Clinical trial results:
A master phase 1/2/3 protocol to investigate the safety, tolerability, and immunogenicity of variant- adapted BNT162b2 RNA-based vaccine candidates(s) in healthy children

Summary

EudraCT number	2024-000001-33
Trial protocol	Outside EU/EEA
Global end of trial date	

Results information

Result version number	v2
This version publication date	11 July 2024
First version publication date	06 March 2024
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	C4591048

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05543616
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech SE, BioNTech clinical trials patient information, +49 6131 90840, patients@biontech.de
Scientific contact	BioNTech SE, BioNTech clinical trials patient information, +49 6131 90840, patients@biontech.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002861-PIP02-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	25 October 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

SSB:Safety&tolerability profiles of bivalent BNT162b2 given as 3rd and/or 4th dose in participants>=6 months to <5 years(6M-<5Y).Compare anti–Omicron BA.4/BA.5 immune response between participants(6M-<5Y) who received 3 prior doses of BNT162b2 3 µg&received BNT162b2 as 4th dose in Group 2&Study C4591007 Phase 2/3 participants who received 3 doses of BNT162b2 3 µg.SSC:Safety&tolerability profiles of prophylactic bivalent BNT162b2 at each dose level given as 4th dose in participants 6M-<5Y.Describe immune responses elicited by prophylactic bivalent BNT162b2 at each dose level given as 4th dose in participants 6M-<5Y.SSD:Safety&tolerability profiles of bivalent BNT162b2 given as 3rd or 4th dose in participants 5 to 12 years(5-12y).Compare the anti–Omicron BA.4/BA.5 immune response between participants(5-12y) who received 3 prior doses of BNT162b2 10 µg&received bivalent BNT162b2 as 4th dose in Group 2&Study C4591007 Phase 2/3 participants(5-12y)who received 3 doses of BNT162b2 10 µg.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 September 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1610
Worldwide total number of subjects	1610
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	145
Children (2-11 years)	1465
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

SSB:1398 participants enrolled, 1397 were vaccinated. SSC: 100 participants randomised, 98 were vaccinated.SSD: 136 participants enrolled and 134 were vaccinated.Data is reported at study completion date for SSB, SSC and SSD. PCD for SSA and SSE have not been reached;data collection is still ongoing, hence no data are reported for SSA and E.

Period 1

Period 1 title	Baseline Period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	SSB: Group 1a: 2 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received two prior doses of BNT162b2 3 microgram (mcg) with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 1b: 2 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received two prior doses of BNT162b2 3 mcg with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 2a: 3 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 2b: 3 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 3a: 3 prior doses of BNT162b2

Arm description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 3b: 3 prior doses of BNT162b2

Arm description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSC: Group 1a: 3 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants

received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

6 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSC: Group 1b: 3 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSC: Group 2a: 3 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

6 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSC: Group 2b: 3 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSD: Group 1: 2 prior doses of BNT162b2

Arm description:

Participants aged 5 to 11 years who had received two prior doses of BNT162b2 10 microgram (mcg) 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms (original BNT162b2 5 mcg and BNT162b2 Omicron [B.1.1.529 sublineage BA.4/BA.5] 5 mcg) administered intramuscularly.

Arm title	SSD: Group 2: 3 prior doses of BNT162b2

Arm description:

Participants aged 5 to11 years who had received three prior doses of BNT162b2 10 mcg 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms (original BNT162b2 5 mcg and BNT162b2 Omicron [B.1.1.529 sublineage BA.4/BA.5] 5 mcg) administered intramuscularly.

Number of subjects in period 1	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2
Started	17	13	92
Completed	17	13	92

Number of subjects in period 1	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 3a: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2
Started	218	68	989
Completed	218	68	989

Number of subjects in period 1	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2
Started	17	19	32
Completed	17	19	32

Number of subjects in period 1	SSC: Group 2b: 3 prior doses of BNT162b2	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2
Started	30	2	113
Completed	30	2	113

Period 2

Period 2 title	Phase 1
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Single blinded sponsor open label

Arms

Are arms mutually exclusive?	No
Arm title	SSC: Group 1a: 3 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

6 micrograms BNT162b2 administered intramuscularly.

Arm title	SSC: Group 1b: 3 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms BNT162b2 administered intramuscularly.

Arm title	SSC: Group 2a: 3 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

6 micrograms BNT162b2 administered intramuscularly.

Arm title	SSC: Group 2b: 3 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms BNT162b2 administered intramuscularly.

Number of subjects in period 2	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2
Started	17	19	32
Completed	17	18	32
Not completed	0	1	0
Lost to follow-up	-	1	-

Number of subjects in period 2	SSC: Group 2b: 3 prior doses of BNT162b2
Started	30
Completed	30
Not completed	0
Lost to follow-up	-

Period 3

Period 3 title	Phase 3
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Open Label Period

Arms

Are arms mutually exclusive?	Yes

Arm title	SSB: Group 1a: 2 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received two prior doses of BNT162b2 3 microgram (mcg) with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 1b: 2 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received two prior doses of BNT162b2 3 mcg with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 2a: 3 prior doses of BNT162b2

Arm description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 2b: 3 prior doses of BNT162b2

Arm description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental

Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 3a: 3 prior doses of BNT162b2

Arm description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSB: Group 3b: 3 prior doses of BNT162b2

Arm description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 micrograms Bivalent BNT162b2 administered intramuscularly.

Arm title	SSD: Group 1: 2 prior doses of BNT162b2

Arm description:

Participants aged 5 to 11 years who had received two prior doses of BNT162b2 10 microgram (mcg) 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms (original BNT162b2 5 mcg and BNT162b2 Omicron [B.1.1.529 sublineage BA.4/BA.5] 5 mcg) administered intramuscularly.

Arm title	SSD: Group 2: 3 prior doses of BNT162b2

Arm description:

Participants aged 5 to11 years who had received three prior doses of BNT162b2 10 mcg 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms (original BNT162b2 5 mcg and BNT162b2 Omicron [B.1.1.529 sublineage BA.4/BA.5] 5 mcg) administered intramuscularly.

Arm title	SSD Historical cohort:Participants from study C4591007 Phase 1

Arm description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged 5 to 11 years who had received three prior doses of BNT162b2 10 mcg at least 90 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Arm type	Active comparator
Investigational medicinal product name	Bivalent BNT162b2 (original/Omicron BA.4/BA.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

10 micrograms (original BNT162b2 5 mcg and BNT162b2 Omicron [B.1.1.529 sublineage BA.4/BA.5] 5 mcg) administered intramuscularly.

Number of subjects in period 3	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2
Started	17	13	92
Completed	17	11	89
Not completed	0	2	3
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Withdrawal by parents/guardian	-	2	3
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 3	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 3a: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2
Started	218	68	989
Completed	210	67	969
Not completed	8	1	20
Physician decision	-	-	1
Consent withdrawn by subject	-	-	-
Withdrawal by parents/guardian	7	-	4
Lost to follow-up	-	1	12
Protocol deviation	1	-	3

Number of subjects in period 3	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort:Participants from study C4591007 Phase 1
Started	2	113	19
Completed	2	111	19
Not completed	0	2	0
Physician decision	-	-	-
Consent withdrawn by subject	-	1	-
Withdrawal by parents/guardian	-	1	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Reporting groups

Reporting group title	SSB: Group 1a: 2 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received two prior doses of BNT162b2 3 microgram (mcg) with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Reporting group title	SSB: Group 1b: 2 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received two prior doses of BNT162b2 3 mcg with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Reporting group title	SSB: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3a: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3b: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a

single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 1: 2 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to 11 years who had received two prior doses of BNT162b2 10 microgram (mcg) 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 2: 3 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to11 years who had received three prior doses of BNT162b2 10 mcg 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2
Number of subjects	17	13	92
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	17	0	92
Children (2-11 years)	0	13	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	5	7	41
Male	12	6	51
Race Units: Subjects			
White	14	7	64
Black or African American	0	0	2
Asian	1	4	11
Multiracial	1	2	15
Not reported	1	0	0
Native Hawaiian or other Pacific Islander	0	0	0
American Indian or Alaska Native	0	0	0
Ethinicity Units: Subjects			
Hispanic/Latino	3	2	18
Non-Hispanic/non-Latino	13	11	74
Not reported	1	0	0

Reporting group values	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 3a: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2
Number of subjects	218	68	989

Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	68	0
Children (2-11 years)	218	0	989
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	113	30	512
Male	105	38	477
Race Units: Subjects			
White	153	58	775
Black or African American	7	5	51
Asian	18	3	57
Multiracial	39	2	100
Not reported	1	0	2
Native Hawaiian or other Pacific Islander	0	0	1
American Indian or Alaska Native	0	0	3
Ethinicity Units: Subjects			
Hispanic/Latino	34	12	136
Non-Hispanic/non-Latino	184	56	852
Not reported	0	0	1

Reporting group values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2
Number of subjects	17	19	32
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	17	0	32
Children (2-11 years)	0	19	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	8	11	16
Male	9	8	16

Race Units: Subjects			
White	13	18	25
Black or African American	0	1	2
Asian	2	0	2
Multiracial	2	0	3
Not reported	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
American Indian or Alaska Native	0	0	0
Ethinicity Units: Subjects			
Hispanic/Latino	2	2	1
Non-Hispanic/non-Latino	15	17	31
Not reported	0	0	0

Reporting group values	SSC: Group 2b: 3 prior doses of BNT162b2	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2
Number of subjects	30	2	113
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	30	2	113
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	13	0	56
Male	17	2	57
Race Units: Subjects			
White	23	2	66
Black or African American	1	0	9
Asian	3	0	13
Multiracial	3	0	22
Not reported	0	0	3
Native Hawaiian or other Pacific Islander	0	0	0
American Indian or Alaska Native	0	0	0
Ethinicity Units: Subjects			
Hispanic/Latino	0	0	23
Non-Hispanic/non-Latino	30	2	90
Not reported	0	0	0

Reporting group values	Total		
Number of subjects	1610		
Age Categorical Units: Participants			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	226		
Children (2-11 years)	1384		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Gender Categorical Units: Participants			
Female	812		
Male	798		
Race Units: Subjects			
White	1218		
Black or African American	78		
Asian	114		
Multiracial	189		
Not reported	7		
Native Hawaiian or other Pacific Islander	1		
American Indian or Alaska Native	3		
Ethinicity Units: Subjects			
Hispanic/Latino	233		
Non-Hispanic/non-Latino	1375		
Not reported	2		

End points

End points reporting groups

Reporting group title	SSB: Group 1a: 2 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received two prior doses of BNT162b2 3 microgram (mcg) with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Reporting group title	SSB: Group 1b: 2 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received two prior doses of BNT162b2 3 mcg with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Reporting group title	SSB: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3a: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3b: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a

single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 1: 2 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to 11 years who had received two prior doses of BNT162b2 10 microgram (mcg) 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 2: 3 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to11 years who had received three prior doses of BNT162b2 10 mcg 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 1a: 2 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received two prior doses of BNT162b2 3 microgram (mcg) with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Reporting group title	SSB: Group 1b: 2 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received two prior doses of BNT162b2 3 mcg with the last dose received 60 to 150 days before enrollment in the study were included. Participants received two doses (third and fourth dose) of BNT162b2 3 mcg via intramuscular route in this study. Third dose was administered on Day 1 of this study and fourth dose was administered approximately 2 months after third dose.

Reporting group title	SSB: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3a: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before

enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3b: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 1: 2 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to 11 years who had received two prior doses of BNT162b2 10 microgram (mcg) 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 2: 3 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to11 years who had received three prior doses of BNT162b2 10 mcg 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD Historical cohort:Participants from study C4591007 Phase 1

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged 5 to 11 years who had received three prior doses of BNT162b2 10 mcg at least 90 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Subject analysis set title	SSD Historical cohort: C4591007 BNT162b2 10 µg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged >=5 to <12 years from study C4591007 (NCT04816643) who received 3 doses of original BNT162b2 10 mcg were included.

Subject analysis set title	SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged >=6 months to <2 years from study C4591007 (NCT04816643) who received 3 doses of original BNT162b2 3 mcg were included.

Subject analysis set title	SSB Historical cohort: C4591007 BNT162b2 3 mcg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged >=2 to <5 years from study C4591007 (NCT04816643) who received 3 doses of original BNT162b2 3 mcg were included.

Primary: SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 1 in Participants Aged >=6 months to <2 Years

End point title	SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 1 in Participants Aged >=6 months to <2 Years[1]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after study vaccination 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe(>7.0 cm) & Grade (G) 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]).Tenderness at injection site was graded as mild(hurts if gently touched),moderate(hurts if gently touched with crying),severe(causes limitation of limb movement) & G4 ER visit or hospitalisation. G4 were classified by investigator or medically qualified person. Percentage of participants with local reactions within 7 days after study vaccination 1 and associated 2-sided 95% CI based on Clopper and Pearson method. Safety population=all participants receiving at least 1dose of study intervention. Here, n=participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 1 (i.e. third dose for Group 1a and fourth dose for Groups 2a and 3a)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 3a: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	92	68	
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (n=17, 92, 68)	5.9 (0.1 to 28.7)	7.6 (3.1 to 15.1)	5.9 (1.6 to 14.4)	
Redness: Mild (n=17, 92, 68)	5.9 (0.1 to 28.7)	7.6 (3.1 to 15.1)	4.4 (0.9 to 12.4)	
Redness: Moderate (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	1.5 (0.0 to 7.9)	
Redness: Severe (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	0 (0.0 to 5.3)	
Redness: Grade 4 (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	0 (0.0 to 5.3)	
Swelling: Any (n=17, 92, 68)	0 (0.0 to 19.5)	5.4 (1.8 to 12.2)	1.5 (0.0 to 7.9)	
Swelling: Mild (n=17, 92, 68)	0 (0.0 to 19.5)	5.4 (1.8 to 12.2)	1.5 (0.0 to 7.9)	
Swelling: Moderate (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	0 (0.0 to 5.3)	
Swelling: Severe (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	0 (0.0 to 5.3)	
Swelling: Grade 4 (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	0 (0.0 to 5.3)	
Tenderness at injection site:Any (n=17,90,64)	23.5 (6.8 to 49.9)	12.2 (6.3 to 20.8)	12.5 (5.6 to 23.2)	
Tenderness at injection site:Mild (n=17,90,64)	17.6 (3.8 to 43.4)	12.2 (6.3 to 20.8)	12.5 (5.6 to 23.2)	
Tenderness at injection site:Moderate(n=17,90,64)	5.9 (0.1 to 28.7)	0 (0.0 to 4.0)	0 (0.0 to 5.6)	
Tenderness at injection site:Severe (n=17,90, 64)	0 (0.0 to 19.5)	0 (0.0 to 4.0)	0 (0.0 to 5.6)	
Tenderness at injection site:Grade 4 (n=17,90,64)	0 (0.0 to 19.5)	0 (0.0 to 4.0)	0 (0.0 to 5.6)	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 2 in Participants Aged >=6 months to <2 Years: Group 1a Only

End point title	SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 2 in Participants Aged >=6 months to <2 Years: Group 1a Only[2]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after study vaccination 2. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe(>7.0 cm)& G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate (hurts if gently touched with crying),severe(causes

limitation of limb movement) & G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person. Percentage of participants with local reactions within 7 days after study vaccination 2 and associated 2-sided 95% CI based on Clopper and Pearson method. Safety population=all participants who received at least 1 dose of study intervention. This endpoint is reported for Group 1a only as only participants from Group 1a received two vaccinations in the study.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 2 (i.e. fourth dose)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1a: 2 prior doses of BNT162b2			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	11.8 (1.5 to 36.4)			
Redness: Mild	11.8 (1.5 to 36.4)			
Redness: Moderate	0 (0.0 to 19.5)			
Redness: Severe	0 (0.0 to 19.5)			
Redness: Grade 4	0 (0.0 to 19.5)			
Swelling: Any	5.9 (0.1 to 28.7)			
Swelling: Mild	5.9 (0.1 to 28.7)			
Swelling: Moderate	0 (0.0 to 19.5)			
Swelling: Severe	0 (0.0 to 19.5)			
Swelling: Grade 4	0 (0.0 to 19.5)			
Tenderness at the injection site: Any	17.6 (3.8 to 43.4)			
Tenderness at the injection site: Mild	11.8 (1.5 to 36.4)			
Tenderness at the injection site: Moderate	0 (0.0 to 19.5)			
Tenderness at the injection site: Severe	5.9 (0.1 to 28.7)			
Tenderness at the injection site: Grade 4	0 (0.0 to 19.5)			

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 1 in Participants Aged >=6 months to <2 Years

End point title	SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 1 in Participants Aged >=6 months to <2 Years[3]

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after study vaccination 1. Fever: oral temperature >=38.0 deg C categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite: mild (decreased interest in eating), moderate (decreased oral intake), severe(refusal to feed). Drowsiness: mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity). Irritability: mild(easily consolable),moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted). G4 for all events: ER visit/hospitalisation and classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used. n=number of participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 1 (i.e. third dose for Group 1a and fourth dose for Groups 2a and 3a)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 3a: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	92	68	
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any (n=17, 92, 68)	0 (0.0 to 19.5)	8.7 (3.8 to 16.4)	11.8 (5.2 to 21.9)	
Fever: >=38.0 to 38.4 deg C (n=17, 92, 68)	0 (0.0 to 19.5)	6.5 (2.4 to 13.7)	2.9 (0.4 to 10.2)	
Fever: >38.4 to 38.9 deg C (n=17, 92, 68)	0 (0.0 to 19.5)	1.1 (0.0 to 5.9)	2.9 (0.4 to 10.2)	
Fever: >38.9 to 40.0 deg C (n=17, 92, 68)	0 (0.0 to 19.5)	1.1 (0.0 to 5.9)	4.4 (0.9 to 12.4)	
Fever: >40.0 deg C (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	0 (0.0 to 5.3)	
Fever: Unknown (n=17, 92, 68)	0 (0.0 to 19.5)	0 (0.0 to 3.9)	1.5 (0.0 to 7.9)	
Decreased appetite: Any (n=17, 89, 64)	23.5 (6.8 to 49.9)	20.2 (12.4 to 30.1)	20.3 (11.3 to 32.2)	
Decreased appetite: Mild (n=17, 89, 64)	11.8 (1.5 to 36.4)	9.0 (4.0 to 16.9)	14.1 (6.6 to 25.0)	
Decreased appetite: Moderate (n=17, 89, 64)	11.8 (1.5 to 36.4)	11.2 (5.5 to 19.7)	6.3 (1.7 to 15.2)	
Decreased appetite: Severe (n=17, 89, 64)	0 (0.0 to 19.5)	0 (0.0 to 4.1)	0 (0.0 to 5.6)	
Decreased appetite: Grade 4 (n=17, 89, 64)	0 (0.0 to 19.5)	0 (0.0 to 4.1)	0 (0.0 to 5.6)	
Drowsiness: Any (n=17, 89, 64)	41.2 (18.4 to 67.1)	20.2 (12.4 to 30.1)	17.2 (8.9 to 28.7)	
Drowsiness: Mild (n=17, 89, 64)	35.3 (14.2 to 61.7)	18.0 (10.6 to 27.5)	15.6 (7.8 to 26.9)	
Drowsiness: Moderate (n=17, 89, 64)	5.9 (0.1 to 28.7)	2.2 (0.3 to 7.9)	1.6 (0.0 to 8.4)	
Drowsiness: Severe (n=17, 89, 64)	0 (0.0 to 19.5)	0 (0.0 to 4.1)	0 (0.0 to 5.6)	
Drowsiness: Grade 4 (n=17, 89, 64)	0 (0.0 to 19.5)	0 (0.0 to 4.1)	0 (0.0 to 5.6)	
Irritability: Any (n=17, 89, 64)	64.7 (38.3 to 85.8)	36.0 (26.1 to 46.8)	45.3 (32.8 to 58.3)	
Irritability: Mild (n=17, 89, 64)	35.3 (14.2 to 61.7)	16.9 (9.8 to 26.3)	23.4 (13.8 to 35.7)	

Irritability: Moderate (n=17, 89, 64)	23.5 (6.8 to 49.9)	18.0 (10.6 to 27.5)	21.9 (12.5 to 34.0)	
Irritability: Severe (n=17, 89, 64)	5.9 (0.1 to 28.7)	1.1 (0.0 to 6.1)	0 (0.0 to 5.6)	
Irritability: Grade 4 (n=17, 89, 64)	0 (0.0 to 19.5)	0 (0.0 to 4.1)	0 (0.0 to 5.6)	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 2 in Participants Aged >=6 months to <2 Years: Group 1a Only

End point title	SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 2 in Participants Aged >=6 months to <2 Years: Group 1a Only[4]

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after Dose 1. Fever:oral temperature >=38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Decreased appetite:mild(decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed).Drowsiness:mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(disabling;not interested in usual daily activity).G4 for all events:ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method.Safety population.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 2 (i.e. fourth dose)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1a: 2 prior doses of BNT162b2			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	11.8 (1.5 to 36.4)			
Fever: >=38.0 to 38.4 deg C	0 (0.0 to 19.5)			
Fever: >38.4 to 38.9 deg C	0 (0.0 to 19.5)			
Fever: >38.9 to 40.0 deg C	11.8 (1.5 to 36.4)			
Fever: >40.0 deg C	0 (0.0 to 19.5)			
Decreased appetite: Any	17.6 (3.8 to 43.4)			
Decreased appetite: Mild	17.6 (3.8 to 43.4)			
Decreased appetite: Moderate	0 (0.0 to 19.5)			
Decreased appetite: Severe	0 (0.0 to 19.5)			
Decreased appetite: Grade 4	0 (0.0 to 19.5)			

Drowsiness: Any	11.8 (1.5 to 36.4)			
Drowsiness: Mild	11.8 (1.5 to 36.4)			
Drowsiness: Moderate	0 (0.0 to 19.5)			
Drowsiness: Severe	0 (0.0 to 19.5)			
Drowsiness: Grade 4	0 (0.0 to 19.5)			
Irritability: Any	52.9 (27.8 to 77.0)			
Irritability: Mild	23.5 (6.8 to 49.9)			
Irritability: Moderate	23.5 (6.8 to 49.9)			
Irritability: Severe	5.9 (0.1 to 28.7)			
Irritability: Grade 4	0 (0.0 to 19.5)			

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants Reporting Serious Adverse Events (SAEs) From the Study Vaccination to 6 Months After Last Study Vaccination in Participants Aged >=6 Months to <2 Years

End point title	SSB: Percentage of Participants Reporting Serious Adverse Events (SAEs) From the Study Vaccination to 6 Months After Last Study Vaccination in Participants Aged >=6 Months to <2 Years[5]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination up to 6 months after last study vaccination

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 3a: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	92	68	
Units: Percentage of participants				
number (not applicable)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants Reporting Adverse Events (AEs) From the First Study Vaccination to 1 Month After Study Vaccination 1 in Participants Aged >=6 Months to <2 Years

End point title	SSB: Percentage of Participants Reporting Adverse Events (AEs) From the First Study Vaccination to 1 Month After Study Vaccination 1 in Participants Aged >=6 Months to <2 Years[6]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs within 1 month after study vaccination were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 1 month after study vaccination 1 (i.e. third dose for Group 1a and fourth dose for Group 2a and 3a)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 3a: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	92	68	
Units: Percentage of participants				
number (not applicable)	5.9	10.9	14.7	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants Reporting Adverse Events (AEs) From the Second Study Vaccination to 1 Month After Study Vaccination 2 in Participants Aged >=6 Months to <2 Years: Group 1a Only

End point title	SSB: Percentage of Participants Reporting Adverse Events (AEs) From the Second Study Vaccination to 1 Month After Study Vaccination 2 in Participants Aged >=6 Months to <2 Years: Group 1a Only[7]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs within 1 month after study vaccination 2 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination 2 up to 1 month after study vaccination 2 (i.e. fourth dose)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1a: 2 prior doses of BNT162b2			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Percentage of participants				
number (not applicable)	5.9			

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 2 in Participants Aged >=2 to <5 Years: Group 1b Only

End point title	SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 2 in Participants Aged >=2 to <5 Years: Group 1b Only[8]

End point description:

Local reactions recorded by participants/parents/legal guardians in e-diary.Redness & swelling recorded in mdu converted to cm.1 mdu=0.5 cm&graded mild:(>0.5 to 2.0cm),moderate:>2.0 to 7.0cm,severe:>7.0 cm,G4: necrosis/exfoliative dermatitis(redness)&necrosis(swelling).Pain at injection site graded mild:did not interfere with daily activity,moderate:interfered with daily activity, severe: prevented daily activity & G4: ER]visit/hospitalisation.G4 classified by investigator/medically qualified person.Percentage of participants with local reactions within 7days after study vaccination and associated 2-sided 95% CI based on Clopper and Pearson method.Safety population=all participants receiving at least 1 dose of study intervention. Number of participants analyzed= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 2 (i.e third dose for Group 1b)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1b: 2 prior doses of BNT162b2			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	0 (0.0 to 28.5)			
Redness: Mild	0 (0.0 to 28.5)			
Redness: Moderate	0 (0.0 to 28.5)			
Redness: Severe	0 (0.0 to 28.5)			
Redness: Grade 4	0 (0.0 to 28.5)			
Swelling: Any	0 (0.0 to 28.5)			

Swelling: Mild	0 (0.0 to 28.5)			
Swelling: Moderate	0 (0.0 to 28.5)			
Swelling: Severe	0 (0.0 to 28.5)			
Swelling: Grade 4	0 (0.0 to 28.5)			
Pain at the injection site: Any	9.1 (0.2 to 41.3)			
Pain at the injection site: Mild	9.1 (0.2 to 41.3)			
Pain at the injection site: Moderate	0 (0.0 to 28.5)			
Pain at the injection site: Severe	0 (0.0 to 28.5)			
Pain at the injection site: Grade 4	0 (0.0 to 28.5)			

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 1 in Participants Aged >=2 to <5 Years

End point title	SSB: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination 1 in Participants Aged >=2 to <5 Years[9]

End point description:

Local reactions recorded by participants/parents/legal guardians in e-diary.Redness & swelling recorded in mdu converted to cm.1 mdu=0.5 cm&graded mild:(>0.5 to 2.0cm),moderate:>2.0 to 7.0cm,severe:>7.0 cm,G4: necrosis/exfoliative dermatitis(redness)&necrosis(swelling).Pain at injection site graded mild:did not interfere with daily activity,moderate:interfered with daily activity, severe: prevented daily activity & G4: ER]visit/hospitalisation.G4 classified by investigator/medically qualified person.Percentage of participants with local reactions within 7days after study vaccination and associated 2-sided 95% CI based on Clopper and Pearson method.Safety population=all participants receiving at least 1 dose of study intervention. Number of participants analyzed= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 1 (i.e. third dose for Group 1b and fourth dose for Groups 2b and 3b)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1b: 2 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	218	986	
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	7.7 (0.2 to 36.0)	6.4 (3.6 to 10.5)	10.1 (8.3 to 12.2)	
Redness: Mild	0 (0.0 to 24.7)	5.5 (2.9 to 9.4)	8.8 (7.1 to 10.8)	
Redness: Moderate	7.7 (0.2 to 36.0)	0.9 (0.1 to 3.3)	1.3 (0.7 to 2.2)	
Redness: Severe	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	

Redness: Grade 4	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Swelling: Any	7.7 (0.2 to 36.0)	4.1 (1.9 to 7.7)	4.0 (2.8 to 5.4)	
Swelling: Mild	7.7 (0.2 to 36.0)	3.7 (1.6 to 7.1)	3.4 (2.4 to 4.8)	
Swelling: Moderate	0 (0.0 to 24.7)	0.5 (0.0 to 2.5)	0.5 (0.2 to 1.2)	
Swelling: Severe	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Swelling: Grade 4	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Pain at the injection site: Any	30.8 (9.1 to 61.4)	30.3 (24.3 to 36.8)	30.3 (27.5 to 33.3)	
Pain at the injection site: Mild	30.8 (9.1 to 61.4)	28.4 (22.6 to 34.9)	27.9 (25.1 to 30.8)	
Pain at the injection site: Moderate	0 (0.0 to 24.7)	1.8 (0.5 to 4.6)	2.5 (1.6 to 3.6)	
Pain at the injection site: Severe	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Pain at the injection site: Grade 4	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 1 in Participants Aged >=2 to <5 Years

End point title	SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 1 in Participants Aged >=2 to <5 Years[10]

End point description:

Systemic events recorded by participants/parents/legal guardians in e-diary. Fever: oral temperature >= 38.0 deg C and categorised as >=38.0-38.4 deg C,>38.4-38.9 deg C,>38.9-40.0 deg C & >40.0 deg C.Fatigue,headache,chills,new/worsened muscle pain&new/worsened joint pain:mild:did not interfere with activity,moderate:some interference with activity&severe: prevented daily routine activity.Vomiting:mild: 1-2 times in 24h,moderate:>2 times in 24h,severe:required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h&severe:6 or more loose stools in 24h.Except fever,G4=ER visit/hospitalisation.G4 events classified by investigator/medically qualified person. Exact 95% CI based on Clopper & Pearson method.Safety population=all participants receiving at least 1 dose of study intervention.N= participants evaluable for this endpoint.n=participants evaluable for specified rows

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 1 (i.e. third dose for Group 1b and fourth dose for Groups 2b and 3b)

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1b: 2 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	218	986	
Units: Percentage of participants				
number (confidence interval 95%)				
Fever:Any (n=13, 218, 986)	0 (0.0 to 24.7)	6.9 (3.9 to 11.1)	5.3 (4.0 to 6.9)	

Fever: >=38.0 to 38.4 deg C (n=13, 218, 986)	0 (0.0 to 24.7)	1.8 (0.5 to 4.6)	1.5 (0.9 to 2.5)	
Fever: >38.4 to 38.9 deg C (n=13, 218, 986)	0 (0.0 to 24.7)	3.2 (1.3 to 6.5)	2.0 (1.2 to 3.1)	
Fever: >38.9 to 40.0 deg C (n=13, 218, 986)	0 (0.0 to 24.7)	1.4 (0.3 to 4.0)	1.4 (0.8 to 2.4)	
Fever: >40.0 deg C (n=13, 218, 986)	0 (0.0 to 24.7)	0.5 (0.0 to 2.5)	0.2 (0.0 to 0.7)	
Fever: Unknown ((n=13, 218, 986)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0.1 (0.0 to 0.6)	
Fatigue: Any (n=13, 217, 976)	30.8 (9.1 to 61.4)	31.3 (25.2 to 38.0)	29.0 (26.2 to 32.0)	
Fatigue: Mild (n=13, 217, 976)	15.4 (1.9 to 45.4)	17.5 (12.7 to 23.2)	17.8 (15.5 to 20.4)	
Fatigue: Moderate (n=13, 217, 976)	15.4 (1.9 to 45.4)	12.4 (8.4 to 17.6)	10.7 (8.8 to 12.8)	
Fatigue: Severe (n=13, 217, 976)	0 (0.0 to 24.7)	1.4 (0.3 to 4.0)	0.5 (0.2 to 1.2)	
Fatigue: Grade 4 (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Headache: Any (n=13, 217, 976)	7.7 (0.2 to 36.0)	4.1 (1.9 to 7.7)	4.4 (3.2 to 5.9)	
Headache: Mild (n=13, 217, 976)	7.7 (0.2 to 36.0)	2.3 (0.8 to 5.3)	3.7 (2.6 to 5.1)	
Headache: Moderate (n=13, 217, 976)	0 (0.0 to 24.7)	1.4 (0.3 to 4.0)	0.7 (0.3 to 1.5)	
Headache: Severe (n=13, 217, 976)	0 (0.0 to 24.7)	0.5 (0.0 to 2.5)	0 (0.0 to 0.4)	
Headache: Grade 4 (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Chills: Any (n=13, 217, 976)	0 (0.0 to 24.7)	4.6 (2.2 to 8.3)	2.5 (1.6 to 3.6)	
Chills: Mild (n=13, 217, 976)	0 (0.0 to 24.7)	3.2 (1.3 to 6.5)	1.8 (1.1 to 2.9)	
Chills: Moderate (n=13, 217, 976)	0 (0.0 to 24.7)	1.4 (0.3 to 4.0)	0.6 (0.2 to 1.3)	
Chills: Severe (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Chills: Grade 4 (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Vomiting: Any (n=13, 217, 976)	7.7 (0.2 to 36.0)	5.1 (2.6 to 8.9)	4.8 (3.6 to 6.4)	
Vomiting: Mild (n=13, 217, 976)	7.7 (0.2 to 36.0)	3.2 (1.3 to 6.5)	4.0 (2.9 to 5.4)	
Vomiting: Moderate (n=13, 217, 976)	0 (0.0 to 24.7)	1.8 (0.5 to 4.7)	0.8 (0.4 to 1.6)	
Vomiting: Severe (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Vomiting: Grade 4 (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
Diarrhea: Any (n=13, 217, 976)	0 (0.0 to 24.7)	5.1 (2.6 to 8.9)	7.0 (5.5 to 8.7)	
Diarrhea: Mild (n=13, 217, 976)	0 (0.0 to 24.7)	4.1 (1.9 to 7.7)	6.0 (4.6 to 7.7)	
Diarrhea: Moderate (n=13, 217, 976)	0 (0.0 to 24.7)	0.9 (0.1 to 3.3)	0.8 (0.4 to 1.6)	
Diarrhea: Severe (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0.1 (0.0 to 0.6)	
Diarrhea: Grade 4 (n=13, 217, 976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
New or worsened muscle pain:Any(n=13,217,976)	0 (0.0 to 24.7)	3.2 (1.3 to 6.5)	2.0 (1.3 to 3.1)	
New or worsened muscle pain:Mild(n=13,217,976)	0 (0.0 to 24.7)	2.3 (0.8 to 5.3)	1.2 (0.6 to 2.1)	
New or worsened muscle pain:Moderate(n=13,217,976)	0 (0.0 to 24.7)	0.9 (0.1 to 3.3)	0.8 (0.4 to 1.6)	
New or worsened muscle pain:Severe(n=13,217,976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
New or worsened muscle pain:Grade4(n=13,217,976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	
New or worsened joint pain:Any(n=13,217,976)	0 (0.0 to 24.7)	0.9 (0.1 to 3.3)	0.9 (0.4 to 1.7)	
New or worsened joint pain:Mild(n=13,217,976)	0 (0.0 to 24.7)	0.9 (0.1 to 3.3)	0.7 (0.3 to 1.5)	
New or worsened joint pain:Moderate(n=13,217,976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0.2 (0.0 to 0.7)	
New or worsened joint pain:Severe(n=13,217,976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	

New or worsened joint pain:Grade 4(n=13,217,976)	0 (0.0 to 24.7)	0 (0.0 to 1.7)	0 (0.0 to 0.4)	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 2 in Participants Aged >=2 to <5 Years: Group 1b Only

End point title	SSB: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination 2 in Participants Aged >=2 to <5 Years: Group 1b Only[11]

End point description:

Systemic events recorded by participants/parents/legal guardians in e-diary. Fever: oral temperature >= 38.0 deg C and categorised as >=38.0-38.4 deg C,>38.4-38.9 deg C,>38.9-40.0 deg C & >40.0 deg C.Fatigue,headache,chills,new/worsened muscle pain&new/worsened joint pain:mild:did not interfere with activity,moderate:some interference with activity&severe: prevented daily routine activity.Vomiting:mild: 1-2 times in 24h,moderate:>2 times in 24h,severe:required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h&severe:6 or more loose stools in 24h.Except fever,G4=ER visit/hospitalisation.G4 events classified by investigator/medically qualified person. Exact 95% CI based on Clopper & Pearson method.Safety population=all participants receiving at least 1 dose of study intervention.N= participants evaluable for this endpoint.n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination 2 (i.e third dose for Group 1b)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1b: 2 prior doses of BNT162b2			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >= 38.0 deg C (n=11)	0 (0.0 to 28.5)			
Fever: 38.0 to 38.4 deg C (n=11)	0 (0.0 to 28.5)			
Fever: >38.4 to 38.9 deg C (n=11)	0 (0.0 to 28.5)			
Fever: >38.9 to 40.0 deg C (n=11)	0 (0.0 to 28.5)			
Fever: >40.0 deg C (n=11)	0 (0.0 to 28.5)			
Fatigue: Any (n=12)	33.3 (9.9 to 65.1)			
Fatigue: Mild (n=12)	16.7 (2.1 to 48.4)			
Fatigue: Moderate (n=12)	16.7 (2.1 to 48.4)			
Fatigue: Severe (n=12)	0 (0.0 to 26.5)			
Fatigue: Grade 4 (n=12)	0 (0.0 to 26.5)			
Headache: Any (n=11)	0 (0.0 to 28.5)			
Headache: Mild (n=11)	0 (0.0 to 28.5)			

Headache: Moderate (n=11)	0 (0.0 to 28.5)			
Headache: Severe (n=11)	0 (0.0 to 28.5)			
Headache: Grade 4 (n=11)	0 (0.0 to 28.5)			
Chills: Any (n=11)	0 (0.0 to 28.5)			
Chills: Mild (n=11)	0 (0.0 to 28.5)			
Chills: Moderate (n=11)	0 (0.0 to 28.5)			
Chills: Severe (n=11)	0 (0.0 to 28.5)			
Chills: Grade 4 (n=11)	0 (0.0 to 28.5)			
Vomiting: Any (n=11)	9.1 (0.2 to 41.3)			
Vomiting: Mild (n=11)	9.1 (0.2 to 41.3)			
Vomiting: Moderate (n=11)	0 (0.0 to 28.5)			
Vomiting: Severe (n=11)	0 (0.0 to 28.5)			
Vomiting: Grade 4 (n=11)	0 (0.0 to 28.5)			
Diarrhea: Any (n=11)	9.1 (0.2 to 41.3)			
Diarrhea: Mild (n=11)	9.1 (0.2 to 41.3)			
Diarrhea: Moderate (n=11)	0 (0.0 to 28.5)			
Diarrhea: Severe (n=11)	0 (0.0 to 28.5)			
Diarrhea: Grade 4 (n=11)	0 (0.0 to 28.5)			
New or worsened muscle pain: Any (n=11)	0 (0.0 to 28.5)			
New or worsened muscle pain: Mild (n=11)	0 (0.0 to 28.5)			
New or worsened muscle pain: Moderate (n=11)	0 (0.0 to 28.5)			
New or worsened muscle pain: Severe (n=11)	0 (0.0 to 28.5)			
New or worsened muscle pain: Grade 4 (n=11)	0 (0.0 to 28.5)			
New or worsened joint pain: Any (n=11)	0 (0.0 to 28.5)			
New or worsened joint pain: Mild (n=11)	0 (0.0 to 28.5)			
New or worsened joint pain: Moderate (n=11)	0 (0.0 to 28.5)			
New or worsened joint pain: Severe (n=11)	0 (0.0 to 28.5)			
New or worsened joint pain: Grade 4 (n=11)	0 (0.0 to 28.5)			

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants Reporting SAEs From the First Study Vaccination to 6 Months After Last Study Vaccination in Participants Aged >=2 to <5 Years

End point title	SSB: Percentage of Participants Reporting SAEs From the First Study Vaccination to 6 Months After Last Study Vaccination in Participants Aged >=2 to <5 Years[12]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect;

was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation. Safety population included all participants who received at least 1 dose of the study intervention.N= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From first study vaccination on Day 1 up to 6 months after last study vaccination

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1b: 2 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	218	989	
Units: Percentage of participants				
number (not applicable)	0	0	0.4	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants Reporting AEs From the First Study Vaccination to 1 Month After Study Vaccination 1 in Participants Aged >=2 to <5 Years

End point title	SSB: Percentage of Participants Reporting AEs From the First Study Vaccination to 1 Month After Study Vaccination 1 in Participants Aged >=2 to <5 Years[13]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs within 1 month after study vaccination were reported in this endpoint.Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 1 month after study vaccination 1 (i.e. third dose for Group 1b and fourth dose for Groups 2b and 3b)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1b: 2 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	218	989	
Units: Percentage of participants				
number (not applicable)	0	4.6	6.6	

Statistical analyses

No statistical analyses for this end point

Primary: SSB: Percentage of Participants Reporting AEs From the Second Study Vaccination to 1 Month After Study Vaccination 2 in Participants Aged >=2 to <5 Years: Group 1b Only

End point title	SSB: Percentage of Participants Reporting AEs From the Second Study Vaccination to 1 Month After Study Vaccination 2 in Participants Aged >=2 to <5 Years: Group 1b Only[14]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs within 1 month after study vaccination were reported in this endpoint. Exact 2-sided CI was calculated using the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.N=participants evaluable for this endpoint.This endpoint is reported for Group 1b only as only participants from Group 1b received two vaccinations in the study.

End point type	Primary

End point timeframe:

From study vaccination 2 up to 1 month after study vaccination 2

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSB: Group 1b: 2 prior doses of BNT162b2			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of participants				
number (confidence interval 95%)	8.3 (0.2 to 38.5)			

Statistical analyses

No statistical analyses for this end point

Primary: SSB: GMR Based on Geometric Mean Titers of Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV2) Omicron (BA.4/BA.5)–Neutralizing Titers at 1 Month After Dose 4 for Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point title	SSB: GMR Based on Geometric Mean Titers of Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV2) Omicron (BA.4/BA.5)–Neutralizing Titers at 1 Month After Dose 4 for

	Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the least square means and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline log-transformed neutralizing titers,postbaseline infection status& vaccine group as covariates.Assay results below the LLOQ were set to 0.5*LLOQ.Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned,had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination,had no other important protocol deviations as determined by clinician.Results are presented for per-protocol subset which included random sample of 240 participants selected from the full group &comprised the same percentages of participants in each age group and baseline SARS-CoV-2 infection status group as the full group.'N'=participants evaluable.

End point type	Primary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years	SSB Historical cohort: C4591007 BNT162b2 3 mcg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	62	161	71	167
Units: Titers				
geometric mean (confidence interval 95%)	1664.4 (1339.3 to 2068.3)	1920.7 (1661.9 to 2219.8)	1031.3 (842.0 to 1263.3)	901.8 (782.4 to 1039.5)

Statistical analyses

Statistical analysis title	Geometric Mean Ratio

Statistical analysis description:

GMRs and 2-sided CIs were calculated by exponentiating the difference of LSMeans for the assay and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline log-transformed neutralizing titers, postbaseline infection status, age group and vaccine group as covariates.

Comparison groups	SSB: Group 2b: 3 prior doses of BNT162b2 v SSB Historical cohort: C4591007 BNT162b2 3 mcg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Mean Ratio
Point estimate	2.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.73
upper limit	2.62

Statistical analysis title	Geometric Mean Ratio

Statistical analysis description:

GMRs and 2-sided CIs were calculated by exponentiating the difference of LSMeans for the assay and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline log-transformed neutralizing titers, postbaseline infection status, age group and vaccine group as covariates.

Comparison groups	SSB: Group 2a: 3 prior doses of BNT162b2 v SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years
Number of subjects included in analysis	133
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Geometric Mean Ratio
Point estimate	1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	2.18

Primary: SSB: Percentage of Participants With Seroresponse to the Omicron (BA.4/BA.5)–Strain at 1 Month After Dose 4 for Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point title	SSB: Percentage of Participants With Seroresponse to the Omicron (BA.4/BA.5)–Strain at 1 Month After Dose 4 for Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 4 for C4591048 Substudy B Group 2 and before Dose 3 for C4591007). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4*LLOQ was considered a seroresponse. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Percentage of participants achieving seroresponse at 1 month after study vaccination was reported in this endpoint. Evaluable immunogenicity population was analyzed. Results were presented for per-protocol subset which included a random sample of 240 participants selected from the full group and comprised of the same percentage of participants in each age group and baseline SARS-CoV-2 infection status group as the full group.'N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years	SSB Historical cohort: C4591007 BNT162b2 3 mcg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	62	161	71	167
Units: Percentage of participants				

number (confidence interval 95%)	54.8 (41.7 to 67.5)	71.4 (63.8 to 78.3)	42.3 (30.6 to 54.6)	53.9 (46.0 to 61.6)

Statistical analyses

Statistical analysis title	Percentages of Participants With Seroresponse
Statistical analysis description:	
Adjusted difference in proportion based on the Miettinen and Nurminen method stratified by baseline neutralizing titer category (<median, ≥median), expressed as a percentage (bivalent BNT162b2 [original/Omi BA.4/BA.5] 3 mcg - BNT162b2 3 mcg).	
Comparison groups	SSB: Group 2b: 3 prior doses of BNT162b2 v SSB Historical cohort: C4591007 BNT162b2 3 mcg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	non-inferiority[15]
Parameter estimate	Percentage Difference
Point estimate	21.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.59
upper limit	31.15

Notes:

[15] - Noninferiority was established if the lower bound of the 2-sided 95% CI for the difference in percentage was greater than -5%.

Statistical analysis title	Percentages of Participants With Seroresponse
Statistical analysis description:	
Adjusted difference in proportion based on the Miettinen and Nurminen method stratified by baseline neutralizing titer category (<median, ≥median), expressed as a percentage (bivalent BNT162b2 [original/Omi BA.4/BA.5] 3 mcg - BNT162b2 3 mcg).	
Comparison groups	SSB: Group 2a: 3 prior doses of BNT162b2 v SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years
Number of subjects included in analysis	133
Analysis specification	Pre-specified
Analysis type	non-inferiority[16]
Parameter estimate	Percentage Difference
Point estimate	16.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	31.67

Notes:

[16] - Noninferiority was established if the lower bound of the 2-sided 95% CI for the difference in percentage was greater than -5%.

Primary: SSC: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination in Participants Aged >=6 Months to <2 Years

End point title	SSC: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination in Participants Aged >=6 Months to <2 Years[17]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after study vaccination. Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe(>7.0 cm) and G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate (hurts if gently touched with crying), severe (causes limitation of limb movement) & G4 ER visit or hospitalisation. G4 were classified by investigator or medically qualified person. Percentage of participants with local reactions within 7 days after study vaccination and associated 2-sided 95% CI based on Clopper and Pearson method is reported. Safety population=all participants receiving at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	19		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	23.5 (6.8 to 49.9)	21.1 (6.1 to 45.6)		
Redness: Mild	17.6 (3.8 to 43.4)	21.1 (6.1 to 45.6)		
Redness: Moderate	5.9 (0.1 to 28.7)	0 (0.0 to 17.6)		
Redness: Severe	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Redness: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Swelling: Any	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Swelling: Mild	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Swelling: Moderate	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Swelling: Severe	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Swelling: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Tenderness at the injection site: Any	5.9 (0.1 to 28.7)	15.8 (3.4 to 39.6)		
Tenderness at the injection site: Mild	5.9 (0.1 to 28.7)	15.8 (3.4 to 39.6)		
Tenderness at the injection site: Moderate	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Tenderness at the injection site: Severe	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Tenderness at the injection site: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 17.6)		

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination in Participants Aged >=6 Months to <2 Years

End point title	SSC: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination in Participants Aged >=6 Months to <2 Years[18]

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after study vaccination.Fever:oral temperature >=38.0 deg C categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C.Decreased appetite:mild(decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed).Drowsiness:mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(disabling;not interested in usual daily activity).G4 for all events except fever:ER visit/hospitalisation& were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population=all participants receiving at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	19		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever:Any	17.6 (3.8 to 43.4)	5.3 (0.1 to 26.0)		
Fever: >=38.0 to 38.4 deg C	11.8 (1.5 to 36.4)	0 (0.0 to 17.6)		
Fever: >38.4 to 38.9 deg C	5.9 (0.1 to 28.7)	5.3 (0.1 to 26.0)		
Fever: >38.9 to 40.0 deg C	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Fever: >40.0 deg C	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Decreased appetite: Any	23.5 (6.8 to 49.9)	15.8 (3.4 to 39.6)		
Decreased appetite: Mild	23.5 (6.8 to 49.9)	15.8 (3.4 to 39.6)		
Decreased appetite: Moderate	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Decreased appetite: Severe	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Decreased appetite: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Drowsiness: Any	29.4 (10.3 to 56.0)	26.3 (9.1 to 51.2)		
Drowsiness: Mild	17.6 (3.8 to 43.4)	21.1 (6.1 to 45.6)		
Drowsiness: Moderate	11.8 (1.5 to 36.4)	5.3 (0.1 to 26.0)		
Drowsiness: Severe	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Drowsiness: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 17.6)		
Irritability: Any	47.1 (23.0 to 72.2)	73.7 (48.8 to 90.9)		
Irritability: Mild	29.4 (10.3 to 56.0)	21.1 (6.1 to 45.6)		
Irritability: Moderate	17.6 (3.8 to 43.4)	52.6 (28.9 to 75.6)		
Irritability: Severe	0 (0.0 to 19.5)	0 (0.0 to 17.6)		

Irritability: Grade 4	0 (0.0 to 19.5)	0 (0.0 to 17.6)		

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination in Participants Aged >=2 to <5 Years

End point title	SSC: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination in Participants Aged >=2 to <5 Years[19]

End point description:

Local reactions recorded by participants/parents/legal guardians in e-diary.Redness & swelling recorded in mdu converted to cm.1 mdu=0.5 cm&graded mild:(>0.5 to 2.0cm),moderate:>2.0 to 7.0cm,severe:>7.0 cm,G4: necrosis/exfoliative dermatitis(redness)&necrosis(swelling).Pain at injection site graded mild:did not interfere with daily activity,moderate:interfered with daily activity, severe: prevented daily activity & G4: ER]visit/hospitalisation.G4 classified by investigator/medically qualified person.Percentage of participants with local reactions within 7days after study vaccination and associated 2-sided 95% CI based on Clopper and Pearson method.Safety population=all participants receiving at least 1 dose of study intervention. Number of subjects analyzed= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	30		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	6.3 (0.8 to 20.8)	3.3 (0.1 to 17.2)		
Redness: Mild	6.3 (0.8 to 20.8)	3.3 (0.1 to 17.2)		
Redness: Moderate	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Redness: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Redness: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Swelling: Any	6.3 (0.8 to 20.8)	0 (0.0 to 11.6)		
Swelling: Mild	6.3 (0.8 to 20.8)	0 (0.0 to 11.6)		
Swelling: Moderate	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Swelling: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Swelling: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Pain at the injection site: Any	31.3 (16.1 to 50.0)	26.7 (12.3 to 45.9)		

Pain at the injection site: Mild	28.1 (13.7 to 46.7)	26.7 (12.3 to 45.9)		
Pain at the injection site: Moderate	3.1 (0.1 to 16.2)	0 (0.0 to 11.6)		
Pain at the injection site: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Pain at the injection site: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentage of Participants Reporting Adverse Events (AEs) Within 1 Month After Study Vaccination in Participants Aged >=6 Months to <2 Years

End point title	SSC: Percentage of Participants Reporting Adverse Events (AEs) Within 1 Month After Study Vaccination in Participants Aged >=6 Months to <2 Years[20]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs within 1 month after study vaccination were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 1 month after study vaccination

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	19		
Units: Percentage of participants				
number (not applicable)	11.8	15.8		

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentage of Participants Reporting Serious Adverse Events (SAEs) Within 6 Months After Study Vaccination in Participants Aged >=6 Months to <2 Years

End point title	SSC: Percentage of Participants Reporting Serious Adverse Events (SAEs) Within 6 Months After Study Vaccination in Participants Aged >=6 Months to <2 Years[21]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-

threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 6 months after study vaccination

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	19		
Units: Percentage of participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination in Participants Aged >=2 to <5 Years

End point title	SSC: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination in Participants Aged >=2 to <5 Years[22]

End point description:

Systemic events recorded by participants/parents/legal guardians in e-diary. Fever: oral temperature >= 38.0 deg C and categorised as >=38.0-38.4 deg C,>38.4-38.9 deg C,>38.9-40.0 deg C & >40.0 deg C.Fatigue,headache,chills,new/worsened muscle pain&new/worsened joint pain:mild:did not interfere with activity,moderate:some interference with activity&severe: prevented daily routine activity.Vomiting:mild: 1-2 times in 24h,moderate:>2 times in 24h,severe:required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h&severe:6 or more loose stools in 24h.Except fever,G4=ER visit/hospitalisation.G4 events classified by investigator/medically qualified person. Exact 95% CI based on Clopper & Pearson method.Safety population=all participants receiving at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	30		
Units: Percentage of participants				

number (confidence interval 95%)				
Fever: Any	25.0 (11.5 to 43.4)	10.0 (2.1 to 26.5)		
Fever:38.0 to 38.4 deg C	6.3 (0.8 to 20.8)	6.7 (0.8 to 22.1)		
Fever: >38.4 to 38.9 deg C	12.5 (3.5 to 29.0)	0 (0.0 to 11.6)		
Fever: >38.9 to 40.0 deg C	6.3 (0.8 to 20.8)	3.3 (0.1 to 17.2)		
Fever: >40.0 deg C	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Fatigue: Any	40.6 (23.7 to 59.4)	36.7 (19.9 to 56.1)		
Fatigue: Mild	12.5 (3.5 to 29.0)	23.3 (9.9 to 42.3)		
Fatigue: Moderate	21.9 (9.3 to 40.0)	13.3 (3.8 to 30.7)		
Fatigue: Severe	6.3 (0.8 to 20.8)	0 (0.0 to 11.6)		
Fatigue: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Headache: Any	12.5 (3.5 to 29.0)	3.3 (0.1 to 17.2)		
Headache: Mild	6.3 (0.8 to 20.8)	3.3 (0.1 to 17.2)		
Headache: Moderate	6.3 (0.8 to 20.8)	0 (0.0 to 11.6)		
Headache: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Headache: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Chills: Any	12.5 (3.5 to 29.0)	3.3 (0.1 to 17.2)		
Chills: Mild	9.4 (2.0 to 25.0)	0 (0.0 to 11.6)		
Chills: Moderate	3.1 (0.1 to 16.2)	3.3 (0.1 to 17.2)		
Chills: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Chills: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Vomiting: Any	9.4 (2.0 to 25.0)	6.7 (0.8 to 22.1)		
Vomiting: Mild	6.3 (0.8 to 20.8)	6.7 (0.8 to 22.1)		
Vomiting: Moderate	3.1 (0.1 to 16.2)	0 (0.0 to 11.6)		
Vomiting: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Vomiting: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Diarrhea: Any	6.3 (0.8 to 20.8)	3.3 (0.1 to 17.2)		
Diarrhea: Mild	3.1 (0.1 to 16.2)	0 (0.0 to 11.6)		
Diarrhea: Moderate	3.1 (0.0 to 10.9)	3.3 (0.1 to 17.2)		
Diarrhea: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
Diarrhea: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
New or worsened muscle pain: Any	9.4 (2.0 to 25.0)	6.7 (0.8 to 22.1)		
New or worsened muscle pain: Mild	6.3 (0.8 to 20.8)	3.3 (0.1 to 17.2)		
New or worsened muscle pain: Moderate	3.1 (0.1 to 16.2)	3.3 (0.1 to 17.2)		
New or worsened muscle pain: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
New or worsened muscle pain: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		

New or worsened joint pain: Any	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
New or worsened joint pain: Mild	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
New or worsened joint pain: Moderate	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
New or worsened joint pain: Severe	0 (0.0 to 10.9)	0 (0.0 to 11.6)		
New or worsened joint pain: Grade 4	0 (0.0 to 10.9)	0 (0.0 to 11.6)		

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentage of Participants Reporting SAEs Within 6 Months After Study Vaccination in Participants Aged >=2 to <5 Years

End point title	SSC: Percentage of Participants Reporting SAEs Within 6 Months After Study Vaccination in Participants Aged >=2 to <5 Years[23]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 6 months after study vaccination

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	30		
Units: Percentage of participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentage of Participants Reporting AEs Within 1 Month After Study Vaccination in Participants Aged >=2 to <5 Years

End point title	SSC: Percentage of Participants Reporting AEs Within 1 Month After Study Vaccination in Participants Aged >=2 to <5 Years[24]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs within 1 month after study vaccination were reported in this endpoint.Only AEs collected by non-systematic assessment (i.e., excluding local

reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 1 month after study vaccination

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	30		
Units: Percentage of participants				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: SSC:Percentages of Participants With Seroresponse to the Omicron (BA.4/BA.5)– Neutralizing Titers at 1 Month After Study Vaccination

End point title	SSC:Percentages of Participants With Seroresponse to the Omicron (BA.4/BA.5)– Neutralizing Titers at 1 Month After Study Vaccination[25]

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before the study vaccination). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4* LLOQ was considered a seroresponse. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse at 1 month after study vaccination was reported in this endpoint. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 Month after study vaccination

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	27	28
Units: Percentage of participants				
number (confidence interval 95%)	55.6 (21.2 to 86.3)	78.6 (49.2 to 95.3)	85.2 (66.3 to 95.8)	92.9 (76.5 to 99.1)

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Geometric Mean Titers of SARSCoV2 Omicron (BA.4/BA.5)–Neutralizing Titers Before Vaccination and 1 Month After Vaccination

End point title	SSC: Geometric Mean Titers of SARSCoV2 Omicron (BA.4/BA.5)–Neutralizing Titers Before Vaccination and 1 Month After Vaccination[26]

End point description:

GMT of SARS-CoV-2 Omicron strain–neutralizing titers before vaccination and 1 month after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

before vaccination and 1 month after study vaccination

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	30	30
Units: Titers				
geometric mean (confidence interval 95%)				
Pre-vaccination (n= 9, 14, 27, 28)	370.6 (62.7 to 2190.9)	225.8 (66.7 to 763.7)	199.3 (102.4 to 387.7)	312.6 (161.5 to 605.0)
1 month after vaccination (n= 11, 14, 30, 30)	3059.7 (767.0 to 12205.5)	2866.8 (772.8 to 10634.9)	3536.4 (2044.2 to 6117.9)	7155.7 (3926.9 to 13039.1)

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers From Study Vaccination to 1 Month After Vaccination

End point title	SSC: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers From Study Vaccination to 1 Month After Vaccination[27]

End point description:

GMFR of SARS-CoV-2 omicron BA.4/BA.5-neutralizing titers at 1 month after study vaccination was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 1 month after study vaccination

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	27	28
Units: Fold rise				
geometric mean (confidence interval 95%)	8.3 (2.5 to 27.3)	12.7 (6.1 to 26.3)	17.4 (11.1 to 27.4)	24.4 (14.9 to 40.0)

Statistical analyses

No statistical analyses for this end point

Primary: SSC:GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers From Study Vaccination to 1 Month After Vaccination

End point title	SSC:GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers From Study Vaccination to 1 Month After Vaccination[28]

End point description:

GMFR of SARS-CoV-2 reference-strain-neutralizing titers before vaccination to 1 month after study vaccination was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5* LLOQ in the analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 Month after study vaccination

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	26	28
Units: Fold rise				
geometric mean (confidence interval 95%)	5.4 (3.1 to 9.6)	8.1 (5.2 to 12.6)	5.7 (3.4 to 9.5)	7.4 (4.9 to 11.2)

Statistical analyses

No statistical analyses for this end point

Primary: SSC:Geometric Mean Titers of SARSCoV2 Reference-Strain-Neutralizing Titers Before Vaccination and 1 Month After Vaccination

End point title	SSC:Geometric Mean Titers of SARSCoV2 Reference-Strain-Neutralizing Titers Before Vaccination and 1 Month After Vaccination[29]

End point description:

GMT of SARS-CoV-2 reference-strain-neutralizing titers before vaccination to 1 month after study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers & the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Before study vaccination and 1 Month after study vaccination

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	30	30
Units: Titers				
geometric mean (confidence interval 95%)				
Before Vaccination (n=9,14,26,28)	1638.1 (690.2 to 3887.9)	1041.5 (641.3 to 1691.5)	1536.5 (952.7 to 2477.9)	2263.8 (1502.2 to 3411.5)
1 Month After Vaccination (n=11, 14, 30, 30)	7698.7 (4384.4 to 13518.6)	8443.8 (5696.8 to 12515.4)	9389.0 (6314.3 to 13961.1)	16541.7 (12265.4 to 22309.0)

Statistical analyses

No statistical analyses for this end point

Primary: SSC: Percentages of Participants With Seroresponse to the SARS-CoV-2 Reference Strain Neutralizing Titers at 1 Month After Study Vaccination

End point title	SSC: Percentages of Participants With Seroresponse to the SARS-CoV-2 Reference Strain Neutralizing Titers at 1 Month After Study Vaccination[30]

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before study vaccination). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4 * LLOQ was considered a seroresponse. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse at 1 month after study vaccination was reported in this endpoint. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. ' N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 Month After Study Vaccination

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2	SSC: Group 2b: 3 prior doses of BNT162b2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	26	28
Units: Percentage of participants				
number (confidence interval 95%)	55.6 (21.2 to 86.3)	85.7 (57.2 to 98.2)	76.9 (56.4 to 91.0)	67.9 (47.6 to 84.1)

Statistical analyses

No statistical analyses for this end point

Primary: SSD: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination

End point title	SSD: Percentage of Participants With Local Reactions Within 7 Days After Study Vaccination[31]

End point description:

Local reactions recorded by participants/parents/legal guardians in electronic diary(e-diary).Redness&swelling recorded in measuring device units(mdu)converted to centimeter(cm).1 mdu=0.5 cm&graded mild:(greater than[>]0.5 to 2.0cm),moderate:>2.0 to 7.0cm,severe:>7.0 cm,Grade 4(G4): necrosis/exfoliative dermatitis(redness)&necrosis(swelling).Pain at injection site graded mild:did not interfere with daily activity,moderate:interfered with daily activity,severe: prevented daily activity&G4:emergency room[ER]visit/hospitalisation.G4 classified by investigator/medically qualified person.Percentage of participants with local reactions within 7days after study vaccination and associated 2-sided 95% confidence interval(CI) based on Clopper and Pearson method.Safety population=all participants receiving at least 1dose of study intervention.Number of Participants Analysed(N)'= participants evaluable.99999=data could not be generated since it was not part of specified analysis in the protocol.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort:Participants from study C4591007 Phase 1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	111	19	
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	0 (-99999 to 99999)	7.2 (3.2 to 13.7)	10.5 (1.3 to 33.1)	
Redness: Mild	0 (-99999 to 99999)	4.5 (1.5 to 10.2)	10.5 (1.3 to 33.1)	
Redness: Moderate	0 (-99999 to 99999)	2.7 (0.6 to 7.7)	0 (0.0 to 17.6)	
Redness: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Redness: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Swelling: Any	0 (-99999 to 99999)	4.5 (1.5 to 10.2)	10.5 (1.3 to 33.1)	
Swelling: Mild	0 (-99999 to 99999)	0.9 (0.0 to 4.9)	10.5 (1.3 to 33.1)	
Swelling: Moderate	0 (-99999 to 99999)	3.6 (1.0 to 9.0)	0 (0.0 to 17.6)	
Swelling: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Swelling: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Pain at the injection site: Any	0 (-99999 to 99999)	64.0 (54.3 to 72.9)	68.4 (43.4 to 87.4)	
Pain at the injection site: Mild	50.0 (-99999 to 99999)	45.0 (35.6 to 54.8)	52.6 (28.9 to 75.6)	
Pain at the injection site: Moderate	0 (-99999 to 99999)	18.9 (12.1 to 27.5)	15.8 (3.4 to 39.6)	
Pain at the injection site: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Pain at the injection site: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	

Statistical analyses

No statistical analyses for this end point

Primary: SSD: Percentage of Participants With Systemic Events Within 7 Days After Study Vaccination

End point title	SSD: Percentage of Participants With Systemic Events Within 7

	Days After Study Vaccination[32]

End point description:

Systemic events recorded by participants/parents/legal guardians in e-diary. Fever: oral temperature >= 38.0 degree Celsius(deg C)&categorised as >=38.0-38.4 deg C,>38.4-38.9 deg C,>38.9-40.0 deg C & >40.0 deg C.Fatigue,headache,chills,new/worsened muscle pain&new/worsened joint pain:mild:did not interfere with activity,moderate:some interference with activity&severe: prevented daily routine activity.Vomiting:mild: 1-2 times in 24hours(h),moderate:>2 times in 24h,severe:required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h&severe:6 or more loose stools in 24h.Except fever,G4=ER visit/hospitalisation.G4 events classified by investigator/medically qualified person. Exact 95% CI based on Clopper & Pearson method.Safety population=all participants receiving at least 1 dose of study intervention.N= participants evaluable for this endpoint.99999=data could not be generated since it was not part of specified analysis in the protocol.

End point type	Primary

End point timeframe:

Day 1 up to Day 7 after study vaccination

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort:Participants from study C4591007 Phase 1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	111	19	
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	0 (-99999 to 99999)	4.5 (1.5 to 10.2)	10.5 (1.3 to 33.1)	
Fever: ≥38.0 to 38.4 deg C	0 (-99999 to 99999)	1.8 (0.2 to 6.4)	0 (0.0 to 17.6)	
Fever: >38.4 to 38.9 deg C	0 (-99999 to 99999)	0.9 (0.0 to 4.9)	5.3 (0.1 to 26.0)	
Fever: >38.9 to 40.0 deg C	0 (-99999 to 99999)	1.8 (0.2 to 6.4)	5.3 (0.1 to 26.0)	
Fever: >40.0 deg C	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Fatigue: Any	0 (-99999 to 99999)	40.5 (31.3 to 50.3)	57.9 (33.5 to 79.7)	
Fatigue: Mild	0 (-99999 to 99999)	23.4 (15.9 to 32.4)	36.8 (16.3 to 61.6)	
Fatigue: Moderate	0 (-99999 to 99999)	16.2 (9.9 to 24.4)	15.8 (3.4 to 39.6)	
Fatigue: Severe	0 (-99999 to 99999)	0.9 (0.0 to 4.9)	5.3 (0.1 to 26.0)	
Fatigue: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Headache: Any	0 (-99999 to 99999)	25.2 (17.5 to 34.4)	36.8 (16.3 to 61.6)	
Headache: Mild	0 (-99999 to 99999)	18.0 (11.4 to 26.4)	26.3 (9.1 to 51.2)	
Headache: Moderate	0 (-99999 to 99999)	6.3 (2.6 to 12.6)	10.5 (1.3 to 33.1)	
Headache: Severe	0 (-99999 to 99999)	0.9 (0.0 to 4.9)	0 (0.0 to 17.6)	
Headache: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	

Chills: Any	0 (-99999 to 99999)	9.0 (4.4 to 15.9)	10.5 (1.3 to 33.1)	
Chills: Mild	0 (-99999 to 99999)	6.3 (2.6 to 12.6)	10.5 (1.3 to 33.1)	
Chills: Moderate	0 (-99999 to 99999)	2.7 (0.6 to 7.7)	0 (0.0 to 17.6)	
Chills: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Chills: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Vomiting: Any	0 (-99999 to 99999)	3.6 (1.0 to 9.0)	0 (0.0 to 17.6)	
Vomiting: Mild	0 (-99999 to 99999)	3.6 (1.0 to 9.0)	0 (0.0 to 17.6)	
Vomiting: Moderate	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Vomiting: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Vomiting: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Diarrhea: Any	0 (-99999 to 99999)	3.6 (1.0 to 9.0)	0 (0.0 to 17.6)	
Diarrhea: Mild	0 (-99999 to 99999)	3.6 (1.0 to 9.0)	0 (0.0 to 17.6)	
Diarrhea: Moderate	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Diarrhea: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
Diarrhea: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
New or worsened muscle pain: Any	0 (-99999 to 99999)	13.5 (7.8 to 21.3)	21.1 (6.1 to 45.6)	
New or worsened muscle pain: Mild	0 (-99999 to 99999)	7.2 (3.2 to 13.7)	10.5 (1.3 to 33.1)	
New or worsened muscle pain: Moderate	0 (-99999 to 99999)	6.3 (2.6 to 12.6)	10.5 (1.3 to 33.1)	
New or worsened muscle pain: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
New or worsened muscle pain: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
New or worsened joint pain: Any	0 (-99999 to 99999)	9.0 (4.4 to 15.9)	10.5 (1.3 to 33.1)	
New or worsened joint pain: Mild	0 (-99999 to 99999)	7.2 (3.2 to 13.7)	5.3 (0.1 to 26.0)	
New or worsened joint pain: Moderate	0 (-99999 to 99999)	1.8 (0.2 to 6.4)	5.3 (0.1 to 26.0)	
New or worsened joint pain: Severe	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	
New or worsened joint pain: Grade 4	0 (-99999 to 99999)	0 (0.0 to 3.3)	0 (0.0 to 17.6)	

Statistical analyses

No statistical analyses for this end point

Primary: SSD: Percentage of Participants Reporting Adverse Events (AEs) 1 Month After Study Vaccination

End point title	SSD: Percentage of Participants Reporting Adverse Events

	(AEs) 1 Month After Study Vaccination[33]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs within 1 month after study vaccination were reported in this endpoint. Exact 2-sided CI was calculated using the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention. 99999= data could not be generated since it was not part of specified analysis in the protocol.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 1 month after study vaccination

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort:Participants from study C4591007 Phase 1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	113	19	
Units: Percentage of participants				
number (confidence interval 95%)	0.0 (-99999 to 99999)	3.5 (1.0 to 8.8)	15.8 (3.4 to 39.6)	

Statistical analyses

No statistical analyses for this end point

Primary: SSD: Percentages of Participants With Seroresponse to the Omicron (BA.4/BA.5)– Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point title	SSD: Percentages of Participants With Seroresponse to the Omicron (BA.4/BA.5)– Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 4 for C4591048 Substudy D Group 2 and before Dose 3 for C4591007). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4 × LLOQ was considered a seroresponse. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Percentage of participants achieving seroresponse at 1 month after study vaccination was reported in this endpoint. Evaluable immunogenicity population was analyzed. Results include those from a comparator group of C4591007 (NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	101	112		
Units: Percentage of participants				
number (confidence interval 95%)	53.5 (43.3 to 63.5)	52.7 (43.0 to 62.2)		

Statistical analyses

Statistical analysis title	Group 2 and Historical cohort from C4591007

Statistical analysis description:

Adjusted difference in proportions based on the Miettinen and Nurminen method stratified by baseline neutralizing titer category (< median, ≥ median), expressed as a percentage (bivalent BNT162b2 [original/Omi BA.4/BA.5] 10 µg - BNT162b2 10 µg). 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions stratified by baseline neutralizing titer category (< median,>= median), expressed as a percentage.

Comparison groups	SSD: Group 2: 3 prior doses of BNT162b2 v SSD Historical cohort: C4591007 BNT162b2 10 µg
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Percentage Difference
Point estimate	8.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.47
upper limit	19.99

Primary: SSD: Percentage of Participants Reporting Serious Adverse Events (SAEs) Within 6 Months After Study Vaccination

End point title	SSD: Percentage of Participants Reporting Serious Adverse Events (SAEs) Within 6 Months After Study Vaccination[34]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 up to 6 months after study vaccination

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort:Participants from study C4591007 Phase 1	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	113	19	
Units: Percentage of participants				
number (not applicable)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: SSD:Geometric Mean Ratio(GMR)Based on Geometric Mean Titers of Severe Acute Respiratory Syndrome Coronavirus 2(SARSCoV2)Omicron(BA.4/BA.5)-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants(1 Month After Dose 3)

End point title	SSD:Geometric Mean Ratio(GMR)Based on Geometric Mean Titers of Severe Acute Respiratory Syndrome Coronavirus 2(SARSCoV2)Omicron(BA.4/BA.5)-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants(1 Month After Dose 3)

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the least square means and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline log-transformed neutralizing titers, postbaseline infection status, and vaccine group as covariates. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Results include those from a comparator group of C4591007 (NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	101	112		
Units: Titers				
geometric mean (confidence interval 95%)	1836.1 (1593.8 to	1632.5 (1427.5 to		

2115.2)	1867.0)

Statistical analyses

Statistical analysis title	Group 2 and Historical cohort from C4591007

Statistical analysis description:

GMRs and 2-sided CIs were calculated by exponentiating the difference of LSMeans for the assay and the corresponding CIs based on a linear regression model with baseline log-transformed neutralizing titers, postbaseline infection status, and vaccine group as covariates.

Comparison groups	SSD: Group 2: 3 prior doses of BNT162b2 v SSD Historical cohort: C4591007 BNT162b2 10 µg
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric Mean Ratio
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.37

Secondary: SSB: GMR Based on Geometric Mean Titers of SARSCoV2 Reference-Strain-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point title	SSB: GMR Based on Geometric Mean Titers of SARSCoV2 Reference-Strain-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the least square means & the corresponding CIs based on analysis of log-transformed assay results using linear regression model with baseline log-transformed neutralizing titers,postbaseline infection status&vaccine group as covariates.Assay results below the LLOQ were set to 0.5*LLOQ.Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned,had atleast one valid&determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.Results are presented for per-protocol subset which included a random sample of 240 participants selected from the full group and comprised the same percentages of participants in each age group & baseline SARS-CoV-2 infection status group as full group.'N'=participants evaluable.

End point type	Secondary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years	SSB Historical cohort: C4591007 BNT162b2 3 mcg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	62	161	72	166
Units: Titers				
geometric mean (confidence interval 95%)	5965.4 (4958.5 to 7176.8)	6921.5 (6160.2 to 7777.0)	7108.9 (5989.2 to 8438.0)	7384.8 (6584.6 to 8282.3)

Statistical analyses

Statistical analysis title	Geometric Mean Ratio

Statistical analysis description:

GMRs and 2-sided CIs were calculated by exponentiating the difference of LSMeans for the assay and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline log-transformed neutralizing titers, postbaseline infection status, age group and vaccine group as covariates.

Comparison groups	SSB: Group 2b: 3 prior doses of BNT162b2 v SSB Historical cohort: C4591007 BNT162b2 3 mcg
Number of subjects included in analysis	327
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Geometric Mean Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.11

Statistical analysis title	Geometric Mean Ratio

Statistical analysis description:

GMRs and 2-sided CIs were calculated by exponentiating the difference of LSMeans for the assay and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline log-transformed neutralizing titers, postbaseline infection status, age group and vaccine group as covariates.

Comparison groups	SSB: Group 2a: 3 prior doses of BNT162b2 v SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Geometric Mean Ratio
Point estimate	0.84

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.08

Secondary: SSB: Percentage of Participants With Seroresponse to the SARSCoV2 Reference-Strain-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point title	SSB: Percentage of Participants With Seroresponse to the SARSCoV2 Reference-Strain-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and at 1 Month After Dose 3 for C4591007 Phase 2/3 Participants

End point description:

Seroresponse was defined as achieving>= 4-fold rise from baseline(before Dose 4 for C4591048 Substudy B Group 2 and before Dose 3 for C4591007).If the baseline measurement was below LLOQ,the postvaccination assay result of>= 4*LLOQ was considered a seroresponse.Exact 2-sided 95% CI was based on Clopper and Pearson method.Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned,had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.Results were presented for per-protocol subset which included a random sample of 240 participants selected from the full group and comprised of the same percentage of participants in each age group and baseline SARS-CoV-2 infection status group as the full group.'N'=participants evaluable.

End point type	Secondary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2	SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years	SSB Historical cohort: C4591007 BNT162b2 3 mcg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	62	161	72	166
Units: Percentage of participants				
number (confidence interval 95%)	40.3 (28.1 to 53.6)	52.8 (44.8 to 60.7)	44.4 (32.7 to 56.6)	65.7 (57.9 to 72.8)

Statistical analyses

Statistical analysis title	Percentages of Participants With Seroresponse

Statistical analysis description:

Adjusted difference in proportion based on the Miettinen and Nurminen method stratified by baseline neutralizing titer category (<median, ≥median), expressed as a percentage (bivalent BNT162b2 [original/Omi BA.4/BA.5] 3 mcg - BNT162b2 3 mcg).

Comparison groups	SSB: Group 2a: 3 prior doses of BNT162b2 v SSB Historical cohort:C4591007 BNT162b2 >=6 months to<2 years

Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	non-inferiority[35]
Parameter estimate	Percentage Difference
Point estimate	5.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.43
upper limit	18.77

Notes:

[35] - Noninferiority was established if the lower bound of the 2-sided 95% CI for the difference in percentage was greater than -10%.

Secondary: SSB: GMT of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at Dose 4 and 1 Month After Dose 4

End point title	SSB: GMT of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at Dose 4 and 1 Month After Dose 4

End point description:

GMT of SARS-CoV-2 Omicron strain–neutralizing titers at 1 month after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ. Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned, had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Group 2: At Dose 4 and 1 month after Dose 4

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	196		
Units: Titers				
geometric mean (confidence interval 95%)				
At dose 4 (n=74, 192)	293.9 (195.4 to 441.9)	224.1 (177.2 to 283.5)		
1 month after Dose 4 (n=78, 196)	1905.1 (1328.9 to 2731.2)	2384.9 (1965.4 to 2893.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMT of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at Dose 3 and 1 Month After Dose 3: Group 1 Only

End point title	SSB: GMT of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at Dose 3 and 1 Month After Dose 3: Group 1 Only

End point description:

GMT of SARS-CoV-2 omicron BA.4/BA.5-neutralizing titers at dose 3 and 1 month after dose 3 was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ. Evaluable immunogenicity population (third dose) included all eligible participants who received first study intervention as third dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the third dose, and had no other important protocol deviations as determined by the clinician.Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint. ‘n’= Participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

At dose 3 and 1 month after dose 3

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	10		
Units: Titer				
geometric mean (confidence interval 95%)				
Dose 3 (n= 14, 10)	142.5 (45.6 to 444.9)	323.2 (83.7 to 1248.8)		
1 month after dose 3 (n=13, 10)	1548.9 (408.0 to 5879.6)	2699.9 (580.8 to 12551.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMT of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4: Group 1 Only

End point title	SSB: GMT of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4: Group 1 Only

End point description:

GMT of SARS-CoV-2 Omicron BA.4/BA.5–neutralizing titers at 1 month after dose 4 was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ. Evaluable immunogenicity population (fourth dose) included all eligible participants who received 2 doses of the study intervention as third and fourth dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At 1 month after dose 4

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	9		
Units: Titer				
geometric mean (confidence interval 95%)	2800.0 (1260.5 to 6219.8)	4128.5 (1158.9 to 14708.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMT of SARS-CoV-2 Reference-Strain–Neutralizing Titers at Dose 3 and 1 Month After Dose 3: Group 1 Only

End point title	SSB: GMT of SARS-CoV-2 Reference-Strain–Neutralizing Titers at Dose 3 and 1 Month After Dose 3: Group 1 Only

End point description:

GMT of SARS-CoV-2 reference strain–neutralizing titers at dose 3 and 1 month after dose 3 was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ. Evaluable immunogenicity population (third dose) included all eligible participants who received first study intervention as third dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the third dose, and had no other important protocol deviations as determined by the clinician.Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint. ‘n’= Participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

At dose 3 and 1 month After dose 3

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	10		
Units: Titer				
geometric mean (confidence interval 95%)				
Dose 3 (n= 14, 10)	271.7 (114.6 to 644.3)	636.6 (262.7 to 1542.5)		
1 month after dose 3 (n= 13, 10)	3536.4 (2024.4 to 6177.6)	2576.5 (1204.5 to 5511.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMT of SARS-CoV-2 Reference-Strain–Neutralizing Titers at Dose 4 and 1 Month After Dose 4

End point title	SSB: GMT of SARS-CoV-2 Reference-Strain–Neutralizing Titers at Dose 4 and 1 Month After Dose 4

End point description:

GMT of SARS-CoV-2 reference-strain-neutralizing titers before vaccination to 1 month after study vaccination was reported in this endpoint.GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers & the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5* LLOQ.Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned, had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (at dose 4) and 1 Month after Dose 4

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	196		
Units: Titers				
geometric mean (confidence interval 95%)				
Pre-vaccination (n=74, 192)	1688.3 (1271.6 to 2241.6)	1734.9 (1466.0 to 2053.3)		
1 month after Dose 4 (n= 78,196)	6312.0 (5143.6 to 7746.0)	7897.3 (6952.0 to 8971.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMT of SARS-CoV-2 Reference-Strain–Neutralizing Titers at 1 Month After Dose 4: Group 1 Only

End point title	SSB: GMT of SARS-CoV-2 Reference-Strain–Neutralizing Titers

	at 1 Month After Dose 4: Group 1 Only

End point description:

GMT of SARS-CoV-2 reference strain–neutralizing titers at 1 month after dose 4 was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ. Evaluable immunogenicity population (fourth dose) included all eligible participants who received 2 doses of the study intervention as third and fourth dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At 1 month after dose 4

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	9		
Units: Titer				
geometric mean (confidence interval 95%)	2357.1 (1485.0 to 3741.3)	2468.2 (1188.8 to 5124.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers From Dose 4 to 1 Month after Dose 4

End point title	SSB: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers From Dose 4 to 1 Month after Dose 4

End point description:

GMFR of SARS-CoV-2 omicron BA.4/BA.5-neutralizing titers from dose 4 to 1 month after dose 4 was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned, had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From dose 4 to 1 month after dose 4

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	192		
Units: Fold rise				
geometric mean (confidence interval 95%)	6.7 (5.1 to 8.8)	10.5 (8.9 to 12.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers From Dose 4 to 1 Month after Dose 4

End point title	SSB: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers From Dose 4 to 1 Month after Dose 4

End point description:

GMFR of SARS-CoV-2 reference-strain-neutralizing titers before vaccination from dose 4 to 1 month after dose 4 was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ in the analysis. Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned, had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From dose 4 to 1 month after dose 4

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	192		
Units: Fold rise				
geometric mean (confidence interval 95%)	3.7 (2.9 to 4.7)	4.5 (3.9 to 5.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMFR of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers From Dose 3 to 1 Month After Dose 3: Group 1 Only

End point title	SSB: GMFR of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing

	Titers From Dose 3 to 1 Month After Dose 3: Group 1 Only

End point description:

GMFR of SARS-CoV-2 omicron BA.4/BA.5-neutralizing titers from dose 3 to 1 month after dose 3 was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population (third dose) included all eligible participants who received first study intervention as third dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the third dose, and had no other important protocol deviations as determined by the clinician.Participants with or without evidence of prior infection were included in the analysis.
'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From dose 3 to 1 month after dose 3

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: Fold rise				
geometric mean (confidence interval 95%)	9.1 (3.6 to 22.8)	8.4 (3.8 to 18.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers From Dose 3 to 1 Month After Dose 3: Group 1 Only

End point title	SSB: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers From Dose 3 to 1 Month After Dose 3: Group 1 Only

End point description:

GMFR of SARS-CoV-2 reference strain-neutralizing titers from dose 3 to 1 month after dose 3 was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population (third dose) included all eligible participants who received first study intervention as third dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the third dose, and had no other important protocol deviations as determined by the clinician.Participants with or without evidence of prior infection were included in the analysis.
'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From dose 3 to 1 month after dose 3

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: Fold rise				
geometric mean (confidence interval 95%)	12.6 (4.9 to 32.1)	4.0 (2.2 to 7.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMFR of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers From Dose 3 to 1 Month After Dose 4: Group 1 Only

End point title	SSB: GMFR of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers From Dose 3 to 1 Month After Dose 4: Group 1 Only

End point description:

GMFR of SARS-CoV-2 omicron BA.4/BA.5-neutralizing titers at dose 3 to 1 month After dose 4 was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population (fourth dose) included all eligible participants who received 2 doses of the study intervention as third and fourth dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From dose 3 to 1 month after dose 4

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	9		
Units: Fold rise				
geometric mean (confidence interval 95%)	14.9 (7.4 to 30.0)	17.2 (7.6 to 39.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: Percentage of Participants With Seroresponse to Reference-Strain-Neutralizing Titers at 1 Month After Dose 4

End point title	SSB: Percentage of Participants With Seroresponse to

	Reference-Strain-Neutralizing Titers at 1 Month After Dose 4

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 4 for C4591048 Substudy B Group 2). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4* LLOQ was considered a seroresponse. Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned, had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse to reference-strain-neutralizing titers at 1 month after dose 4 was reported in this endpoint. Participants with or without evidence of prior infection were included in the analysis.' N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

1 Month after Dose 4

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	192		
Units: Percentage of participants				
number (confidence interval 95%)	43.2 (31.8 to 55.3)	52.1 (44.8 to 59.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: Percentage of Participants With Seroresponse to Reference-Strain-Neutralizing Titers at 1 Month After Dose 4: Group 1 Only

End point title	SSB: Percentage of Participants With Seroresponse to Reference-Strain-Neutralizing Titers at 1 Month After Dose 4: Group 1 Only

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 3). If the baseline measurement was below the LLOQ, the postvaccination assay result of >= 4*LLOQ was considered a seroresponse. Evaluable immunogenicity population (fourth dose) included all eligible participants who received 2 doses of the study intervention as third and fourth dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse to reference-strain-neutralizing titers at 1 month after dose 4 was reported in this endpoint. Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At 1 month after dose 4

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	9		
Units: Percentage of participants				
number (confidence interval 95%)	64.3 (35.1 to 87.2)	77.8 (40.0 to 97.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: Percentage of Participants With Seroresponse to Reference-Strain-Neutralizing Titers at 1 Month After Dose 3: Group 1 Only

End point title	SSB: Percentage of Participants With Seroresponse to Reference-Strain-Neutralizing Titers at 1 Month After Dose 3: Group 1 Only

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 3). If the baseline measurement was below the LLOQ, the postvaccination assay result of >= 4*LLOQ was considered a seroresponse.Evaluable immunogenicity population (third dose) included all eligible participants who received first study intervention as third dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the third dose, and had no other important protocol deviations as determined by the clinician. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse to reference-strain-neutralizing titers at 1 month after dose 3 was reported in this endpoint.

End point type	Secondary

End point timeframe:

1 month after dose 3

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: Percentage of participants				
number (confidence interval 95%)	81.8 (48.2 to 97.7)	50.0 (18.7 to 81.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4

End point title	SSB: Percentage of Participants With Seroresponse to SARS-

	CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 4 for C4591048 Substudy D Group 2). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4* LLOQ was considered a seroresponse. Evaluable immunogenicity population included all eligible participants who received the study intervention to which they were assigned, had atleast one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse to SARS-CoV-2 omicron BA.4/BA.5–neutralizing titers at 1 month after dose 4 was reported in this endpoint. Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

1 Month after Dose 4

End point values	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 2b: 3 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	192		
Units: Percentage of participants				
number (confidence interval 95%)	56.8 (44.7 to 68.2)	74.5 (67.7 to 80.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers At 1 Month After Dose 4: Group 1 Only

End point title	SSB: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers At 1 Month After Dose 4: Group 1 Only

End point description:

GMFR of SARS-CoV-2 reference strain-neutralizing titers at 1 month after dose 4 was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population included all eligible participants who received 2 doses of the study intervention as third and fourth dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At 1 month after dose 4

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	9		
Units: Fold rise				
geometric mean (confidence interval 95%)	8.8 (4.5 to 17.0)	4.6 (2.4 to 8.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 3: Group 1 Only

End point title	SSB: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 3: Group 1 Only

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 3). If the baseline measurement was below the LLOQ, the postvaccination assay result of >= 4*LLOQ was considered a seroresponse. Evaluable immunogenicity population (third dose) included all eligible participants who received first study intervention as third dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the third dose, and had no other important protocol deviations as determined by the clinician. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse to SARS-CoV-2 omicron BA.4/BA.5–neutralizing titers at 1 month after dose 3 was reported in this endpoint. Participants with or without evidence of prior infection were included in the analysis. 'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

1 month after dose 3

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: Percentage of participants				
number (confidence interval 95%)	45.5 (16.7 to 76.6)	70.0 (34.8 to 93.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSB: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4: Group 1 Only

End point title	SSB: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4: Group 1 Only

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 3). If the baseline measurement was below the LLOQ, the postvaccination assay result of >= 4*LLOQ was considered a seroresponse. Evaluable immunogenicity population (fourth dose) included all eligible participants who received 2 doses of the study intervention as third and fourth dose to which they were assigned, had at least one valid and determinate immunogenicity result from the blood sample collected within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse to SARS-CoV-2 omicron BA.4/BA.5–neutralizing titers at 1 month after dose 3 and 1 month after dose 4 was reported in this endpoint. Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At 1 month after dose 4

End point values	SSB: Group 1a: 2 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	9		
Units: Percentage of participants				
number (confidence interval 95%)	78.6 (49.2 to 95.3)	88.9 (51.8 to 99.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSD: Geometric Mean Titers (GMT) of SARS-CoV-2 Reference-Strain–Neutralizing Titers at Baseline and 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point title	SSD: Geometric Mean Titers (GMT) of SARS-CoV-2 Reference-Strain–Neutralizing Titers at Baseline and 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point description:

GMT of SARS-CoV-2 reference-strain-neutralizing titers before vaccination to 1 month after study vaccination was reported in this endpoint.GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers & the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5 × LLOQ.Evaluable immunogenicity population was analyzed. Results include those from a comparator group of C4591007(NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Group 2: Baseline and 1 month after Dose 4; C4591007 control arm: Baseline and 1 month after Dose 3

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	102	113		
Units: Titers				
geometric mean (confidence interval 95%)				
Baseline	2904.0 (2372.6 to 3554.5)	1323.1 (1055.7 to 1658.2)		
1 Month	8245.9 (7108.9 to 9564.9)	7235.1 (6331.5 to 8267.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSD: Geometric Mean Titers (GMT) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at Baseline and 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point title	SSD: Geometric Mean Titers (GMT) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at Baseline and 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point description:

GMT of SARS-CoV-2 Omicron strain–neutralizing titers at 1 month after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ. Evaluable immunogenicity population was analyzed. Results include those from a comparator group of C4591007 (NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Group 2: Baseline and 1 month after Dose 4; C4591007 control arm: Baseline and 1 month after Dose 3

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	102	113		
Units: Titers				

geometric mean (confidence interval 95%)				
Baseline (n=102,112)	488.3 (361.9 to 658.8)	248.3 (187.2 to 329.5)		
1 Month (n=102,113)	2189.9 (1742.8 to 2751.7)	1393.6 (1175.8 to 1651.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSD: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point title	SSD: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point description:

GMFR of SARS-CoV-2 omicron BA.4/BA.5-neutralizing titers at 1 month after study vaccination was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis. Evaluable immunogenicity population was analyzed. Results include those from a comparator group of C4591007 (NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	101	112		
Units: Fold rise				
geometric mean (confidence interval 95%)	4.5 (3.8 to 5.4)	5.6 (4.5 to 6.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSD: Percentages of Participants With Seroresponse to SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point title	SSD: Percentages of Participants With Seroresponse to SARS-CoV-2 Omicron BA.4/BA.5–Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 4 for C4591048 Substudy D Group 2 and before Dose 3 for C4591007). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4 ×* LLOQ was considered a seroresponse. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse at 1 month after study vaccination was reported in this endpoint. Evaluable immunogenicity population was analyzed. Results include those from a comparator group of C4591007 (NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	101	112		
Units: Percentage of participants				
number (confidence interval 95%)	53.5 (43.3 to 63.5)	52.7 (43.0 to 62.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSD: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point title	SSD: GMFR of SARS-CoV-2 Reference-Strain–Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point description:

GMFR of SARS-CoV-2 reference-strain-neutralizing titers before vaccination to 1 month after study vaccination was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.Evaluable immunogenicity population was analyzed. Results include those from a comparator group of C4591007 (NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	101	113		
Units: Fold rise				
geometric mean (confidence interval 95%)	2.8 (2.5 to 3.3)	5.5 (4.5 to 6.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: SSD: Percentages of Participants With Seroresponse to Reference-Strain-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point title	SSD: Percentages of Participants With Seroresponse to Reference-Strain-Neutralizing Titers at 1 Month After Dose 4 for Group 2 and C4591007 Phase 2/3 Participants (1 Month After Dose 3)

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before Dose 4 for C4591048 Substudy D Group 2 and before Dose 3 for C4591007). If the baseline measurement was below the lower limit of quantification (LLOQ), the postvaccination assay result of >= 4 ×* LLOQ was considered a seroresponse. Exact 2-sided 95% CI, based on the Clopper and Pearson method. Percentage of participants achieving seroresponse at 1 month after study vaccination was reported in this endpoint.Results include those from a comparator group of C4591007 (NCT04816643) Phase 2/3 participants of the same age who received 3 doses of original BNT162b2 10 µg as of the data cutoff date of 27 May 2022.Participants with or without evidence of prior infection were included in the analysis.' N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

1 month after Dose 4 for Group 2 and 1 month after Dose 3 for C4591007 control arm

End point values	SSD: Group 2: 3 prior doses of BNT162b2	SSD Historical cohort: C4591007 BNT162b2 10 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	101	113		
Units: Percentage of participants				
number (confidence interval 95%)	30.7 (21.9 to 40.7)	54.9 (45.2 to 64.2)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Local reactions/systemic events(systematic assessment):up to Day 7 after vaccination.Non-SAEs (non-systematic assessment):From Day 1 up to 1 month after study vaccination.For SAE (non-systematic assessment)from Day 1 to 6 months after study vaccination.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	SSD: Group 1: 2 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to 11 years who had received two prior doses of BNT162b2 10 microgram (mcg) 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 2: 3 prior doses of BNT162b2

Reporting group description:

Participants aged 5 to 11 years who had received three prior doses of BNT162b2 10 mcg 90 to 240 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 1b: 2 prior doses of BNT162b2 (Second Vaccination)

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 1a: 2 prior doses of BNT162b2 (Second Vaccination)

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 1b: 2 prior doses of BNT162b2 (First Vaccination)

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSD: Group 3: Participants from study C4591007 Phase 1

Reporting group description:

Participants from C4591007 phase 1 trial, aged 5 to 11 years who had received three prior doses of BNT162b2 10 mcg at least 90 days before enrollment in the study were included. Participants received a single dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 1b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 6 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSC: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single (fourth) dose of BNT162b2 10 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 1a: 2 prior doses of BNT162b2 (First Vaccination)

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3a: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=6 months to <2 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 2b: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=2 to <5 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 2a: 3 prior doses of BNT162b2

Reporting group description:

Participants aged >=6 months to <2 years who had received three prior doses of BNT162b2 10 mcg with the last dose received 60 to 240 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Reporting group title	SSB: Group 3b: 3 prior doses of BNT162b2

Reporting group description:

Participants from C4591007 (NCT04816643) phase 1 trial, aged >=2 to <5 years who had received three prior doses of BNT162b2 3 mcg with the last dose received at least 60 days before enrollment in the study were included. Participants received a single dose (fourth) of BNT162b2 3 mcg via intramuscular route on Day 1 of the study.

Serious adverse events	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2 (Second Vaccination)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Hypothermia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breathing-related sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SSB: Group 1a: 2 prior doses of BNT162b2 (Second Vaccination)	SSB: Group 1b: 2 prior doses of BNT162b2 (First Vaccination)	SSD: Group 3: Participants from study C4591007 Phase 1
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			

subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Hypothermia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breathing-related sleep disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			

subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Hypothermia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breathing-related sleep disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mental status changes			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SSC: Group 2b: 3 prior doses of BNT162b2	SSB: Group 1a: 2 prior doses of BNT162b2 (First Vaccination)	SSB: Group 3a: 3 prior doses of BNT162b2
Total subjects affected by serious adverse events			

subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Hypothermia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Breathing-related sleep disorder			

subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 218 (0.46%)	0 / 92 (0.00%)	11 / 989 (1.11%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Hypothermia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	2 / 989 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Breathing-related sleep disorder			
subjects affected / exposed	1 / 218 (0.46%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	SSD: Group 1: 2 prior doses of BNT162b2	SSD: Group 2: 3 prior doses of BNT162b2	SSB: Group 1b: 2 prior doses of BNT162b2 (Second Vaccination)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	88 / 113 (77.88%)	5 / 13 (38.46%)
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	28 / 113 (24.78%)	0 / 13 (0.00%)
occurrences (all)	0	28	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	45 / 113 (39.82%)	3 / 13 (23.08%)
occurrences (all)	0	45	3
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	10 / 113 (8.85%)	0 / 13 (0.00%)
occurrences (all)	0	10	0
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	5 / 113 (4.42%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 2 (50.00%)	71 / 113 (62.83%)	1 / 13 (7.69%)
occurrences (all)	1	71	1
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	8 / 113 (7.08%)	0 / 13 (0.00%)
occurrences (all)	0	8	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	5 / 113 (4.42%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
Injection site haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injection site pain (TENDERNESS)			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	4 / 113 (3.54%)	1 / 13 (7.69%)
occurrences (all)	0	4	1
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	4 / 113 (3.54%)	1 / 13 (7.69%)
occurrences (all)	0	4	1
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	15 / 113 (13.27%)	0 / 13 (0.00%)
occurrences (all)	0	15	0
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	10 / 113 (8.85%)	0 / 13 (0.00%)
occurrences (all)	0	10	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infections			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 113 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	SSB: Group 1a: 2 prior doses of BNT162b2 (Second Vaccination)	SSB: Group 1b: 2 prior doses of BNT162b2 (First Vaccination)	SSD: Group 3: Participants from study C4591007 Phase 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 17 (64.71%)	7 / 13 (53.85%)	16 / 19 (84.21%)
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	1 / 13 (7.69%)	7 / 19 (36.84%)
occurrences (all)	0	1	7
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 17 (11.76%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Somnolence			
subjects affected / exposed	1 / 17 (5.88%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	4 / 13 (30.77%)	11 / 19 (57.89%)
occurrences (all)	0	4	11
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 17 (5.88%)	1 / 13 (7.69%)	2 / 19 (10.53%)
occurrences (all)	1	1	2
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	4 / 13 (30.77%)	13 / 19 (68.42%)
occurrences (all)	0	4	13
Injection site erythema (REDNESS)			

alternative assessment type: Systematic			
subjects affected / exposed	2 / 17 (11.76%)	1 / 13 (7.69%)	2 / 19 (10.53%)
occurrences (all)	2	1	2
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 17 (11.76%)	0 / 13 (0.00%)	2 / 19 (10.53%)
occurrences (all)	2	0	2
Injection site haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site pain (TENDERNESS)			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 17 (0.00%)	1 / 13 (7.69%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 17 (52.94%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	9	0	0

Musculoskeletal and connective tissue disorders			
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	4 / 19 (21.05%)
occurrences (all)	0	0	4
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	1 / 17 (5.88%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Upper respiratory tract infections			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 17 (17.65%)	0 / 13 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0

Non-serious adverse events	SSC: Group 1a: 3 prior doses of BNT162b2	SSC: Group 1b: 3 prior doses of BNT162b2	SSC: Group 2a: 3 prior doses of BNT162b2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 17 (76.47%)	17 / 19 (89.47%)	24 / 32 (75.00%)
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 17 (0.00%)	1 / 19 (5.26%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	4
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 17 (29.41%)	5 / 19 (26.32%)	0 / 32 (0.00%)
occurrences (all)	5	5	0
Somnolence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	13 / 32 (40.63%)
occurrences (all)	0	0	13
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	4
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 17 (5.88%)	3 / 19 (15.79%)	10 / 32 (31.25%)
occurrences (all)	1	3	10
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 17 (23.53%)	4 / 19 (21.05%)	2 / 32 (6.25%)
occurrences (all)	4	4	2
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 17 (17.65%)	1 / 19 (5.26%)	8 / 32 (25.00%)
occurrences (all)	3	1	8
Injection site haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 19 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Injection site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injection site pain (TENDERNESS)			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	1 / 19 (5.26%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			

subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 17 (0.00%)	1 / 19 (5.26%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 17 (47.06%)	14 / 19 (73.68%)	0 / 32 (0.00%)
occurrences (all)	8	14	0
Musculoskeletal and connective tissue disorders			
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infections			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	1 / 17 (5.88%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 19 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 17 (23.53%)	3 / 19 (15.79%)	0 / 32 (0.00%)
occurrences (all)	4	3	0

Non-serious adverse events	SSC: Group 2b: 3 prior doses of BNT162b2	SSB: Group 1a: 2 prior doses of BNT162b2 (First Vaccination)	SSB: Group 3a: 3 prior doses of BNT162b2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 30 (56.67%)	14 / 17 (82.35%)	44 / 68 (64.71%)
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 30 (0.00%)	7 / 17 (41.18%)	11 / 68 (16.18%)
occurrences (all)	0	7	11
Somnolence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 30 (36.67%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	11	0	0
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 30 (26.67%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	8	0	0
Injection site erythema (REDNESS)			

alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)	1 / 17 (5.88%)	4 / 68 (5.88%)
occurrences (all)	1	1	4
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 30 (10.00%)	0 / 17 (0.00%)	7 / 68 (10.29%)
occurrences (all)	3	0	7
Injection site haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 17 (5.88%)	2 / 68 (2.94%)
occurrences (all)	0	1	2
Injection site pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Injection site pain (TENDERNESS)			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	8 / 68 (11.76%)
occurrences (all)	0	0	8
Gastrointestinal disorders			
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			

subjects affected / exposed	2 / 30 (6.67%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	3 / 68 (4.41%)
occurrences (all)	0	0	3
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Tachypnoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 30 (0.00%)	11 / 17 (64.71%)	29 / 68 (42.65%)
occurrences (all)	0	11	29

Musculoskeletal and connective tissue disorders			
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 30 (6.67%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infections			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	1 / 30 (3.33%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 17 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			

Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 30 (0.00%)	4 / 17 (23.53%)	13 / 68 (19.12%)
occurrences (all)	0	4	13

Non-serious adverse events	SSB: Group 2b: 3 prior doses of BNT162b2	SSB: Group 2a: 3 prior doses of BNT162b2	SSB: Group 3b: 3 prior doses of BNT162b2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	130 / 218 (59.63%)	48 / 92 (52.17%)	532 / 989 (53.79%)
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 218 (0.00%)	1 / 92 (1.09%)	0 / 989 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 218 (4.13%)	0 / 92 (0.00%)	43 / 989 (4.35%)
occurrences (all)	9	0	43
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 218 (0.00%)	18 / 92 (19.57%)	0 / 989 (0.00%)
occurrences (all)	0	18	0
Somnolence			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	68 / 218 (31.19%)	0 / 92 (0.00%)	283 / 989 (28.61%)
occurrences (all)	68	0	283
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 218 (4.59%)	0 / 92 (0.00%)	24 / 989 (2.43%)
occurrences (all)	10	0	24
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 218 (4.13%)	5 / 92 (5.43%)	39 / 989 (3.94%)
occurrences (all)	9	5	39
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	14 / 218 (6.42%)	7 / 92 (7.61%)	100 / 989 (10.11%)
occurrences (all)	14	7	100
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	15 / 218 (6.88%)	8 / 92 (8.70%)	51 / 989 (5.16%)
occurrences (all)	15	8	51
Injection site haemorrhage			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 218 (1.38%)	1 / 92 (1.09%)	8 / 989 (0.81%)
occurrences (all)	3	2	8
Injection site pain			
subjects affected / exposed	1 / 218 (0.46%)	1 / 92 (1.09%)	0 / 989 (0.00%)
occurrences (all)	1	1	0
Fatigue			

subjects affected / exposed	0 / 218 (0.00%)	1 / 92 (1.09%)	2 / 989 (0.20%)
occurrences (all)	0	1	2
Injection site erythema			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Injection site pain (TENDERNESS)			
subjects affected / exposed	0 / 218 (0.00%)	10 / 92 (10.87%)	0 / 989 (0.00%)
occurrences (all)	0	10	0
Gastrointestinal disorders			
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 218 (5.05%)	0 / 92 (0.00%)	68 / 989 (6.88%)
occurrences (all)	11	0	68
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 218 (5.05%)	0 / 92 (0.00%)	47 / 989 (4.75%)
occurrences (all)	11	0	47
Vomiting			
subjects affected / exposed	1 / 218 (0.46%)	2 / 92 (2.17%)	7 / 989 (0.71%)
occurrences (all)	1	2	7
Diarrhoea			
subjects affected / exposed	0 / 218 (0.00%)	2 / 92 (2.17%)	0 / 989 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	1 / 989 (0.10%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	2 / 989 (0.20%)
occurrences (all)	0	0	2
Tachypnoea			

subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 218 (0.46%)	1 / 92 (1.09%)	0 / 989 (0.00%)
occurrences (all)	1	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 218 (0.00%)	32 / 92 (34.78%)	0 / 989 (0.00%)
occurrences (all)	0	32	0
Musculoskeletal and connective tissue disorders			
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 218 (3.21%)	0 / 92 (0.00%)	20 / 989 (2.02%)
occurrences (all)	7	0	20
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infections			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	3 / 989 (0.30%)
occurrences (all)	0	0	3
Gastroenteritis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	0 / 989 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 92 (1.09%)	0 / 989 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 218 (0.00%)	1 / 92 (1.09%)	0 / 989 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 218 (0.00%)	1 / 92 (1.09%)	0 / 989 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 218 (0.00%)	0 / 92 (0.00%)	2 / 989 (0.20%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 218 (0.00%)	18 / 92 (19.57%)	0 / 989 (0.00%)
occurrences (all)	0	18	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 October 2022	Amendment 1: SSB: Updated section 1.1 Increased samples size in Group 2 to 300 and Group 3 to 3600; Decreased the number of days since last dose prior to enrollment in Group 3 to 60 days;Removed restriction on Group 3 that only participants from the C4591007 study in Phase 1 could participate; Updated section 10.8.3: Updated and added objectives, estimands, and endpoints to demonstrate noninferiority with respect to the level of neutralizing titers and the seroresponse rate of the anti–reference-strain immune response;Updated Section 10.8.9.1.2: Added multiplicity adjustment method for evaluating superiority and noninferiority with respect to level of neutralizing titer for GMR and seroresponse rate; Updated Section 10.8.9.3.2:Clarified immunogenicity endpoint analysis and success criterion for newly added superiority and noninferiority of anti–Omicron BA.4/BA.5 immune response objective;Updated Section 10.8.9.5 Added sample size and power calculation for the newly added superiority and noninferiority of anti- Omicron and anti–reference-strain immune response objectives SSD: Updated section 1.1 :Decreased the number of days since last dose prior to enrollment in Group 3 to 90 days. Updated Sections 10.7.5.2, 10.8.5.2, 10.9.5.2, 10.10.5.2 Exclusion Criteria Substudy A, B,C, D: Added radiotherapy,within 60 days before enrollment. Updated section 10.10.3 Clarified that the primary immunogenicity comparison would be between the SSD Group 1 to C4591007 Phase 2/3 participants and made editorial change to the estimands. Updated section 10.10.1.2: Removed 1-month postdose blood draw group 3 only. Updated section 10.10.1.3.2: Added the group numbers to rows specific to blood sample collection. Updated section 10.10.1.3.2: Added row specific to Group 3 blood draw to be collected at baseline only.
01 August 2023	Amendment 3: SSB: Updated Section 10.8.3: Added a secondary immunogenicity endpoint for SARS-CoV-2 reference-strain– neutralizing titers(previously omitted) SSC: Updated Section 10.9 Removed all references to the Phase 2/3 portion of Substudy C;Updated Section 10.9.1 Updated expanded enrollment numbers in Substudy C Phase 1 to reflect actual enrollment figures SSD: Updated section: 10.10.3: Added "at 1 month after Dose 4" to the second primary immunogenicity objective.
01 September 2023	Amendment 4:SSB: Updated Section 10.8.3 and Section 10.8.9.3.2 Removed objectives for immunogenicity comparisons related to Group 1. Section 10.8.9.2 Corrected the description of the all-available immunogenicity population to reflect all assigned participants instead of all randomized participants.SSC: Updated Section 10.9.3 and Section 10.9.9.3. Removed the analysis across both age groups combined. 2SSD: Updated section 10.10.3 and 10.10.9.3.2: Removed objectives for immunogenicity comparisons and descriptive summaries related to Group 1.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported