-CoV-2 Status (Positive and Negative)
    - Comorbidities (Yes and No)
    - Obese (Yes and No)

5.2.2 ADAE – Adverse Events Analysis Dataset

This is the main safety analysis dataset comprised of adverse events recorded on the CRF. 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 VII.

DATCHGFL is used to identify the new AEs that occurred since the data cutoff used for the EUA Amendment submission for individuals 12 through 15 years of age.

Note: One AE record was dropped since the data cutoff used for the EUA Amendment submission for individuals 12 through 15 years of age. See the AE as below.

USUBJID	AESPID	AETERM	AEDECOD	AESTDTC	AEENRTPT
C4591001 1131 11311301	2	broken collar bone	Clavicle fracture	2021-02-19	ONGOING

DATACHGC is used to identify what type of AE data change occurred since the data cutoff used for the EUA Amendment submission for individuals 12 through 15 years of age.
See type of updates as below.

Type of Updates (DATACHGC)
AE onset date changed from EUA to sBLA
AE outcome changed from EUA to sBLA

Actions to the AE changed from EUA to sBLA
AERELTXT changed from EUA to sBLA Note: AERELTXT = Event Due to Other Specify
Minor AE term changed from EUA to sBLA
AEDECOD changed from EUA to sBLA Note: AEDECOD=Dictionary-Derived Term

Note: One AE record could have multiple types of change combined in DATACHGC and EUA refers to the EUA Amendments submission in Apr2021 for 12-15 Years of age (EUA snapshot 25Mar2021 with the cutoff date 13Mar2021).

DATCHGFL and DATACHGC are derived to address FDA's response for question 1.a 'please include an interim summary of new or updated safety events that occurred/have been updated since the data cutoff used for the EUA Amendment submission for individuals 12 through 15 years of age, using the same time periods, and insert a flag into the datasets to indicate which safety events are new/updated' of "IND 19736.434_Comments_ReqCommentsAdvice_sBLA_12-15yoa".

In addition, a set of AE tables have 'New Adverse Events After the EUA Snapshot' as part of title and a listing has 'Adverse Events Updated After the EUA Snapshot' as part of title are generated to respond FDA's response.

5.2.3 ADCM – Concomitant Medications Analysis Dataset

The dataset contains information of nonstudy vaccines (CMCAT = "VACCINATIONS") and prohibited concomitant medications (CMCAT=' CORTICOSTEROIDS').

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

5.2.4 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

5.2.5 ADDV – Protocol Deviations 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 population exclusion flag was capture in SUPPDV.QNAM='CAPE'.

5.2.6 ADMH – Medical History Analysis Dataset

This dataset contains all medical histories (MHCAT = "GENERAL MEDICAL HISTORY") collected on the CRF. Partial start dates or partial end dates medical histories were imputed using rules described in Appendix III.

5.2.7 ADSYMPT – Covid-19 Signs and Symptoms Analysis Dataset

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, DS, HO, SUPPHO, FA (FACE), IS, LB, MB, MH, 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 throat, Vomiting.".

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".

PARAMN	PARAMCD	PARAM	Derivation
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".
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.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".

PARAMN	PARAMCD	PARAM	Derivation
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".
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".

PARAMN	PARAMCD	PARAM	Derivation
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").
92	HCUHSP	HOSPITALIZED DUE TO COVID-19	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".

5.2.8 ADC19EF – Covid-19 Efficacy Analysis Dataset

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, 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 V and Appendix VI 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 FOR SARS-COV-2
90	C19NIG	N-BINDING ANTIBODY
92	HCUHSP	HOSPITALIZED DUE TO COVID-19 ILLNESS?
101	PRPDSAD	PRESENCE OF PROTOCOL DEFINED SYMPTOMS AFTER
102	PRCDCSAD	PRESENCE OF CDC DEFINED SYMPTOMS AFTER DOSE
103	SEVCVS	SEVERE COVID-19 SYMPTOMS - VITAL SIGNS
107	PRSVCSAD	PRESENCE OF PROTOCOL DEFINED SEVERE COVID-19 SYMPTOMS AFTER DOSE
108	PRSCDCAD	PRESENCE OF CDC DEFINED SEVERE COVID-19 SYMPTOMS AFTER DOSE

PARAMN	PARAMCD	PARAM
110	NAATRAD	COVID-19 NAAT RESULT AFTER DOSE
120	C19ONST	PROTOCOL DEFINED COVID-19 ILLNESS ONSET
125	CDCONST	CDC DEFINED COVID-19 ILLNESS ONSET
130	SEVCONST	PROTOCOL DEFINED 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 COVID19 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
202	ST17PDA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL

PARAMN	PARAMCD	PARAM
203	ST2PDA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL
204	ST27PDA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL
205	ST214PDA	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR PROTOCOL DEFINED COVID19 SYMPTOMS - ALL
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
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
215	ST214CDA	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR CDC DEFINED COVID19 SYMPTOMS - ALL
221	ST1SEA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 1 FOR PROTOCOL DEFINED SEVERE COVID19 SYMPTOMS - ALL
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
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
232	STC17SA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 1 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL
233	STC2SA	SUBJECT'S SURVEILLANCE TIME AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL
234	STC27SA	SUBJECT'S SURVEILLANCE TIME 7 DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL
235	STC214SA	SUBJECT'S SURVEILLANCE TIME 14 DAYS AFTER DOSE 2 FOR CDC DEFINED SEVERE COVID19 SYMPTOMS - ALL
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

5.2.9 ADXB – Sequencing Analysis Dataset

The purpose of this dataset is to get SARS-CoV-2 lineage (WHO classification) phylogenetic analysis information for the COVID-19 cases. Key variable used for this analysis is FC19D27 that indicates subjects who had their first COVID-19 occurrence 7 days post dose 2.

6. Data Conformance Summary

6.1 Conformance Inputs

Was a validator used to evaluate conformance? **Yes**

If yes, specify the version(s) of the validation rules: **Pinnacle 21 Enterprise version 4.2.1**
Validation Engine version 2010.1

Were sponsor-defined validation rules used to evaluate conformance? **No**

If yes, describe any significant sponsor-defined validation rules: **NA**

Were the ADaM datasets evaluated in relation to define.xml? **Yes**

Was define.xml evaluated? **Yes**

Provide any additional compliance evaluation information: **NA**

6.2 Issues Summary

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
AD0034	CDRMUPFL value is not Y or null	Error	ADC19EF	119345 (98.14%)	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.
AD0034	PDRMUPFL value is not Y or null	Error	ADC19EF	119455 (98.23%)	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.
AD0099	ASTDY is greater than AENDY	Error	ADC19EF	234 (0.25%)	ASTDT is greater than AENDT in some cases when deriving surveillance times since surveillance times are defined to start at various time points in the study for a given subject, it possible that subject's surveillance time may have come to an end prior to starting due a positive Covid case or other definitions described in specifications and in these instances ASTDT would be greater than AENDT. As a result, ASTDY is also greater than AENDY.
AD0253	Record key from SDTM AE is not traceable to ADaM ADAE (not enough ADAE recs)	Error	AE	481 (30.87%)	AECAT="REACTOGENICITY" records (from ediary) was not kept in ADAE (Based on flat model).
AD0361	Value of ASTDT is greater than value of AENDT	Error	ADC19EF	234 (0.25%)	ASTDT is greater than AENDT in some cases when deriving surveillance times since surveillance times are defined to start at various time points in the study for a given subject, it possible that subject's surveillance time may have come to an end prior to starting due a positive Covid case or other definitions described in specifications and in these instances ASTDT would be greater than AENDT.
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.

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	ADSL	5 (21.74%)	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.
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADC19EF	2919 (2.40%)	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	3 (0.73%)	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	161 (2.44%)	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	87 (2.61%)	New terms were added to extensible codelist RACE for the study protocol needs: Multiple
CT2002	RACE value not found in 'Race' extensible codelist	Warning	ADMH	120 (2.74%)	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	53 (2.34%)	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	793 (2.28%)	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. ADXB is dependent on ADC19EF. 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 mh 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
admh-sas.txt	admh.xpt	mh suppmh adsl	NA
adc19ef-sas.txt	adc19ef.xpt	adsympt adsl	NA
adsympt-sas.txt	adsympt.xpt	ce cm ds face ho suppho is mb mh lb vs adsl	NA
adxb-sas.txt	adxb.xpt	mb adsl adc19ef	NA

7.2 Analysis Output Programs

Table	Program Name	Output Name	Title	Input	Population Subset used
1	adsl-s005-all1-ped6-saf-sas.txt	adsl_s005_all1_ped6_saf.html	Demographic Characteristics – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population	ADSL	ADSL.SAFFL="Y" and ADSL.AGEGR4N=1
2	adds-s002-all1-ped6-sas.txt	adds_s002_all1_ped6.html	Disposition of All Randomized Subjects – Phase 2/3 Subjects 12 Through 15 Years of Age	ADSL, ADDS	ADSL.RANDFL="Y" and ADSL.AGEGR4N =1
3	adsl-fu-d21-ped6-	adsl_fu_d21_ped6.h	Follow-up Time After Dose 2 – Phase 2/3	ADSL	ADSL.SAFFL="Y" and

Table	Program Name	Output Name	Title	Input	Population Subset used
	sas.txt	tml	Subjects 12 Through 15 Years of Age – Safety Population		ADSL.AGEGR4N=1
4	adae-s092-all-unb1-ped6-sas.txt	adae_s092_all_unb1_ped6.html	Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population	ADSL ADAE	ADSL.SAFFL="Y" and ADSL.AGEGR4N =1
5	adae-s091-6m1-ped6-sas.txt	adae_s091_6m1_ped6 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 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population	ADSL ADAE	ADSL.SAFFL="Y" and ADSL.TRT01AN=8 and ADSL.DS3KFL="Y" and ADSL.AGEGR4N=1
6	adae-s092-cut1-ped6-sas.txt	adae_s092_cut1_ped6 html	Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population	ADSL ADAE	ADSL.SAFFL="Y" and ADSL.TRT01AN=9 and ADSL.TRT02AN=8 and ADSL.VAX201DT > . and ADSL.X1CSRDT > . and ADSL.AGEGR4N=1
7	adae-s091-all-unb2-ped6-sas.txt	adae_s091_all_unb2_ped6.html	Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population	ADSL ADAE	ADSL.SAFFL="Y" and (ADSL.EOSDCDT gt input("13MAR2021", date9.) or ADSL.EOSDCDT =.) and ADSL.AGEGR4N=1
8	adae-s130-sae-unb2-ped6-sas.txt	adae_s130_sae_unb2_ped6.html	Number (%) of Subjects Reporting at Least 1 New Serious Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term –	ADSL ADAE	ADSL.SAFFL="Y" and (ADSL.EOSDCDT gt input("13MAR2021", date9.) or ADSL.EOSDCDT =.) and ADSL.AGEGR4N =1

Table	Program Name	Output Name	Title	Input	Population Subset used
			Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population		
9	adae-s091-6m2-ped6-sas.txt	adae_s091_6m2_ped6.html	Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population	ADSL ADAE	ADSL.SAFFL="Y" and ADSL.TRT01AN=8 and ADSL.DS3KFL="Y" and ADSL.AGEGR4N =1
10	adc19ef-ve-cov-7pd2-peds-wo-eval-sas.txt	adc19ef_ve_cov_7pd2_peds_wo_eval.html	Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADC19EF.PDP27FL="Y" and ADSL.AGEGR4N=1
11	adc19ef-ve-cov-7pd2-peds-eval-sas.txt	adc19ef_ve_cov_7pd2_peds_eval.html	Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADSL.AGEGR4N =1
12	adc19ef-ve-cov-7pd2-p-wo-sg-eval-sas.txt	adc19ef_ve_cov_7pd2_p_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 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 –	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADC19EF.PDP27FL="Y" and ADSL.AGEGR4N=1

Table	Program Name	Output Name	Title	Input	Population Subset used
			Evaluable Efficacy (7 Days) Population		
13	adc19ef-ve-cov-7pd2-p-sg-eval-sas.txt	adc19ef_ve_cov_7pd2_p_sg_eval.html	Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADSL.AGEGR4N =1
14	adsl-demo-7d-peds-eval-eff-sas.txt	adsl_demo_7d_peds_eval_eff.html	Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADC19EF.PDP27FL="Y" and ADSL.AGEGR4N=1
15	adsl-demo-7d-wwo-peds-eval-eff-sas.txt	adsl_demo_7d_wwo_peds_eval_eff.html	Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population	ADSL ADC19EF ADSYMPT	ADSL.EVALEFFL="Y" and ADSL.AGEGR4N =1

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.

Mock Table 1

Demographic Characteristics – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

ADSL.SAFFL eq 'Y' and ADSL.AGEGR4N =1

ADSL.TRT01A

	Vaccine Group (as Administered)		
	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")	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.ARACEN=1)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Black or African American (ADSL.ARACEN=2)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
All Others (ADSL.ARACEN in (3,4,5,6,7))	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
American Indian or Alaska Native (ADSL.ARACEN=3)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Asian (ADSL.ARACEN=4)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Native Hawaiian or other Pacific Islander	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Multiracial (ADSL.ARACEN=5)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Not reported (ADSL.ARACEN=6)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
(ADSL.ARACEN=7)			
Racial designation			
Japanese (ADSL.RACIALDN=5)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Ethnicity			
Hispanic/Latino (ADSL.ETHNICN=1)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)

Non-Hispanic/non-Latino (ADSL.ETHNICN=2)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Not reported (ADSL.ETHNICN=3)	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Country			
USA (ADSL.COUNTRY="USA")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Baseline SARS-CoV-2 status			
Positive[c] (ADSL.COVBLST= "POS")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Negative[d] (ADSL.COVBLST= "NEG")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Missing (ADSL.COVBLST= " ")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Comorbidities[e]			
Yes (ADSL.COMBODFL= "Y")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
No (ADSL.COMBODFL= "N")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Obese[f]			
Yes (ADSL.OBESEFL= "Y")	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
No (ADSL.OBESEFL= "N")	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.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

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

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

c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

e. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI $\geq 95^{th}$ percentile.

f. Obese is defined as BMI $\geq 95^{th}$ percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

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

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

Mock Table 2

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

	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)	xx (xxx.x)
Not vaccinated	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Original blinded placebo-controlled follow-up period			
Vaccinated	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Dose 1	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Dose 2			
Discontinued from original blinded placebo-controlled vaccination period[c]			
Reason for discontinuation			
Adverse event	xx (xxx.x)	xx (xxx.x)	
Withdrawal by subject			
Physician decision			
Death			
Pregnancy			
Other			
Unblinded before 1-month post–Dose 2 visit			
Completed 1-month post–Dose 2 visit			
Withdrawn from the study			
Withdrawn after Dose 1 and before Dose 2			
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit			
Withdrawn after 1-month post–Dose 2 visit			
Reason for withdrawal from the study			
Adverse event			

ADSL.TRT01P

ADSL.RANDFL="Y" and ADSL.AGEGR4N=1

ADSL.RANDFL eq 'Y' and ADSL.AGEGR4N eq 1

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.AGEGR4N=1 and (ADSL.VAX101DT ne . or ADSL.VAX102DT ne .)

ADSL.RANDFL eq 'Y' and ADSL.AGEGR4N=1 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 ADDS.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 ADDS.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.AGEGR4N=1 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)

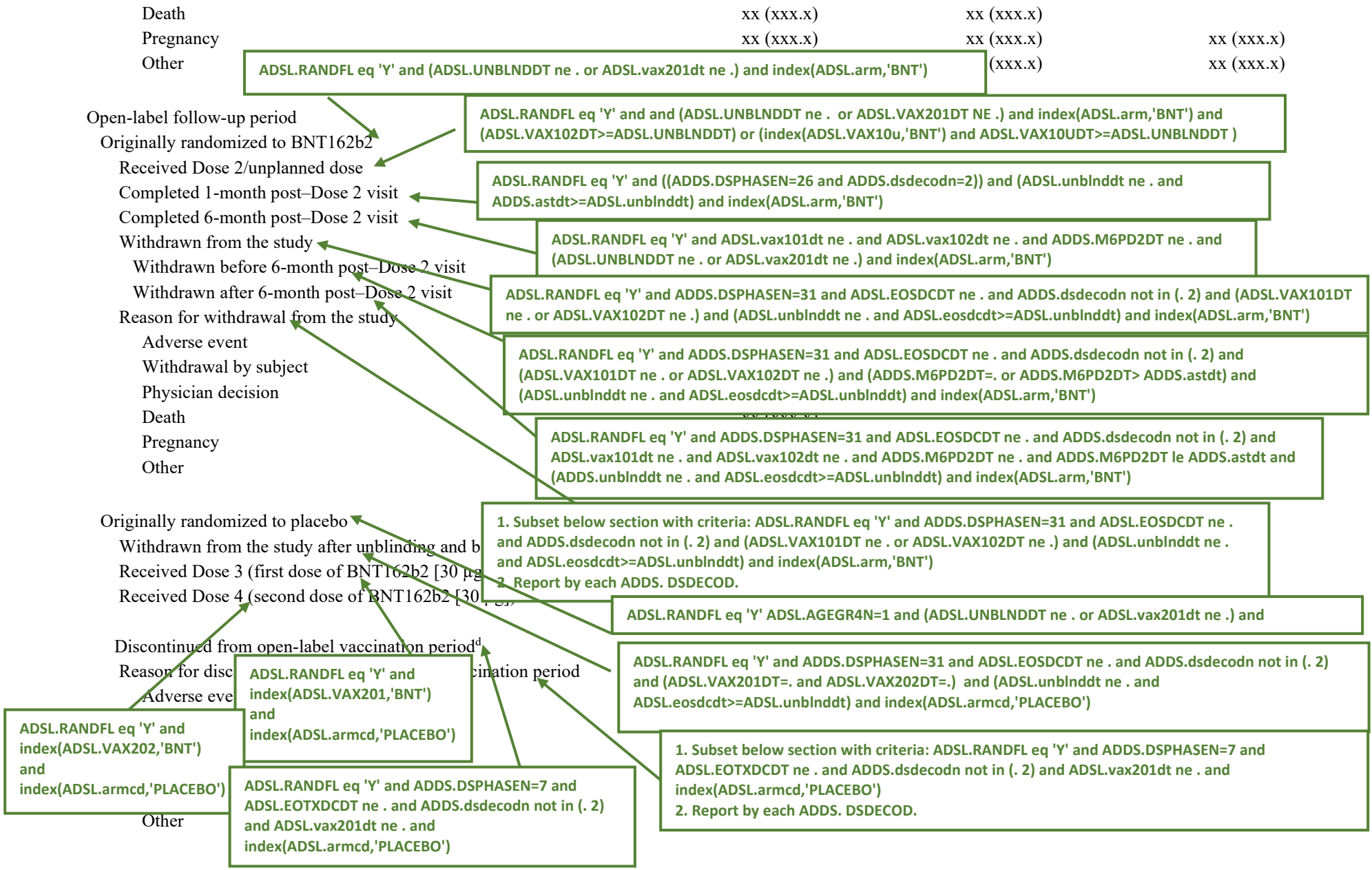
ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and (ADSL.VAX101DT ne . or ADSL.VAX102DT ne .) and (ADSL.unblnddt=. or ADSL.eosdcdt<ADSL.unblnddt) and ADSL.EOSDCDT ne ADSL.EOTXDCDT

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and ADSL.vax101dt ne . and ((ADSL.vax101dt<=ADDS.astdt and ADSL.vax102dt eq .) or ADSL.vax101dt<=ADDS.astdt < ADSL.vax102dt) and (ADSL.unblnddt=. or ADSL.eosdcdt<ADSL.unblnddt) and ADSL.EOSDCDT ne ADSL.EOTXDCDT

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and ADSL.vax101dt ne . and ADSL.vax102dt ne . and (ADSL.vax102dt <=ADDS.astdt and (ADDS.M1PD2DT eq . or ADDS.astdt<ADDS.M1PD2DT)) and (ADSL.unblnddt=. or ADSL.eosdcdt<ADSL.unblnddt) and ADSL.EOSDCDT ne ADSL.EOTXDCDT

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and ADSL.vax101dt ne . and ADSL.vax102dt ne . and ADDS.M1PD2DT ne . and ADDS.M1PD2DT le ADDS.astdt and (ADSL.unblnddt=. or ADSL.eosdcdt<ADSL.unblnddt) and ADSL.EOSDCDT ne ADSL.EOTXDCDT

1. Subset below section with criteria: ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and (ADSL.VAX101DT ne . or ADSL.VAX102DT ne .) and (ADSL.unblnddt=. or ADSL.eosdcdt<ADSL.unblnddt) and ADSL.EOSDCDT ne ADSL.EOTXDCDT
2. Report by each ADDS. DSDECOD.



Completed 1-month post–Dose 4 visit

Withdrawn from the study
Withdrawn after Dose 3 and before Dose 4
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit
Withdrawn after 1-month post–Dose 4 visit
Reason for withdrawal from the study
Adverse event
Withdrawal by subject
Physician decision
Death
Pregnancy
Other

xx (xxx.x) xx (xxx.x)

Note: Subjects who were randomized but did not sign an informed co
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

tions.

ond dose of BNT162b2 [30 µg])

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

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=7 and ADDS.dsdecodn=2 and index(ADSL.armcd,'PLACEBO')

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and ADSL.vax201dt ne . and ((ADSL.vax201dt<=ADDS.astdt and ADSL.vax202dt eq .) or ADSL.vax201dt<=ADDS.astdt < ADSL.vax202dt) and ((ADSL.unblnddt ne . and ADSL.eosdcdt>=ADSL.unblnddt) or ADSL.eosdcdt=ADSL.eotxdcdt) and index(ADSL.armcd,'PLACEBO')

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and ADSL.vax201dt ne . and ADSL.vax202dt ne . and (ADSL.vax202dt <=ADDS.astdt and (ADDS.M1PX2DT eq . or ADDS.astdt<ADDS.M1PX2DT)) and ((ADSL.unblnddt ne . and ADSL.eosdcdt>=ADSL.unblnddt) or ADSL.eosdcdt=ADSL.eotxdcdt) and index(ADSL.armcd,'PLACEBO')

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and ADSL.vax201dt ne . and ADSL.vax202dt ne . and ADDS.M1PX2DT ne . and ADDS.M1PX2DT le ADDS.astdt and ((ADSL.unblnddt ne . and ADSL.eosdcdt>=ADSL.unblnddt) or ADSL.eosdcdt=ADSL.eotxdcdt) and index(ADSL.armcd,'PLACEBO')

ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and (ADSL.VAX201DT ne . or ADSL.VAX202DT ne .) and ((ADSL.unblnddt ne . and ADSL.eosdcdt>=ADSL.unblnddt) or ADSL.eosdcdt=ADSL.eotxdcdt) and index(ADSL.armcd,'PLACEBO')

1. Subset below section with criteria: ADSL.RANDFL eq 'Y' and ADDS.DSPHASEN=31 and ADSL.EOSDCDT ne . and ADDS.dsdecodn not in (. 2) and (ADSL.VAX201DT ne . or ADSL.VAX202DT ne .) and ((ADSL.unblnddt ne . and ADSL.eosdcdt>=ADSL.unblnddt) or ADSL.eosdcdt=ADSL.eotxdcdt) and index(ADSL.armcd,'PLACEBO')
2. Report by each ADDS. DSDECOD.

Mock Table 3

Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety P

ADSL.TRT01A

ADSL.SAFFL eq 'Y' and ADSL.AGEGR4N eq 1

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=xx) n[b] (%)	Placebo (N[a]=xx) n[b] (%)	Total (N[a]=xx) n[b] (%)
Original blinded placebo-controlled follow-up period			
<2 Months	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥2-<4 Months	x (xx.x)	xx (xx.x)	xx (xx.x)
≥4-<6 Months	xx (xx.x)	xx (xx.x)	xx (xx.x)
≥6 Months	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Total follow-up period from Dose 2 to cutoff date			
<2 Months	xx (xx.x)		
≥2-<4 Months			
≥4-<6 Months	xx (xx.x)		
≥6-<8 Months			
≥8-<10 Months			
≥10 Months	xx (xx.x)		
Mean (SD)	xx.x (xx.xx)		
Median	xx.x		
Min, max	(xx.x, xx.x)		

ADSL.AGEGR4N=1 and .<ADSL.FUP2CA2N<=2

2<ADSL.FUP2CA2N <=4

4<ADSL.FUP2CA2N <=6

6<ADSL. FUP2CA2N

.<ADSL.FUP2CA1N<=2

2<ADSL.FUP2CA1N<=4

4<ADSL.FUP2CA1N<=6

6<ADSL.FUP2CA1N<=8

8<ADSL.FUP2CA1N<=10

10<ADSL.FUP2CA1N

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

Mock Table 4

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

ADSL.SAFFL="Y" and ADSL.AGEGR4N=1

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

ADSL.TRT01A

upcase(ADAE.AREL)="RELATED"

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADAE.AESER="Y"

ADAE.AESER in ('N',' ')

ADAE.AESUBJDC = 'Y' or ADAE AEACN = 'DRUG WITHDRAWN'

ADAE.AEOUT='FATAL

SUM(ADSL.FUP1UNB)/(356.25*100)

ADAE.AECAT="ADVERSE EVENT" and ADAE.VPHASEN >0 and ADSL.SAFFL="Y" and ADSL.AGEGR4N eq 1 and (.<ADSL.VAX101DT<=ADAE.ASTDT <= ADSL.BDCSRDT)

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

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

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

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

e. 2-sided CI based on Poisson distribution.

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

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

Mock Table 5

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

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

ADSL.TRT01A

ADSL.SAFFL="Y" and ADSL.TRT01AN=8 and ADSL.DS3KFL="Y" and ADSL.AGEGR4N=1

upcase(ADAE.AREL)="RELATED"

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADAE.AECAT="ADVERSE EVENT" and ADSL.SAFFL="Y" and (ADAE.ASTDT NE . and ADSL.V02OBDT >= ADAE.ASTDT) and ADAE.VPHASEN >0 and ADSL.TRT01AN=8 and ADSL.DS3KFL="Y"

ADAE.AESER="Y"

ADAE.AESER IN ('N',' ')

ADAE.AESUBJDC = 'Y' or ADAE.AEACN = 'DRUG WITHDRAWN'

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. Exact 2-sided CI based on the Clopper and Pearson method.
d. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: xxxx Table Generation: DDMMMYYYY (HH:MM)

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

Mock Table 6

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

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

ADSL.TRT02A

upcase(ADAE.AREL)="RELATED"

SUM(ADSL.FPX1CUT)/(356.25*100)

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADSL.SAFFL="Y" and ADSL.TRT01AN=9 and ADSL.TRT02AN=8 and ADSL.VAX201DT > . and ADSL.X1CSRDT > . and ADSL.AGEGR4N=1

ADAE.AESER="Y"

ADAE.AECAT="ADVERSE EVENT" and ADAE.VPHASEN ge 5 and ADAE.VPHASEN ne 99 and ADSL.SAFFL="Y" and ADSL.AGEGR4N eq 1 and (.<ADSL.VAX201DT<=ADAE.ASTDT <= ADSL.X1CSRDT) and ADSL.TRT01AN=9 and ADSL.TRT02AN=8

ADAE.AESER in ('N',' ')

ADAE.AESUBJDC = 'Y' or ADAE.AEACN = 'DRUG WITHDRAWN'

ADAE.AEOUT='FATAL

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

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

b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.

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

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

e. 2-sided CI based on Poisson distribution.

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

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

Mock Table 7

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

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

ADSL.TRT01A

ADSL.SAFFL="Y" and (ADSL.EOSDCDT gt input("13MAR2021", date9.) or ADSL.EOSDCDT =.) and ADSL.AGEGR4N=1

upcase(ADAE.AREL)="RELATED"

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADAE.AESER="Y"

ADAE.AECAT="ADVERSE EVENT" and ADAE.DATCHGFL= "Y" and ADAE.VPHASEN >0 and ADSL.SAFFL="Y" and ADSL.AGEGR4N eq 1 and (.<ADSL.VAX101DT<=ADAE.ASTDT <= ADSL.BDCSRDT)

ADAE.AESER IN ('N',' ')

ADAE.AESUBJDC = 'Y' or ADAE.AEACN = 'DRUG WITHDRAWN'

ADAE.AEOUT='FATAL

Abbreviation: EUA = emergency use authorization.

a. N = number of subjects in the specified group, subjects who end of study before EUA snapshot are not included. This value is the denominator for the percentage calculations.

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

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

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

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

Mock Table 8

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

ADAE.AEBODSYS

ADSL.TRT01A

ADAE.AEDECOD

ADSL.SAFFL="Y" and (ADSL.EOSDCDT gt input("13MAR2021", date9.) or ADSL.EOSDCDT =.) and ADSL.AGEGR4N=1

ADAE.AECAT="ADVERSE EVENT" and ADAE.DATCHGFL="Y" and ADAE.VPHASEN >0 and ADSL.SAFFL="Y" and and ADAE.AESER="Y" and ADSL.AGEGR4N eq 1 and (.<ADSL.VAX101DT<=ADAE.ASTDT <= ADSL.BDCSRDT)

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

Abbreviation: EUA = emergency use authorization.
Note: MedDRA (v24.0) coding dictionary applied.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
a. N = number of subjects in the specified group, subjects who end of study before EUA snapshot are not included. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: DDMMYYY (HH:MM) Source Data: ADSL Table Generation: DDMMYYY (HH:MM) (Data Cutoff date: ddMmmYYYY, Data Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

Mock Table 9

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

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

ADSL.TRT01A

upcase(ADAE.AREL)="RELATED"

ADAE.ATOXGRN=3

ADAE.ATOXGRN=4

ADAE.AESER="Y"

ADAE.AESER IN ('N',' ')

ADAE.AESUBJDC = 'Y' or ADAE.AEACN = 'DRUG WITHDRAWN'

ADAE.AEOUT='FATAL

ADSL.SAFFL="Y" and ADSL.TRT01AN=8 and ADSL.DS3KFL="Y" and ADSL.AGEGR4N =1

ADAE.AECAT="ADVERSE EVENT" and ADAE.DATCHGFL="Y" and ADAE.VPHASEN >0 and ADSL.SAFFL="Y" and (ADAE.ASTDT NE . and ADSL.V02OBDT >=ADAE.ASTDT) and ADSL.TRT01AN=8 and ADSL.DS3KFL="Y"

Abbreviation: EUA = emergency use authorization.

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

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

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

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

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

Mock Table 10

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period

...ears of Age and Without Evidence of Infection Prior to 7 Days After Dose 2

– Evaluable Efficacy (7 Days) Population

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 (DVSTDT) and ADT <= DVSTDT) or missing(DVSTDT))

ADSL.TRT01P

ADSL.EVALEFFL="Y" and ADC19EF.PDP27FL="Y" and ADSL.AGEGR4N=1

	Vaccine Group (as Random...					
	BNT162b2 (30 µg) (N[a]=nn)		(N =nn)			
	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						
≥7 days after Dose 2 to <2 Months after Dose 2						
≥2 Months after Dose 2 to <4 Month...				xxx (nnn)	xx.x	(xx.x, xx.x)
≥4 Months after Dose 2	nnn	xxx (nnn)	nnn	xxx (nnn)	xx.x	(xx.x, xx.x)

(Sum of ADC19EF.AVAL)/365.25/1000 where ADC19EF.PARAMCD IN ("ST27PD")
(For subgroup the surveillance time will be custom and derived at reporting level for each period)

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

not missing (ADC19EF.VAX102DT) and ADC19EF.VAX102DT + 7 <= ADC19EF.ADT < ADC19EF.VAX102DT + 56

not missing (ADC19EF.VAX102DT) and ADC19EF.VAX102DT + 112 <= ADC19EF.ADT

not missing (ADC19EF.VAX102DT) and ADC19EF.VAX102DT + 56 <= ADC19EF.ADT < ADC19EF.VAX102DT + 112

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2) were included in the analysis.

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

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

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

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

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

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

Mock Table 11

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

Programming note: for tables 11: remove footnote "Note: Subjects had no serological.."

Follow same annotations as table 10 except remove ADC19EF. PDP27FL = "Y" from subset condition as this table is for subject With or Without Evidence of Infection Prior to 7 Days After Dose 2

Mock Table 12

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects 12 Through 15 Years of Age and 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.AGEGR4N=1

ADSL.TRT01P

Efficacy Endpoint Subgroup	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])
First COVID-19 occurrence						
Overall		xxx (xx)			xx.x	(xx.x, xx.x)
Sex						
Male		xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Female				x)	xx.x	(xx.x, xx.x)
Race						
White	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Black or	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
All others	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)
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						
USA	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)

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 (DVSTDT) and adt <= DVSTDT) or missing (DVSTDT))

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

(Sum of ADC19EF.AVAL)/365.25/1000 where ADC19EF.PARAMCD IN ("ST27PD")

ADSL.SEX

ADSL.ARACE

ADSL.ETHNIC

ADSL.COUNTRY

Comorbidities[f]						
Yes	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
No	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Obese[g]						
Yes	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
No	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Prior SARS-CoV-2 status						
Positive at baseline[h]	xx	xxx (xx)	xx	xxx (xx)	xx.x	(xx.x, xx.x)
Positive N-binding only					x	(xx.x, xx.x)
Positive NAAT only					x	(xx.x, xx.x)
Positive NAAT and N-binding						(xx.x, xx.x)
Negative at baseline but positive						(xx.x, xx.x)
Dose 2[i]						
Negative prior to 7 days after Dos						(xx.x, xx.x)
Unknown						(xx.x, xx.x)

If ADSL.COMBODFL=" Y" or ADSL. OBESEFL="Y" then "Yes" else "No"

If ADSL. OBESEFL="Y" then "Yes" else "No"

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

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.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

Abbreviatio

SARS-CoV-2 = severe acute respirato

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2 and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2) were included in the analysis.

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

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

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

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

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

f. Comorbidities are defined as having at least one of the Charlson comorbidity index category or obesity (BMI ≥95th percentile).

g. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

h. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

i. Negative N-binding antibody result 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.

j. 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

Programming note:

1) Remove any rows with zero counts if present in both the treatment groups. If n1 is zero across both placebo and bnt then delete that row in the table. This applies to all the similar tables in the document.
2) Prior Infection status rows (Prior SARS-CoV-2 Status and subrows) will be only part of 7 days post dose 2, Eval efficacy population, Dose 2 All-Available population With or Without evidence of infection tables. This section is to be presented only for table 13. Add 'unknown' row if there are subjects with unclassified status due to missing test.

Mock Table 13

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

Programming Note: Remove the "Note: Subjects who had no …".

Follow same annotations as table 12 except remove ADC19EF. PDP27FL = "Y" from subset condition as this table is for subject With or Without Evidence of Infection Prior to 7 Days After Dose 2

Mock Table 14

Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

ADSL.EVALEFFL="Y" and ADC19EF.PDP27FL="Y" and ADSL.AGEGR4N=1

	Vaccine Group (as Randomized)		
ADSL.TRT01P	BNT162b2 (30 µg)	Placebo	Total
	(N[a]=xx)	(N[a]=xx)	(N[a]=xx)
	n[b] (%)	n[b] (%)	n[b] (%)
Sex — ADSL.SEX			
Male	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Female	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Race — ADSL.ARACE			
White	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Black or African American	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
All others			
American Indian or Alaska Native	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Asian	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Native Hawaiian or other Pacific Islander	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Multiracial	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Not reported	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Ethnicity — ADSL.ETHNIC			
Hispanic/Latino	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Non-Hispanic/non-Latino	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Not reported	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Country — ADSL.COUNTRY			
USA	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Comorbidities[c] — If ADSL.COMBODFL=" Y" or ADSL. OBESEFL="Y" then "Yes" else "No"			

Yes	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
No	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Obese[d] (If ADSL.OBESEFL="Y" then "Yes" else "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)			
Positive[e]	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Negative[f]	xx (xxx.x)	xx (xxx.x)	xx (xxx.x)
Unknown	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)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
d. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
f. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: DDMMMYYYY (HH:MM) Source Data: abcdefgh Table Generation: DDMMMYYYY (HH:MM)
(Cutoff date: ddMmmYYYY, Snapshot Date: ddMmmYYYY) Output File: (CDISC)/C4591001/abcd_XNNN

Programming note: for without evidence of infection don't show "Baseline SARS-CoV-2 status section". Also adjust the footnotes accordingly.

Mock Table 15

Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

Follow same annotations as table 14 except remove ADC19EF. PDP27FL = "Y" from subset condition as this table is for subject With or Without Evidence of Infection Prior to 7 Days After Dose 2

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' etc. window. Dose x could be Dose 1, Dose 2, Dose 3 (first dose of BNT162b2 [30 μg]) or Dose 4 (second dose of BNT162b2 [30 μg]).

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 (for subjects unblinded without dose 3)	Open-label follow-up period
	Event start on or after unblinding and before dose 3 (for subjects unblinded and take 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

VPHASE		Comments
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
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 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

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:

Rules	Programming Logic
	- 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
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: 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. A copy of the data included in these files was combined into a supplementaldatadefinitions.pdf file and is linked to the define.xml package for reference.

ID	File Name	Comments
Rheumatic	report-cci-rheumatic-06aug2021.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-30oct2020.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)
Pulmonary	report-cci-pulmonary-30oct2020.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-30oct2020.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-30oct2020.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-06aug2021.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-30oct2020.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-30oct2020.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-30oct2020.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-30oct2020.xlsx	Used for ADMH creation to flag the medical history terms with comorbidities (record level)

ID	File Name	Comments
		Used for ADSL creation to flag the subject with comorbidities (subject level)
Leukemia	report-cci-leukemia-30oct2020.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-30oct2020.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-30oct2020.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-06aug2021.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-30oct2020.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-30oct2020.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-30oct2020.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-06aug2021.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-30oct2020.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)
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.
Phase2	first-c4591001-360-participants-enrolled-v1-13aug20-update.xlsx	Used for ADSL creation to flag the subjects from Phase 2 DS360 subset
Phase3	newlist-c4591001-6k-	Used for ADSL creation to flag the subjects from Phase 3 DS6000 subset

ID	File Name	Comments
DS6000	participants-enrolled-v3-17sep2020.csv	
HIV PT	201114-hiv-preferred-terms.xlsx	Used for ADSL creation to flag the HIV Positive subjects
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 V: 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 (only for analysis based on the evaluable efficacy population).
4. When the participant is unblinded at the time of being eligible for receipt of BNT162b2 or other reasons.

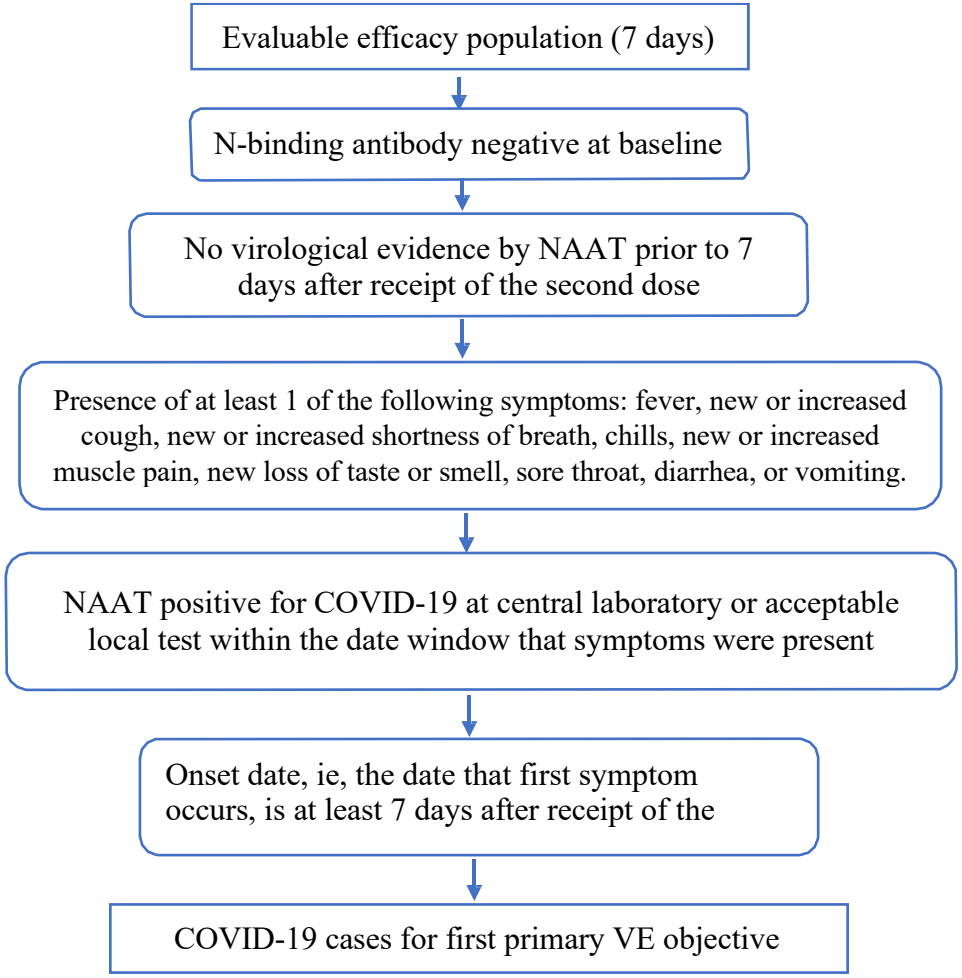
For all VE-related endpoints in this study, the end of a surveillance period for each participant is summarized below:

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 VI: 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,

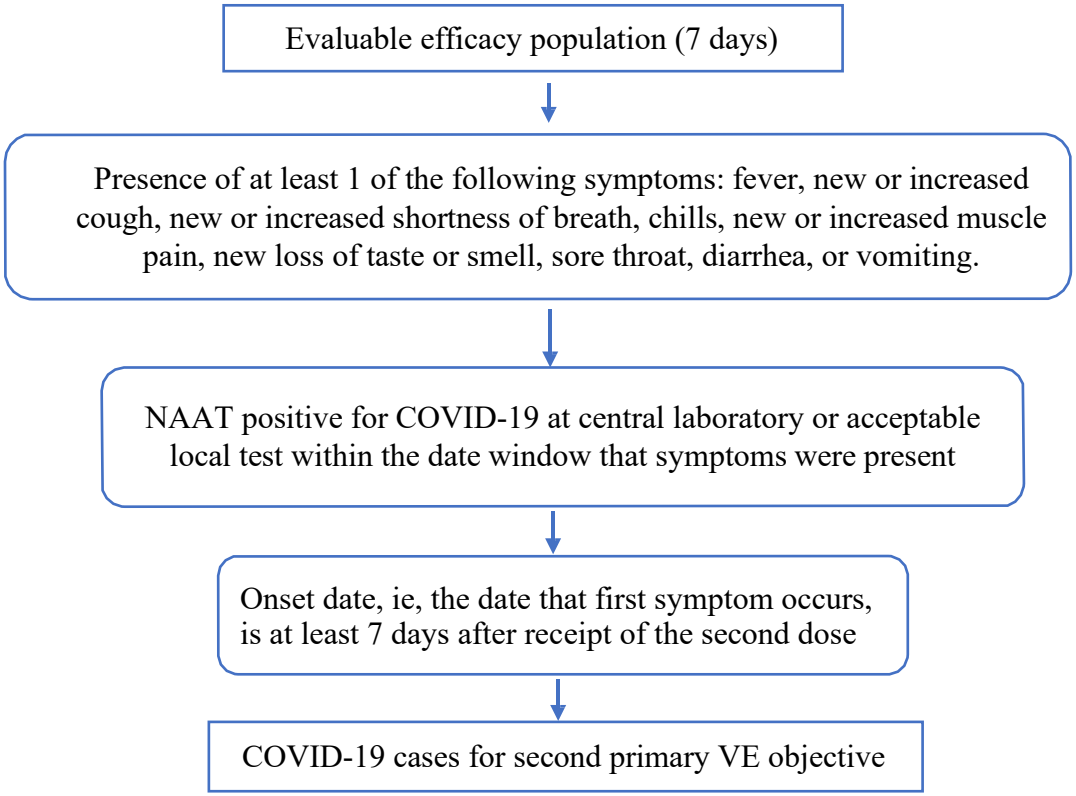
in which case a local NAAT result may be used if it was obtained using 1 of the following assays:

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 VII: Detailed subsetting for Analysis:

1. Key Analysis Population Subsetting:

1.1 Safety Analysis

1.2 Efficacy Analysis

Table Category	Analysis Population		Number of Subjects (N)			Subset Condition for Total N
		Sub-Category	BNT162b2 (30 µg)	Placebo	Total	
Efficacy	Dose 1 All-Available Efficacy		1131	1129	2260	Refer to Appendix I for more details. ADSL.AAI1EFFL="Y" and ADSL.AGEGR4N =1
	Dose 2 All-Available Efficacy	Subjects without evidence of infection prior to 7 days after dose 2	1061	1037	2098	Refer to Appendix I for more details. ADSL.AAI2EFFL="Y" and ADC19EF.PDP27FL="Y" and ADSL.AGEGR4N =1
	Evaluable Efficacy Evaluable Efficacy	Subjects without evidence of infection prior to 7 days after dose 2	1057	1030	2087	Refer to Appendix I for more details. ADSL.EVALEFFL="Y" and ADC19EF.PDP27FL="Y" and ADSL.AGEGR4N =1
		Subjects with or without evidence of infection prior to 7 days after dose 2	1119	1109	2228	Refer to Appendix I for more details ADSL.EVALEFFL="Y" and ADSL.AGEGR4N =1

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	From dose 1 to unblinding (the day before unblinding)	All AEs	ADAE.AECAT="ADVERSE EVENT" and ADAE.VPHASEN in (1,2,3,99)
		New AEs after the EUA Snapshot	ADAE.AECAT="ADVERSE EVENT" and ADAE.VPHASEN in (1,2,3,99) and ADAE.DATCHGFL="Y"
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	All AEs	ADAE.AECAT="ADVERSE EVENT" and ADAE.VPHASEN>=1 and . <ADAE.ASTDT<=ADSL.V02OBDT
		New AEs after the EUA Snapshot	ADAE.AECAT="ADVERSE EVENT" and ADAE.VPHASEN>=1 and . <ADAE.ASTDT<=ADSL.V02OBDT and ADAE.DATCHGFL="Y"
Open-label vaccination 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)	All AEs	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	All AEs	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	All AEs	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	All AEs	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	All AEs	ADAE.AECAT="ADVERSE EVENT" and ADAE.VPHASEN>=4 and ADAE.VPHASEN ne 99 and .<ADAE.ASTDT<=ADSL. X1CSRDT

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