Clinical trial results:
An Interventional, Randomized, Active-Controlled, Phase 1/2/3 Study to Investigate the Safety, Tolerability, and Immunogenicity of BNT162b RNA-Based Vaccine Candidates in COVID-19 Vaccine-Experienced Healthy Individuals

Summary

EudraCT number	2022-002008-19
Trial protocol	Outside EU/EEA
Global end of trial date	26 March 2024

Results information

Result version number	v1 (current)
This version publication date	12 October 2024
First version publication date	12 October 2024

Trial information

Trial identification

Sponsor protocol code	C4591044

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05472038
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 clinical trials patient information, BioNTech SE, +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	Final
Date of interim/final analysis	22 April 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate safety, tolerability, and immunogenicity of BNT162b RNA-based vaccine candidates in COVID-19 vaccine–experienced healthy individuals. These candidates included:
1. Cohort 2 and Cohort 3: Omicron BA.4/BA.5 variant-adapted BNT162b2.
- BNT162b2 Bivalent (WT/OMI BA.4/BA.5) in participants 12 years and older. Participants 18 and older received either 30 mcg or 60 mcg dose. Some immunogenicity analyses compared to historic study of BNT162b2 30 mcg, or BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg or 60 mcg.
2. Cohort 1 and Cohort 4: BNT162b5, BNT162b6, BNT162b7, containing modified versions of mRNA segments of the spike protein in adults 18 through 55 years of age.
- Cohort 1: BNT162b5 Bivalent (WT/OMI BA.2) with BNT162b2 Bivalent (WT/OMI BA.1) as a comparison.
- Cohort 4: BNT162b5 Bivalent (WT/OMI BA.4/BA.5), BNT162b6 Bivalent (WT/OMI BA.4/BA.5), BNT162b7 Bivalent (WT/OMI BA.4/BA.5), BNT162b7 Monovalent (OMI BA.4/BA.5) with BNT162b2 Bivalent (WT/OMI BA.4/BA.5) as a comparison.

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	26 July 2022
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1451
Worldwide total number of subjects	1451
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	107
Adults (18-64 years)	1144
From 65 to 84 years	197
85 years and over	3

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Where appropriate, and as per planned analyses, data is summarised and combined for Cohort 2 (C2) and Cohort 3 (C3) 30 micrograms (mcg) groups (G) per age category to provide sufficient power for the immunogenicity hypotheses for each of the age groups.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Cohort 3 and Cohort 2 (participants 12 through 17 years of age) were open label.

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)

Arm description:

Participants aged 18-55 years received BNT162b5 Bivalent (wild type [WT]/omicron [OMI] BA.2) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b5 Bivalent (WT/OMI BA.2)
Investigational medicinal product code	PF-07302048
Other name	BNT162b5 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b5 Bivalent (WT/OMI BA.2) 30 mcg intramuscularly at Visit 1.

Arm title	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)

Arm description:

Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b2 Bivalent (WT/OMI BA.1)
Investigational medicinal product code	PF-07302048
Other name	BNT162b2 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg intramuscularly at Visit 1.

Arm title	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)

Arm description:

Participants aged 12-17 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental

Investigational medicinal product name	BNT162b2 Bivalent (WT/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b2 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Arm title	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)

Arm description:

Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b2 Bivalent (WT/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b2 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Arm title	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)

Arm description:

Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b2 Bivalent (WT/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b2 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1.

Arm title	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg)

Arm description:

Participants aged more than (>) 55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b2 Bivalent (WT/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b2 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Arm title	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)

Arm description:

Participants aged >55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental

Investigational medicinal product name	BNT162b2 Bivalent (WT/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b2 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1.

Arm title	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Arm description:

Participants aged 18-55 years received BNT162b2 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Active comparator
Investigational medicinal product name	BNT162b2 Bivalent (Original/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b2 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b2 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Arm title	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Arm description:

Participants aged 18-55 years received BNT162b5 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b5 Bivalent (Original/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b5 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b5 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Arm title	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Arm description:

Participants aged 18-55 years received BNT162b6 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b6 Bivalent (Original/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b6 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b6 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Arm title	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Arm description:

Participants aged 18-55 years received BNT162b7 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental

Investigational medicinal product name	BNT162b7 Bivalent (Original/OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b7 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b7 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Arm title	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)

Arm description:

Participants aged 18-55 years received BNT162b7 Monovalent (OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Arm type	Experimental
Investigational medicinal product name	BNT162b7 Monovalent (OMI BA.4/BA.5)
Investigational medicinal product code	PF-07302048
Other name	BNT162b7 RNA-LNP vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

BNT162b7 Monovalent (OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1.

Number of subjects in period 1	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Started	104	102	107
Completed	102	96	102
Not completed	2	6	5
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	3	1
Physician decision	-	-	-
Adverse event, non-fatal	-	-	1
Lost to follow-up	1	3	3
Protocol deviation	-	-	-

Number of subjects in period 1	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg)
Started	313	110	306
Completed	298	106	300
Not completed	15	4	6
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	6	1	3
Physician decision	-	1	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	9	2	2

Protocol deviation	-	-	-

Number of subjects in period 1	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Started	102	62	62
Completed	101	59	57
Not completed	1	3	5
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	2	3
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	1	-	1
Protocol deviation	-	1	1

Number of subjects in period 1	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)
Started	60	60	63
Completed	58	55	59
Not completed	2	5	4
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	2	2
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	2	1
Protocol deviation	1	1	1

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b5 Bivalent (wild type [WT]/omicron [OMI] BA.2) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Reporting group description:	
Participants aged 12-17 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged more than (>) 55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)
Reporting group description:	
Participants aged >55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b5 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b6 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b7 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	

Reporting group title	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b7 Monovalent (OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Number of subjects	104	102	107
Age categorical Units: Participants			
Adolescents (12-17 years)	0	0	107
Adults (18-64 years)	104	102	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Sex: Female, Male Units: Participants			
Female	52	58	48
Male	52	44	59
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	11	10	3
Native Hawaiian or Other Pacific Islander	1	2	0
Black or African American	10	15	9
White	81	71	91
More than one race	1	4	3
Unknown or Not Reported	0	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	18	23	7
Not Hispanic or Latino	84	79	99
Unknown or Not Reported	2	0	1

Reporting group values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg)
Number of subjects	313	110	306
Age categorical Units: Participants			
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	313	110	147
From 65-84 years	0	0	157
85 years and over	0	0	2
Sex: Female, Male Units: Participants			
Female	201	63	167
Male	112	47	139

Race Units: Subjects			
American Indian or Alaska Native	0	0	3
Asian	32	9	8
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	26	11	48
White	251	90	243
More than one race	4	0	3
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	39	15	37
Not Hispanic or Latino	272	94	267
Unknown or Not Reported	2	1	2

Reporting group values	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Number of subjects	102	62	62
Age categorical Units: Participants			
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	61	62	62
From 65-84 years	40	0	0
85 years and over	1	0	0
Sex: Female, Male Units: Participants			
Female	55	39	31
Male	47	23	31
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	7	10
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	8	4	11
White	92	49	40
More than one race	0	2	1
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	11	7	10
Not Hispanic or Latino	89	55	52
Unknown or Not Reported	2	0	0

Reporting group values	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)
Number of subjects	60	60	63

Age categorical Units: Participants			
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	60	60	63
From 65-84 years	0	0	0
85 years and over	0	0	0
Sex: Female, Male Units: Participants			
Female	40	37	38
Male	20	23	25
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	11	3	7
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	3	4
White	43	53	52
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity Units: Subjects			
Hispanic or Latino	7	12	13
Not Hispanic or Latino	53	48	50
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	1451		
Age categorical Units: Participants			
Adolescents (12-17 years)	107		
Adults (18-64 years)	1144		
From 65-84 years	197		
85 years and over	3		
Sex: Female, Male Units: Participants			
Female	829		
Male	622		
Race Units: Subjects			
American Indian or Alaska Native	3		
Asian	113		
Native Hawaiian or Other Pacific Islander	4		
Black or African American	155		
White	1156		
More than one race	18		
Unknown or Not Reported	2		
Ethnicity Units: Subjects			
Hispanic or Latino	199		
Not Hispanic or Latino	1242		

Unknown or Not Reported	10		

End points

End points reporting groups

Reporting group title	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b5 Bivalent (wild type [WT]/omicron [OMI] BA.2) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Reporting group description:	
Participants aged 12-17 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged more than (>) 55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)
Reporting group description:	
Participants aged >55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b2 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b5 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b6 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	
Reporting group title	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Reporting group description:	
Participants aged 18-55 years received BNT162b7 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).	

Reporting group title	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b7 Monovalent (OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Subject analysis set title	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Subject analysis set title	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged > 55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Subject analysis set title	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged 18 to 55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Subject analysis set title	18-55 Years (BNT162b2 Bivalent(WT/OMI BA.1)30mcg):C4591031 SSE
Subject analysis set type	Per protocol

Subject analysis set description:

A subset of 100 participants in each age group (18 through 55 years of age, >55 years of age) and dose group (30 mcg, 60 mcg) from C4591031 Substudy E (SSE) expanded cohort who received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg or 60 mcg as a second booster dose were selected for this objective. The subset selected from C4591031 Substudy E included similar percentage of participants with baseline positive SARS-CoV-2 infection status as the groups in Cohort 2 of this study.

Subject analysis set title	18-55 Years(BNT162b2 Bivalent[WT/OMI BA.1] 60mcg):C4591031 SSE
Subject analysis set type	Per protocol

Subject analysis set description:

A subset of 100 participants in each age group (18 through 55 years of age, >55 years of age) and dose group (30 mcg, 60 mcg) from C4591031 Substudy E expanded cohort who received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg or 60 mcg as a second booster dose were selected for this objective. The subset selected from C4591031 Substudy E included similar percentage of participants with baseline positive SARS-CoV-2 infection status as the groups in Cohort 2 of this study.

Subject analysis set title	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30mcg):C4591031 SSE
Subject analysis set type	Per protocol

Subject analysis set description:

A subset of 100 participants in each age group (18 through 55 years of age, >55 years of age) and dose group (30 mcg, 60 mcg) from C4591031 Substudy E expanded cohort who received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg or 60 mcg as a second booster dose were selected for this objective. The subset selected from C4591031 Substudy E included similar percentage of participants with baseline positive SARS-CoV-2 infection status as the groups in Cohort 2 of this study.

Subject analysis set title	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 60mcg):C4591031 SSE
Subject analysis set type	Per protocol

Subject analysis set description:

A subset of 100 participants in each age group (18 through 55 years of age, >55 years of age) and dose group (30 mcg, 60 mcg) from C4591031 Substudy E expanded cohort who received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg or 60 mcg as a second booster dose were selected for this objective. The subset selected from C4591031 Substudy E included similar percentage of participants with baseline positive SARS-CoV-2 infection status as the groups in Cohort 2 of this study.

Subject analysis set title	BNT162b2 30 mcg: C4591031 Substudy E

Subject analysis set type	Per protocol

Subject analysis set description:

BNT162b2 experienced participants >55 years of age in study C4591031 [NCT04955626] received one dose (30 mcg) of BNT162b2 intramuscularly. As planned this group served as immunogenicity control arm and participants are not included in enrollment number of current C4591044 [NCT05472038] study.

Primary: Cohort 1: Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination

End point title	Cohort 1: Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination[1][2]

End point description:

Local reactions recorded by participants in electronic diary (e-diary). Local reactions: redness, swelling, pain at injection site. Redness, swelling graded mild: > 2.0-5.0 cm, moderate: >5.0-10.0 cm, severe: >10.0 cm, grade 4: 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, grade 4: emergency room (ER) visit/hospitalisation. Grade 4 reactions (potentially life threatening) classified by investigator/medically qualified person. Any events recorded on the adverse event (AE) case report form (CRF) that are considered local reactions within 7 days after vaccination were consolidated with e-diary data and included in the reactogenicity report. Safety population: all participants receiving study intervention and obtaining informed consent.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after study vaccination

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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	102		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	5.8 (2.1 to 12.1)	5.9 (2.2 to 12.4)		
Redness: Mild	3.8 (1.1 to 9.6)	3.9 (1.1 to 9.7)		
Redness: Moderate	1.0 (0.0 to 5.2)	2.0 (0.2 to 6.9)		
Redness: Severe	1.0 (0.0 to 5.2)	0 (0.0 to 3.6)		
Redness: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Swelling: Any	10.6 (5.4 to 18.1)	10.8 (5.5 to 18.5)		
Swelling: Mild	6.7 (2.7 to 13.4)	4.9 (1.6 to 11.1)		
Swelling: Moderate	2.9 (0.6 to 8.2)	5.9 (2.2 to 12.4)		
Swelling: Severe	1.0 (0.0 to 5.2)	0 (0.0 to 3.6)		
Swelling: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Pain at injection site: Any	82.7 (74.0 to 89.4)	81.4 (72.4 to 88.4)		
Pain at injection site: Mild	67.3 (57.4 to 76.2)	62.7 (52.6 to 72.1)		

Pain at injection site: Moderate	15.4 (9.1 to 23.8)	18.6 (11.6 to 27.6)		
Pain at injection site: Severe	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Pain at injection site: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination

End point title	Cohort 1: Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination[3][4]

End point description:

Systemic events recorded by participants in e-diary. Fever: oral temperature >= 38 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 24 hours (h), moderate: >2 times in 24h, severe: required intravenous (IV) hydration. Diarrhea= mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6/more loose stools in 24h. Except fever, Grade 4= ER visit/hospitalisation. Grade 4 events classified by investigator/medically qualified person. Systemic events reported as AEs in CRF within 7 days after vaccination included. Safety population= participants receiving study intervention and obtaining informed consent.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after study vaccination

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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	102		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	1.9 (0.2 to 6.8)	5.9 (2.2 to 12.4)		
Fever: >=38.0 deg C to 38.4 deg C	1.0 (0.0 to 5.2)	2.0 (0.2 to 6.9)		
Fever: >38.4 deg C to 38.9 deg C	0 (0.0 to 3.5)	1.0 (0.0 to 5.3)		
Fever: >38.9 deg C to 40.0 deg C	1.0 (0.0 to 5.2)	2.9 (0.6 to 8.4)		
Fever: >40.0 deg C	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Fatigue: Any	73.1 (63.5 to 81.3)	62.7 (52.6 to 72.1)		
Fatigue: Mild	37.5 (28.2 to 47.5)	27.5 (19.1 to 37.2)		

Fatigue: Moderate	34.6 (25.6 to 44.6)	34.3 (25.2 to 44.4)		
Fatigue: Severe	1.0 (0.0 to 5.2)	1.0 (0.0 to 5.3)		
Fatigue: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Headache: Any	52.9 (42.8 to 62.8)	46.1 (36.2 to 56.2)		
Headache: Mild	29.8 (21.2 to 39.6)	22.5 (14.9 to 31.9)		
Headache: Moderate	21.2 (13.8 to 30.3)	22.5 (14.9 to 31.9)		
Headache: Severe	1.9 (0.2 to 6.8)	1.0 (0.0 to 5.3)		
Headache: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Chills: Any	21.2 (13.8 to 30.3)	19.6 (12.4 to 28.6)		
Chills: Mild	10.6 (5.4 to 18.1)	7.8 (3.4 to 14.9)		
Chills: Moderate	10.6 (5.4 to 18.1)	11.8 (6.2 to 19.6)		
Chills: Severe	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Chills: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Vomiting: Any	1.0 (0.0 to 5.2)	2.0 (0.2 to 6.9)		
Vomiting: Mild	1.0 (0.0 to 5.2)	2.0 (0.2 to 6.9)		
Vomiting: Moderate	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Vomiting: Severe	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Vomiting: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
Diarrhea: Any	14.4 (8.3 to 22.7)	19.6 (12.4 to 28.6)		
Diarrhea: Mild	13.5 (7.6 to 21.6)	14.7 (8.5 to 23.1)		
Diarrhea: Moderate	1.0 (0.0 to 5.2)	3.9 (1.1 to 9.7)		
Diarrhea: Severe0	0 (0.0 to 3.5)	1.0 (0.0 to 5.3)		
Diarrhea: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
New or worsened muscle pain: Any	35.6 (26.4 to 45.6)	38.2 (28.8 to 48.4)		
New or worsened muscle pain: Mild	18.3 (11.4 to 27.1)	23.5 (15.7 to 33.0)		
New or worsened muscle pain: Moderate	17.3 (10.6 to 26.0)	14.7 (8.5 to 23.1)		
New or worsened muscle pain: Severe	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
New or worsened muscle pain: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
New or worsened joint pain: Any	18.3 (11.4 to 27.1)	17.6 (10.8 to 26.4)		
New or worsened joint pain: Mild	7.7 (3.4 to 14.6)	11.8 (6.2 to 19.6)		
New or worsened joint pain: Moderate	10.6 (5.4 to 18.1)	5.9 (2.2 to 12.4)		
New or worsened joint pain: Severe	0 (0.0 to 3.5)	0 (0.0 to 3.6)		
New or worsened joint pain: Grade 4	0 (0.0 to 3.5)	0 (0.0 to 3.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Geometric Mean Titer (GMT) of SARS-CoV-2 Omicron Strain (BA.1

and BA.2) and Reference Strain Neutralising Titers (NTs) at Baseline- Participants Without Evidence of Infection

End point title	Cohort 1: Geometric Mean Titer (GMT) of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain Neutralising Titers (NTs) at Baseline- Participants Without Evidence of Infection[5][6]

End point description:

GMTs and the corresponding 2-sided confidence intervals (CIs) were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on student's t distribution). Evaluable immunogenicity population (EIP) included all eligible randomised/assigned participants who received the study intervention to which they were randomised/assigned, had at least 1 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. Analysis was performed in participants without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

At baseline (before 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.2 (n=29, 29)	169.3 (96.7 to 296.3)	377.8 (229.2 to 622.8)		
Omicron BA.1 (n=30, 29)	103.3 (60.4 to 176.6)	209.5 (147.2 to 298.2)		
Reference strain (n=30, 29)	892.0 (526.5 to 1511.3)	1544.2 (993.8 to 2399.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Percentage of Participants With Adverse Events (AEs) From Study Vaccination Through 1 Month After Study Vaccination

End point title	Cohort 1: Percentage of Participants With Adverse Events (AEs) From Study Vaccination Through 1 Month After Study Vaccination[7][8]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. Results excluded local reactions and systemic events data. Safety population included all participants who received the study

intervention and where appropriate informed consent was obtained.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 through 1 month after study vaccination

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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	102		
Units: Percentage of participants				
number (confidence interval 95%)	8.7 (4.0 to 15.8)	12.7 (7.0 to 20.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Percentage of Participants With Serious Adverse Events (SAEs) From Study Vaccination Through 6 Months After Study Vaccination

End point title	Cohort 1: Percentage of Participants With Serious Adverse Events (SAEs) From Study Vaccination Through 6 Months After Study Vaccination[9][10]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. An SAE was an AE that 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 the study intervention and where appropriate informed consent was obtained.

End point type	Primary

End point timeframe:

From study vaccination on Day 1 through 6 months after study vaccination

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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	102		
Units: Percentage of participants				
number (confidence interval 95%)	1.0 (0.0 to 5.2)	2.0 (0.2 to 6.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain NTs at Baseline- Participants With or Without Evidence of Infection

End point title	Cohort 1: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain NTs at Baseline- Participants With or Without Evidence of Infection[11][12]

End point description:

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). Evaluable immunogenicity population included all eligible randomised/assigned participants who received the study intervention to which they were randomised/assigned, had at least 1 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. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

At baseline (before study vaccination)

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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	98		
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.2 (n=102, 96)	1269.1 (854.7 to 1884.6)	1527.5 (1061.3 to 2198.6)		
Omicron BA.1 (n=103, 98)	652.7 (448.9 to 949.0)	818.7 (595.9 to 1124.7)		

Reference strain (n=103, 98)	3469.8 (2536.5 to 4746.7)	3755.9 (2896.8 to 4869.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain NTs at 1 Month- Participants Without Evidence of Infection

End point title	Cohort 1: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain NTs at 1 Month- Participants Without Evidence of Infection[13][14]

End point description:

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). Evaluable immunogenicity population included all eligible randomised/assigned participants who received the study intervention to which they were randomised/assigned, had at least 1 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. Analysis was performed in participants without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the study vaccination

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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.2 (n=30, 28)	2414.8 (1508.5 to 3865.4)	2768.5 (1948.5 to 3933.7)		
Omicron BA.1 (n=30, 29)	1666.1 (1085.8 to 2556.6)	1993.8 (1309.1 to 3036.6)		
Reference strain (n=30, 29)	8268.9 (5901.9 to 11585.1)	7391.6 (5117.5 to 10676.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain NTs at 1 Month- Participants With or Without Evidence of Infection

End point title	Cohort 1: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain NTs at 1 Month- Participants With or Without Evidence of Infection[15][16]

End point description:

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). Evaluable immunogenicity population included all eligible randomised/assigned participants who received the study intervention to which they were randomised/assigned, had at least 1 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. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the study vaccination

Notes:

[15] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	98		
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.2 (n=102, 95)	6267.9 (4766.0 to 8243.1)	4984.2 (3976.4 to 6247.4)		
Omicron BA.1 (n=103, 98)	3582.2 (2813.7 to 4560.7)	3571.8 (2899.6 to 4399.8)		
Reference strain (n=103, 98)	14342.3 (11811.9 to 17414.9)	11246.8 (9395.1 to 13463.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination- Participants Without Evidence of Infection

End point title	Cohort 1: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination- Participants Without Evidence of Infection[17][18]

End point description:

GMFR from before study vaccination to 1 month after study vaccination for each strain-specific neutralising titer was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating mean logarithm of fold rises and corresponding CIs (based on student-t distribution). Assay results below lower limit of quantitation (LLOQ) were set to 0.5*LLOQ in analysis. EIP included all eligible randomised/assigned participants who received study intervention to which they were randomised/assigned, had at least 1 valid and determinate immunogenicity result from blood sample collected within 28-42 days after study vaccination, and had no other important protocol deviations as determined by clinician. Analysis was performed in participants without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

From before the study vaccination to 1 month after the 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron BA.2 (n= 29, 28)	14.6 (8.4 to 25.5)	6.9 (4.4 to 10.9)		
Omicron BA.1 (n= 30, 29)	16.1 (10.9 to 23.9)	9.5 (6.5 to 13.8)		
Reference strain (n= 30, 29)	9.3 (5.9 to 14.6)	4.8 (3.1 to 7.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: GMFR of SARS-CoV-2 Omicron Strain (BA.1 and BA2) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination- Participants With or Without Evidence of Infection

End point title	Cohort 1: GMFR of SARS-CoV-2 Omicron Strain (BA.1 and BA2) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination- Participants With or Without Evidence of Infection[19][20]

End point description:

GMFR from before study vaccination to 1 month after study vaccination for each strain-specific neutralising titer was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating mean logarithm of fold rises and corresponding CIs (based on student-t distribution). Assay results below LLOQ were set to 0.5*LLOQ in analysis. EIP included all eligible randomised/assigned participants who received study intervention to which they were randomised/assigned, had at least 1 valid and determinate immunogenicity result from blood sample collected within 28-42 days after study vaccination, and had no other important protocol deviations as determined by clinician. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

From before the study vaccination to 1 month after the 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	98		
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron BA.2 (n=101, 93)	5.0 (3.6 to 6.8)	3.2 (2.3 to 4.3)		
Omicron BA.1 (n=103, 98)	5.5 (4.3 to 7.1)	4.4 (3.4 to 5.6)		
Reference strain (n=103, 98)	4.1 (3.3 to 5.2)	3.0 (2.4 to 3.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain– NTs at 1 Month After Study Vaccination- Participants Without Evidence of Infection

End point title	Cohort 1: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain– NTs at 1 Month After Study Vaccination- Participants Without Evidence of Infection[21][22]

End point description:

Seroresponse was defined as achieving >= 4-fold rise in NTs from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination measure of >= 4*LLOQ was considered a seroresponse. EIP included all eligible randomised/assigned participants who received study intervention to which they were randomised/assigned, had at least 1 valid and determinate immunogenicity result from blood sample collected within 28-42 days after study vaccination, and had no other important protocol deviations as determined by clinician. Analysis was performed in participants without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron BA.2 (n=29, 28)	82.8 (64.2 to 94.2)	71.4 (51.3 to 86.8)		
Omicron BA.1 (n=30, 29)	93.3 (77.9 to 99.2)	86.2 (68.3 to 96.1)		
Reference (n=30, 29)	73.3 (54.1 to 87.7)	51.7 (32.5 to 70.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain– NTs at 1 Month After Study Vaccination- Participants With or Without Evidence of Infection

End point title	Cohort 1: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.1 and BA.2) and Reference Strain– NTs at 1 Month After Study Vaccination- Participants With or Without Evidence of Infection[23][24]

End point description:

Seroresponse was defined as achieving >= 4-fold rise in NTs from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination measure of >= 4*LLOQ was considered a seroresponse. EIP included all eligible randomised/assigned participants who received study intervention to which they were randomised/assigned, had at least 1 valid and determinate immunogenicity result from blood sample collected within 28-42 days after study vaccination, and had no other important protocol deviations as determined by clinician. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 1 reporting groups only.

End point values	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	98		
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron BA.2 (n=101, 93)	53.5 (43.3 to 63.5)	40.9 (30.8 to 51.5)		
Omicron BA.1 (n=103, 98)	58.3 (48.1 to 67.9)	49.0 (38.7 to 59.3)		
Reference strain (n=103, 98)	43.7 (33.9 to 53.8)	30.6 (21.7 to 40.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2: Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination

End point title	Cohort 2: Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination[25][26]

End point description:

Local reactions recorded by participants in e-diary. Local reactions: redness, swelling, pain at injection (inj) site. Redness, swelling graded mild: > 2.0-5.0 cm, moderate: >5.0-10.0 cm, severe: >10.0 cm, grade 4 (potentially life threatening): necrosis/exfoliative dermatitis (redness), necrosis (swelling). Pain at inj site graded mild: did not interfere with daily activity, moderate: interfered with daily activity, severe: prevented daily activity, grade 4 (potentially life threatening): ER visit/hospitalisation. Grade 4 reactions classified by investigator/medically qualified person. Reactions reported as AEs in CRF within 7 days after study vaccination reported. Safety population: all participants receiving study intervention

and obtaining informed consent. "Number of Participants Analysed"=participants evaluable for endpoint; "n"=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	107	110	102	102
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (n=107,110,101,102,105)	5.6 (2.1 to 11.8)	10.9 (5.8 to 18.3)	6.9 (2.8 to 13.8)	5.9 (2.2 to 12.4)
Redness: Mild (n=107,110,101,102,105)	3.7 (1.0 to 9.3)	5.5 (2.0 to 11.5)	4.0 (1.1 to 9.8)	4.9 (1.6 to 11.1)
Redness: Moderate (n=107,110,101,102,105)	1.9 (0.2 to 6.6)	4.5 (1.5 to 10.3)	3.0 (0.6 to 8.4)	1.0 (0.0 to 5.3)
Redness: Severe (n=107,110,101,102,105)	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Redness: Grade 4 (n=107,110,101,102,105)	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Swelling: Any (n=107,110,101,102,105)	7.5 (3.3 to 14.2)	15.5 (9.3 to 23.6)	8.9 (4.2 to 16.2)	6.9 (2.8 to 13.6)
Swelling: Mild (n=107,110,101,102,105)	5.6 (2.1 to 11.8)	6.4 (2.6 to 12.7)	5.0 (1.6 to 11.2)	4.9 (1.6 to 11.1)
Swelling: Moderate (n=107,110,101,102,105)	1.9 (0.2 to 6.6)	9.1 (4.4 to 16.1)	4.0 (1.1 to 9.8)	2.0 (0.2 to 6.9)
Swelling: Severe (n=107,110,101,102,105)	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Swelling: Grade 4 (n=107,110,101,102,105)	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Pain at inj site: Any (n=107,110,102,102,105)	70.1 (60.5 to 78.6)	93.6 (87.3 to 97.4)	70.6 (60.7 to 79.2)	79.4 (70.3 to 86.8)
Pain at inj site: Mild (n=107,110,102,102,105)	42.1 (32.6 to 52.0)	53.6 (43.9 to 63.2)	52.9 (42.8 to 62.9)	63.7 (53.6 to 73.0)
Pain at inj site: Moderate (n=107,110,102,102,105)	27.1 (19.0 to 36.6)	40.0 (30.8 to 49.8)	17.6 (10.8 to 26.4)	15.7 (9.2 to 24.2)
Pain at inj site: Severe (n=107,110,102,102,105)	0.9 (0.0 to 5.1)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Pain at inj site: Grade 4 (n=107,110,102,102,105)	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)

End point values	C2 G4: >55			

	Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)			
Subject group type	Subject analysis set			
Number of subjects analysed	105			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (n=107,110,101,102,105)	2.9 (0.6 to 8.1)			
Redness: Mild (n=107,110,101,102,105)	1.0 (0.0 to 5.2)			
Redness: Moderate (n=107,110,101,102,105)	1.9 (0.2 to 6.7)			
Redness: Severe (n=107,110,101,102,105)	0 (0.0 to 3.5)			
Redness: Grade 4 (n=107,110,101,102,105)	0 (0.0 to 3.5)			
Swelling: Any (n=107,110,101,102,105)	1.9 (0.2 to 6.7)			
Swelling: Mild (n=107,110,101,102,105)	1.0 (0.0 to 5.2)			
Swelling: Moderate (n=107,110,101,102,105)	1.0 (0.0 to 5.2)			
Swelling: Severe (n=107,110,101,102,105)	0 (0.0 to 3.5)			
Swelling: Grade 4 (n=107,110,101,102,105)	0 (0.0 to 3.5)			
Pain at inj site: Any (n=107,110,102,102,105)	56.2 (46.2 to 65.9)			
Pain at inj site: Mild (n=107,110,102,102,105)	50.5 (40.5 to 60.4)			
Pain at inj site: Moderate (n=107,110,102,102,105)	5.7 (2.1 to 12.0)			
Pain at inj site: Severe (n=107,110,102,102,105)	0 (0.0 to 3.5)			
Pain at inj site: Grade 4 (n=107,110,102,102,105)	0 (0.0 to 3.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2: Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination

End point title	Cohort 2: Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination[27][28]

End point description:

Systemic events recorded by participants in e-diary. Fever: oral temperature >= 38 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 24 h, moderate: >2 times in 24h, severe: required IV hydration. Diarrhea= mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6/more loose stools in 24h. Except fever, Grade 4= ER visit/hospitalisation. Grade 4 events classified by investigator/medically qualified person. Systemic events reported as AEs in CRF within 7 days after vaccination included. Safety population= participants

receiving study intervention and obtaining IC. "Number of Participants Analysed" =participants evaluable for endpoint.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	107	110	101	102
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	9.3 (4.6 to 16.5)	11.8 (6.4 to 19.4)	13.9 (7.8 to 22.2)	4.9 (1.6 to 11.1)
Fever: >=38.0 deg C to 38.4 deg C	6.5 (2.7 to 13.0)	7.3 (3.2 to 13.8)	7.9 (3.5 to 15.0)	2.0 (0.2 to 6.9)
Fever: >38.4 deg C to 38.9 deg C	1.9 (0.2 to 6.6)	2.7 (0.6 to 7.8)	4.0 (1.1 to 9.8)	2.9 (0.6 to 8.4)
Fever: >38.9 deg C to 40.0 deg C	0.9 (0.0 to 5.1)	1.8 (0.2 to 6.4)	2.0 (0.2 to 7.0)	0 (0.0 to 3.6)
Fever: >40.0 deg C	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Fatigue: Any	67.3 (57.5 to 76.0)	69.1 (59.6 to 77.6)	53.5 (43.3 to 63.5)	62.7 (52.6 to 72.1)
Fatigue: Mild	25.2 (17.3 to 34.6)	24.5 (16.8 to 33.7)	23.8 (15.9 to 33.3)	30.4 (21.7 to 40.3)
Fatigue: Moderate	42.1 (32.6 to 52.0)	43.6 (34.2 to 53.4)	25.7 (17.6 to 35.4)	30.4 (21.7 to 40.3)
Fatigue: Severe	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	4.0 (1.1 to 9.8)	2.0 (0.2 to 6.9)
Fatigue: Grade 4	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Headache: Any	50.5 (40.6 to 60.3)	45.5 (35.9 to 55.2)	35.6 (26.4 to 45.8)	44.1 (34.3 to 54.3)
Headache: Mild	26.2 (18.1 to 35.6)	27.3 (19.2 to 36.6)	20.8 (13.4 to 30.0)	32.4 (23.4 to 42.3)
Headache: Moderate	24.3 (16.5 to 33.5)	17.3 (10.7 to 25.7)	13.9 (7.8 to 22.2)	11.8 (6.2 to 19.6)
Headache: Severe	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	1.0 (0.0 to 5.4)	0 (0.0 to 3.6)
Headache: Grade 4	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Chills: Any	23.4 (15.7 to 32.5)	27.3 (19.2 to 36.6)	22.8 (15.0 to 32.2)	14.7 (8.5 to 23.1)
Chills: Mild	17.8 (11.0 to 26.3)	17.3 (10.7 to 25.7)	11.9 (6.3 to 19.8)	8.8 (4.1 to 16.1)
Chills: Moderate	5.6 (2.1 to 11.8)	9.1 (4.4 to 16.1)	10.9 (5.6 to 18.7)	5.9 (2.2 to 12.4)
Chills: Severe	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Chills: Grade 4	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Vomiting: Any	2.8 (0.6 to 8.0)	1.8 (0.2 to 6.4)	3.0 (0.6 to 8.4)	2.0 (0.2 to 6.9)
Vomiting: Mild	2.8 (0.6 to 8.0)	0.9 (0.0 to 5.0)	2.0 (0.2 to 7.0)	1.0 (0.0 to 5.3)

Vomiting: Moderate	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	1.0 (0.0 to 5.4)	1.0 (0.0 to 5.3)
Vomiting: Severe	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Vomiting: Grade 4	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
Diarrhea: Any	6.5 (2.7 to 13.0)	12.7 (7.1 to 20.4)	6.9 (2.8 to 13.8)	13.7 (7.7 to 22.0)
Diarrhea: Mild	6.5 (2.7 to 13.0)	11.8 (6.4 to 19.4)	5.9 (2.2 to 12.5)	9.8 (4.8 to 17.3)
Diarrhea: Moderate	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	1.0 (0.0 to 5.4)	2.9 (0.6 to 8.4)
Diarrhea: Severe	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	1.0 (0.0 to 5.3)
Diarrhea: Grade 4	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
New or worsened muscle pain: Any	26.2 (18.1 to 35.6)	41.8 (32.5 to 51.6)	22.8 (15.0 to 32.2)	31.4 (22.5 to 41.3)
New or worsened muscle pain: Mild	11.2 (5.9 to 18.8)	21.8 (14.5 to 30.7)	12.9 (7.0 to 21.0)	17.6 (10.8 to 26.4)
New or worsened muscle pain: Moderate	15.0 (8.8 to 23.1)	19.1 (12.2 to 27.7)	8.9 (4.2 to 16.2)	13.7 (7.7 to 22.0)
New or worsened muscle pain: Severe	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	1.0 (0.0 to 5.4)	0 (0.0 to 3.6)
New or worsened muscle pain: Grade 4	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)
New or worsened joint pain: Any	12.1 (6.6 to 19.9)	24.5 (16.8 to 33.7)	14.9 (8.6 to 23.3)	16.7 (10.0 to 25.3)
New or worsened joint pain: Mild	8.4 (3.9 to 15.4)	11.8 (6.4 to 19.4)	5.9 (2.2 to 12.5)	9.8 (4.8 to 17.3)
New or worsened joint pain: Moderate	3.7 (1.0 to 9.3)	11.8 (6.4 to 19.4)	7.9 (3.5 to 15.0)	6.9 (2.8 to 13.6)
New or worsened joint pain: Severe	0 (0.0 to 3.4)	0.9 (0.0 to 5.0)	1.0 (0.0 to 5.4)	0 (0.0 to 3.6)
New or worsened joint pain: Grade 4	0 (0.0 to 3.4)	0 (0.0 to 3.3)	0 (0.0 to 3.6)	0 (0.0 to 3.6)

End point values	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)			
Subject group type	Subject analysis set			
Number of subjects analysed	105			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	7.6 (3.3 to 14.5)			
Fever: >=38.0 deg C to 38.4 deg C	5.7 (2.1 to 12.0)			
Fever: >38.4 deg C to 38.9 deg C	1.9 (0.2 to 6.7)			
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 3.5)			
Fever: >40.0 deg C	0 (0.0 to 3.5)			
Fatigue: Any	39.0 (29.7 to 49.1)			
Fatigue: Mild	20.0 (12.8 to 28.9)			
Fatigue: Moderate	18.1 (11.3 to 26.8)			
Fatigue: Severe	1.0 (0.0 to 5.2)			
Fatigue: Grade 4	0 (0.0 to 3.5)			
Headache: Any	29.5 (21.0 to 39.2)			

Headache: Mild	21.9 (14.4 to 31.0)			
Headache: Moderate	7.6 (3.3 to 14.5)			
Headache: Severe	0 (0.0 to 3.5)			
Headache: Grade 4	0 (0.0 to 3.5)			
Chills: Any	12.4 (6.8 to 20.2)			
Chills: Mild	6.7 (2.7 to 13.3)			
Chills: Moderate	5.7 (2.1 to 12.0)			
Chills: Severe	0 (0.0 to 3.5)			
Chills: Grade 4	0 (0.0 to 3.5)			
Vomiting: Any	1.0 (0.0 to 5.2)			
Vomiting: Mild	1.0 (0.0 to 5.2)			
Vomiting: Moderate	0 (0.0 to 3.5)			
Vomiting: Severe	0 (0.0 to 3.5)			
Vomiting: Grade 4	0 (0.0 to 3.5)			
Diarrhea: Any	8.6 (4.0 to 15.6)			
Diarrhea: Mild	8.6 (4.0 to 15.6)			
Diarrhea: Moderate	0 (0.0 to 3.5)			
Diarrhea: Severe	0 (0.0 to 3.5)			
Diarrhea: Grade 4	0 (0.0 to 3.5)			
New or worsened muscle pain: Any	20.0 (12.8 to 28.9)			
New or worsened muscle pain: Mild	12.4 (6.8 to 20.2)			
New or worsened muscle pain: Moderate	7.6 (3.3 to 14.5)			
New or worsened muscle pain: Severe	0 (0.0 to 3.5)			
New or worsened muscle pain: Grade 4	0 (0.0 to 3.5)			
New or worsened joint pain: Any	11.4 (6.0 to 19.1)			
New or worsened joint pain: Mild	6.7 (2.7 to 13.3)			
New or worsened joint pain: Moderate	4.8 (1.6 to 10.8)			
New or worsened joint pain: Severe	0 (0.0 to 3.5)			
New or worsened joint pain: Grade 4	0 (0.0 to 3.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2: Percentage of Participants With AEs From Study Vaccination Through 1 Month After Study Vaccination

End point title	Cohort 2: Percentage of Participants With AEs From Study Vaccination Through 1 Month After Study Vaccination[29][30]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. Results excluded local reactions and systemic events data. Safety population included all participants who received the study

intervention and where appropriate informed consent was obtained.

End point type	Primary

End point timeframe:

From study vaccination through 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	107	110	102	103
Units: Percentage of participants				
number (confidence interval 95%)	7.5 (3.3 to 14.2)	8.2 (3.8 to 15.0)	6.9 (2.8 to 13.6)	2.9 (0.6 to 8.3)

End point values	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)			
Subject group type	Subject analysis set			
Number of subjects analysed	106			
Units: Percentage of participants				
number (confidence interval 95%)	3.8 (1.0 to 9.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2: Percentage of Participants With SAEs From Study Vaccination Through 6 Months After Study Vaccination

End point title	Cohort 2: Percentage of Participants With SAEs From Study Vaccination Through 6 Months After Study Vaccination[31][32]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. An SAE was an AE that 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 the study intervention and where appropriate informed consent was obtained.

End point type	Primary

End point timeframe:

From study vaccination through 6 months 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	107	110	102	103
Units: Percentage of participants				
number (confidence interval 95%)	0.9 (0.0 to 5.1)	0.9 (0.0 to 5.0)	0 (0.0 to 3.6)	0 (0.0 to 3.5)

End point values	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)			
Subject group type	Subject analysis set			
Number of subjects analysed	106			
Units: Percentage of participants				
number (confidence interval 95%)	3.8 (1.0 to 9.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and 2): Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination

End point title	Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and 2): Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination[33][34]

End point description:

Local reactions recorded by participants in e-diary. Local reactions: redness, swelling, pain at injection site. Redness, swelling graded mild: >2.0-5.0 cm, moderate: >5.0-10.0 cm, severe: >10.0 cm, grade 4: necrosis/exfoliative dermatitis (redness), necrosis (swelling). Pain at injection site graded mild: did not interfere with activity, moderate: interfered with activity, severe: prevented daily activity, grade 4: ER visit/hospitalisation. Grade 4 reactions (potentially life threatening) classified by investigator/medically qualified person. Reactions reported as AEs in CRF within 7 days after study vaccination included. Safety population: all participants receiving study intervention and obtaining appropriate informed consent. "Number of Participants Analysed"=participants evaluable for the

endpoint, ''n''=participants evaluable for specified rows. Endpoint was planned to be analysed in participants combined from C2 G2 + C3 G1 and C2 G4 + C3 G2.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	310	301		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (n=309,300)	6.5 (4.0 to 9.8)	4.0 (2.1 to 6.9)		
Redness: Mild (n=309,300)	4.9 (2.7 to 7.9)	2.3 (0.9 to 4.7)		
Redness: Moderate (n=309,300)	1.6 (0.5 to 3.7)	1.7 (0.5 to 3.8)		
Redness: Severe (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Redness: Grade 4 (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Swelling: Any (n=309,300)	7.1 (4.5 to 10.6)	2.7 (1.2 to 5.2)		
Swelling: Mild (n=309,300)	5.8 (3.5 to 9.1)	1.7 (0.5 to 3.8)		
Swelling: Moderate (n=309,300)	1.3 (0.4 to 3.3)	1.0 (0.2 to 2.9)		
Swelling: Severe (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Swelling: Grade 4 (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Pain at the injection site: Any (n=310,301)	76.1 (71.0 to 80.8)	57.1 (51.3 to 62.8)		
Pain at the injection site: Mild (n=310,301)	57.4 (51.7 to 63.0)	48.8 (43.1 to 54.6)		
Pain at the injection site: Moderate (n=310,301)	18.7 (14.5 to 23.5)	8.0 (5.2 to 11.6)		
Pain at the injection site: Severe (n=310,301)	0 (0.0 to 1.2)	0.3 (0.0 to 1.8)		
Pain at the injection site: Grade 4 (n=310,301)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and Group 2): Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination

End point title	Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and Group 2): Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination[35][36]

End point description:

Systemic events recorded in e-diary. Fever: oral temperature>=38 degC, categorised:>=38.0-38.4 degC, >38.4-38.9 degC, >38.9-40.0 degC, >40.0 degC. Fatigue, headache, chills, new/worsened muscle pain, new/worsened joint pain: mild (didn’t interfere activity), moderate (some interference in activity), severe (prevented daily routine activity). Vomiting: mild (1-2 times in 24h), moderate (>2 times in 24h), severe (required IV 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, Grade 4= ER visit/hospitalisation. Grade 4 events classified by investigator/medically qualified person. Systemic events reported as AEs in CRF within 7 days post vaccination. Safety population evaluated. "Number of Participants analysed" (N)= participants evaluable for the endpoint, ''n''=participants evaluable for specified rows. Endpoint planned to be analysed in participants combined from C2G2 + C3G1 and C2G4 + C3G2.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after study vaccination

Notes:

[35] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 + 3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	309	301		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any (n=309,300)	4.9 (2.7 to 7.9)	4.3 (2.3 to 7.3)		
Fever: >=38.0 deg C to 38.4 deg C (n=309,300)	2.9 (1.3 to 5.5)	3.3 (1.6 to 6.0)		
Fever: >38.4 deg C to 38.9 deg C (n=309,300)	1.9 (0.7 to 4.2)	1.0 (0.2 to 2.9)		
Fever: >38.9 deg C to 40.0 deg C (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Fever: >40.0 deg C (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Fatigue: Any (n=309,301)	61.2 (55.5 to 66.6)	38.5 (33.0 to 44.3)		
Fatigue: Mild (n=309,301)	26.9 (22.0 to 32.2)	18.6 (14.4 to 23.5)		
Fatigue: Moderate (n=309,301)	32.4 (27.2 to 37.9)	18.6 (14.4 to 23.5)		
Fatigue: Severe (n=309,301)	1.9 (0.7 to 4.2)	1.3 (0.4 to 3.4)		
Fatigue: Grade 4 (n=309,301)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Headache: Any (n=309,300)	46.6 (40.9 to 52.3)	30.7 (25.5 to 36.2)		
Headache: Mild (n=309,300)	28.2 (23.2 to 33.5)	20.7 (16.2 to 25.7)		
Headache: Moderate (n=309,300)	17.8 (13.7 to 22.5)	10.0 (6.8 to 14.0)		
Headache: Severe (n=309,300)	0.6 (0.1 to 2.3)	0 (0.0 to 1.2)		
Headache: Grade 4 (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Chills: Any (n=309,300)	22.0 (17.5 to 27.0)	12.0 (8.5 to 16.2)		

Chills: Mild (n=309,300)	12.3 (8.9 to 16.5)	7.0 (4.4 to 10.5)		
Chills: Moderate (n=309,300)	9.1 (6.1 to 12.8)	4.7 (2.6 to 7.7)		
Chills: Severe (n=309,300)	0.6 (0.1 to 2.3)	0.3 (0.0 to 1.8)		
Chills: Grade 4 (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Vomiting: Any (n=309,300)	1.9 (0.7 to 4.2)	0.7 (0.1 to 2.4)		
Vomiting: Mild (n=309,300)	1.6 (0.5 to 3.7)	0.7 (0.1 to 2.4)		
Vomiting: Moderate (n=309,300)	0.3 (0.0 to 1.8)	0 (0.0 to 1.2)		
Vomiting: Severe (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Vomiting: Grade 4 (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
Diarrhea: Any (n=309,301)	10.7 (7.5 to 14.7)	9.6 (6.5 to 13.5)		
Diarrhea: Mild (n=309,301)	8.7 (5.8 to 12.5)	7.6 (4.9 to 11.2)		
Diarrhea: Moderate (n=309,301)	1.6 (0.5 to 3.7)	2.0 (0.7 to 4.3)		
Diarrhea: Severe (n=309,301)	0.3 (0.0 to 1.8)	0 (0.0 to 1.2)		
Diarrhea: Grade 4 (n=309,301)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
New or worsened muscle pain: Any (n=309,300)	30.4 (25.3 to 35.9)	18.0 (13.8 to 22.8)		
New or worsened muscle pain: Mild (n=309,300)	15.2 (11.4 to 19.7)	10.0 (6.8 to 14.0)		
New or worsened muscle pain: Moderate (n=309,300)	15.2 (11.4 to 19.7)	8.0 (5.2 to 11.7)		
New or worsened muscle pain: Severe (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
New or worsened muscle pain: Grade 4 (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
New or worsened joint pain: Any (n=309,300)	14.9 (11.1 to 19.4)	12.0 (8.5 to 16.2)		
New or worsened joint pain: Mild (n=309,300)	6.8 (4.3 to 10.2)	6.7 (4.1 to 10.1)		
New or worsened joint pain: Moderate (n=309,300)	8.1 (5.3 to 11.7)	5.3 (3.1 to 8.5)		
New or worsened joint pain: Severe (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		
New or worsened joint pain: Grade 4 (n=309,300)	0 (0.0 to 1.2)	0 (0.0 to 1.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and Group 2): Percentage of Participants With AEs From Study Vaccination Through 1 Month After Study Vaccination

End point title	Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and Group 2): Percentage of Participants With AEs From Study Vaccination Through 1 Month After Study Vaccination[37][38]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. Results excluded local reactions and systemic events data. Safety population included all participants who received the study intervention and where appropriate informed consent was obtained. The endpoint was planned per protocol to be analysed in participants combined from Cohort 2 Group 2 + Cohort 3 Group 1 and Cohort 2 Group 4 + Cohort 3 Group 2.

End point type	Primary

End point timeframe:

From study vaccination through 1 month after study vaccination

Notes:

[37] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	313	306		
Units: Percentage of participants				
number (confidence interval 95%)	6.1 (3.7 to 9.3)	6.9 (4.3 to 10.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and Group 2): Percentage of Participants With SAEs From Study Vaccination Through 6 Months After Study Vaccination

End point title	Cohort 2 (Group 2 and 4) + Cohort 3 (Group 1 and Group 2): Percentage of Participants With SAEs From Study Vaccination Through 6 Months After Study Vaccination[39][40]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. An SAE was an AE that 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 the study intervention and where appropriate informed consent was obtained. The endpoint was planned per protocol to be analysed in participants combined from Cohort 2 Group 2 + Cohort 3 Group 1 and Cohort 2 Group 4 + Cohort 3 Group 2.

End point type	Primary

End point timeframe:

From study vaccination through 6 months after study vaccination

Notes:

[39] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 + 3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	313	306		
Units: Percentage of participants				
number (confidence interval 95%)	0.6 (0.1 to 2.3)	3.3 (1.6 to 5.9)		

Statistical analyses

No statistical analyses for this end point

Primary: GMR of Omicron (BA.4/BA.5)– NTs of BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg C2 G4/C3 G2 Combined in C4591044 Compared to NT of BNT162b2 30 mcg in C4591031– 1 Month After Vaccination Among Participants >55 Years of Age

End point title	GMR of Omicron (BA.4/BA.5)– NTs of BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg C2 G4/C3 G2 Combined in C4591044 Compared to NT of BNT162b2 30 mcg in C4591031– 1 Month After Vaccination Among Participants >55 Years of Age[41]

End point description:

Model based GMT of OMI BA.4/BA.5 NTs induced by BNT162b2 Bivalent 30 mcg groups of C4591044 C2/3 combined and BNT162b2 30 mcg of C4591031 Substudy E in participants >55 years = descriptive data. GMTs and 95% CIs were calculated by exponentiating least square (LS) means and corresponding CI based on analysis of logarithmically transformed NT using linear regression model with terms of baseline NT (log scale) and vaccine group. Assay results below LLOQ=0.5*LLOQ. Model based geometric mean ratio (GMR) = statistical section: OMI BA.4/BA.5 NTs induced 1 month post BNT162b2 Bivalent vaccination in C4591044 to 1 month post BNT162b2 vaccination in C4591031 in participants >55 years. Endpoint was planned to be analysed in participants of C2G4 + C3G2 of C4591044 and BNT162b2 experienced participants of study C4591031 (control arm). Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. "N"=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after study vaccination

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 + 3 reporting groups only.

End point values	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m	BNT162b2 30 mcg: C4591031 Substudy E		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	282	273		
Units: Titer				
geometric mean (confidence interval 95%)	3373.4 (3000.3 to 3793.0)	1160.7 (1030.3 to 1307.7)		

Statistical analyses

Statistical analysis title	C2 (G4)+C3 (G2): >55 Years Vs C4591031 Substudy E

Statistical analysis description:

Superiority based on model-based GMR was declared if the lower limit of the 2-sided 95% CI for the model-based GMR was greater than 1.

Comparison groups	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg) v BNT162b2 30 mcg: C4591031 Substudy E
Number of subjects included in analysis	555
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Model-Based GMR
Point estimate	2.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.45
upper limit	3.44

Primary: Difference in Percentage of Participants With Seroresponse to OMI BA.4/BA.5 for BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg C2 G4/C3 G2 Combined in C4591044 and for BNT162b2 30 mcg in C4591031– 1 Month After Vaccination Among Participants >55 Years of Age

End point title	Difference in Percentage of Participants With Seroresponse to OMI BA.4/BA.5 for BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg C2 G4/C3 G2 Combined in C4591044 and for BNT162b2 30 mcg in C4591031– 1 Month After Vaccination Among Participants >55 Years of Age[42]

End point description:

Seroresponse: achieving >= 4-fold rise in NTs from baseline (before study vaccination). If baseline measurement was below LLOQ, postvaccination measure of >= 4*LLOQ was considered seroresponse. Percentage of participants with seroresponse to OMI BA.4/BA.5 for BNT Bivalent 30 mcg in Study C4591044 [NCT05472038] Cohort 2/3 combined and BNT 30 mcg in Study C4591031 [NCT04955626] Substudy E in participants >55 years presented as descriptive data. Adjusted difference in seroresponse rate to OMI BA.4/BA.5 between BNT 30 mcg 1 month after vaccination in study C4591044 and 1 month after BNT vaccination in study C4591031 in participants >55 years reported in statistical section. Endpoint was planned to be analysed in participants from C2 G4 + C3 G2 and BNT experienced participants >55 years from study C4591031 Substudy E (control arm). Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. "N" = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after study vaccination

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m	BNT162b2 30 mcg: C4591031 Substudy E		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	282	273		
Units: Percentage of participants				
number (confidence interval 95%)	66.7 (60.8 to 72.1)	46.5 (40.5 to 52.6)		

Statistical analyses

Statistical analysis title	C2 (G4)+C3 (G2) Vs C4591031 Sub study E

Statistical analysis description:

Adjusted difference and 2-Sided CI based on the Miettinen and Nurminen method stratified by baseline NT category (< median,>= median) for difference in proportions. The median of baseline NT was calculated based on pooled data in 2 comparator groups.

Comparison groups	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg) v BNT162b2 30 mcg: C4591031 Substudy E
Number of subjects included in analysis	555
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Adjusted Difference in Percentages
Point estimate	26.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.59
upper limit	33.95

Primary: GMR of Omicron (BA.4/BA.5)– NTs of BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg C2 G2/C3 G1 Combined for 18-55 Years Compared to BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg C2 G4/C3 G2 Combined for >55 Years– 1 Month After Vaccination in C4591044

End point title	GMR of Omicron (BA.4/BA.5)– NTs of BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg C2 G2/C3 G1 Combined for 18-55 Years Compared to BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg C2 G4/C3 G2 Combined for >55 Years– 1 Month After Vaccination in C4591044[43]

End point description:

Model based GMT of OMI BA.4/BA.5 NTs induced by BNT Bivalent 30mcg groups of study C4591044 [NCT05472038] Cohort 2/3 combined in participants 18-55 years of age compared to participants >55 years of age are presented as descriptive data. GMTs and 2-sided 95% CIs were calculated by exponentiating LS means and corresponding CIs based on analysis of logarithmically transformed NT using linear regression model with terms of baseline NT (log scale) and vaccine group. Assay results below LLOQ= 0.5*LLOQ. Model based GMR: OMI BA.4/BA.5 NTs induced 1 month after BNT Bivalent vaccination in study C4591044 among participants 18-55 years of age compared to participants >55 years of age is reported in statistical section. Endpoint was planned to be analysed in participants combined from C2 G2 + C3 G1 and C2 G4 + C3 G2. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. "N"= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after study vaccination

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	282	294		
Units: Titer				
geometric mean (confidence interval 95%)	4344.4 (3850.2 to 4902.1)	4254.2 (3779.6 to 4788.4)		

Statistical analyses

Statistical analysis title	C2(G2)+C3(G1) 18-55 Vs C2(G4)+C3(G2) >55:BNT30mcg

Statistical analysis description:

Noninferiority based on model-based GMR was declared if the lower limit of the 2-sided 95% CI for the model-based
GMR is greater than 0.67.

Comparison groups	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg) v C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)
Number of subjects included in analysis	576
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Model-Based GMR
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.16

Primary: Difference in Percentage of Participants With Seroresponse to OMI BA.4/BA.5 of BNT162b2 30mcg Cohort 2 (Group 2)/ Cohort 3 (Group 1) 18-55 Years of age and Cohort 2 (Group 4)/ Cohort 3 (Group 2) >55 Years of age– 1 Month After Vaccination in C4591044

End point title	Difference in Percentage of Participants With Seroresponse to OMI BA.4/BA.5 of BNT162b2 30mcg Cohort 2 (Group 2)/ Cohort 3 (Group 1) 18-55 Years of age and Cohort 2 (Group 4)/ Cohort 3 (Group 2) >55 Years of age– 1 Month After Vaccination in C4591044[44]

End point description:

Seroresponse: achieving >= 4-fold rise in NTs from baseline (before study vaccination). If baseline measurement was below LLOQ, postvaccination measure of >= 4*LLOQ was considered seroresponse. Percentage of participants with seroresponse to OMI BA.4/BA.5 for BNT162b2 Bivalent 30 mcg in Study C4591044 [NCT05472038] Cohort 2/3 combined in participants 18-55 years of age compared to participants >55 years of age are presented as descriptive data. Adjusted difference in seroresponse rate to OMI BA.4/BA.5 between BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg 1 month after vaccination in study C4591044 in participants 18-55 years of age compared to participants >55 years of age is reported in statistical section. Endpoint was planned to be analysed in participants combined from C2 G2 + C3 G1 and C2 G4 + C3 G2. EIP was analysed with or without evidence of infection up to 1 month post study vaccination. "N"=participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after study vaccination

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	294	282		
Units: Percentage of participants				
number (confidence interval 95%)	61.2 (55.4 to 66.8)	66.7 (60.8 to 72.1)		

Statistical analyses

Statistical analysis title	C2(G2)+C3(G1) 18-55 Vs C2(G4)+C3(G2) >55:BNT30mcg

Statistical analysis description:

Noninferiority based on seroresponse was declared if the lower limit of the 2-sided 95% CI for the difference in percentages of participants with seroresponse is >-10%.

Comparison groups	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg) v C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg)
Number of subjects included in analysis	576
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Adjusted Difference in Percentages
Point estimate	-3.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.68
upper limit	3.63

Primary: Cohort 2: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and Reference Strain NTs at Baseline

End point title	Cohort 2: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and Reference Strain NTs at Baseline[45][46]

End point description:

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). This endpoint was planned per protocol to be analysed in participants from Cohort 2 and control arms of BNT162b2 Bivalent (WT/OMI BA.1) experienced participants 12-17 years of age, 18-55 years of age and >55 years of age from study C4591031 Substudy E. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. Here, "Number of Participants Analysed" signifies participants evaluable for this endpoint and ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

At baseline (before study vaccination)

Notes:

[45] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	105	102	98	95
Units: Titer				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	1105.8 (835.1 to 1464.3)	607.0 (433.2 to 850.6)	582.4 (397.6 to 853.1)	338.3 (238.1 to 480.7)
OMI BA.1(n=105,102,96,100,98,100,97,102,	1190.5 (921.8 to 1537.5)	653.1 (466.3 to 914.8)	581.2 (392.5 to 860.6)	346.0 (240.0 to 498.9)
Reference(n=105,101,98,100,100,100,100,101,95)	6863.3 (5587.8 to 8430.1)	4287.4 (3245.6 to 5663.8)	4324.8 (3099.0 to 6035.4)	2349.0 (1693.4 to 3258.4)

End point values	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)	18-55 Years (BNT162b2 Bivalent(WT/OMI BA.1)30mcg):C4591031 SSE	18-55 Years(BNT162b2 Bivalent[WT/OMI BA.1] 60mcg):C4591	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30mcg):C4591031 SSE
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	102	100	100	100
Units: Titer				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	301.9 (215.6 to 422.8)	151.5 (113.4 to 202.3)	420.6 (312.7 to 565.6)	225.4 (164.1 to 309.6)

OMI BA.1(n=105,102,96,100,98,100,97,102,	365.1 (260.8 to 511.1)	194.6 (142.4 to 266.0)	492.4 (351.5 to 689.9)	316.3 (215.9 to 463.4)
Reference(n=105,101,98,100,100,100,100,101,95)	2643.1 (1990.8 to 3509.1)	1338.4 (1056.9 to 1695.1)	3933.2 (3058.0 to 5058.9)	1985.7 (1510.1 to 2611.0)

End point values	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 60mcg):C4591031 SSE			
Subject group type	Subject analysis set			
Number of subjects analysed	100			
Units: Titer				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	249.6 (180.5 to 345.2)			
OMI BA.1(n=105,102,96,100,98,100,97,102,	285.6 (195.8 to 416.5)			
Reference(n=105,101,98,100,100,100,100,101,95)	2509.3 (1906.8 to 3302.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and Reference Strain NTs at 1 Month

End point title	Cohort 2: GMT of SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and Reference Strain NTs at 1 Month[47][48]

End point description:

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). This endpoint was planned to be analysed in participants from Cohort 2 and control arms of BNT162b2 experienced participants 12-17 years of age, 18-55 years of age and >55 years of age from study C4591031 substudy E. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. Here, "Number of Participants Analysed" signifies participants evaluable for this endpoint and ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the study vaccination

Notes:

[47] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	105	102	99	95
Units: Titer				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=105,102,99,100,100,100,100,102,95)	8212.8 (6807.3 to 9908.7)	5454.2 (4292.2 to 6930.8)	5472.8 (3930.9 to 7619.6)	2839.0 (2150.0 to 3748.8)
OMI BA.1(n=105,101,99,100,99,100,100,102,95)	6687.6 (5617.0 to 7962.3)	4112.4 (3263.6 to 5181.9)	4264.0 (3247.9 to 5597.9)	2407.2 (1884.9 to 3074.2)
Reference(n=105,102,99,99,100,100,99,102,95)	23641.3 (20473.1 to 27299.8)	18614.7 (15754.1 to 21994.7)	22982.3 (18524.3 to 28513.3)	11919.3 (9839.1 to 14439.3)

End point values	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)	18-55 Years (BNT162b2 Bivalent(WT/OMI BA.1)30mcg):C4591031 SSE	18-55 Years(BNT162b2 Bivalent[WT/OMI BA.1] 60mcg):C4591	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30mcg):C4591031 SSE
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	102	100	100	100
Units: Titer				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=105,102,99,100,100,100,100,102,95)	3019.8 (2327.5 to 3918.0)	1072.0 (816.1 to 1408.1)	2525.2 (1970.5 to 3236.0)	943.4 (733.4 to 1213.6)
OMI BA.1(n=105,101,99,100,99,100,100,102,95)	2656.1 (2089.6 to 3376.3)	1819.0 (1401.6 to 2360.6)	3143.8 (2486.9 to 3974.1)	1617.7 (1274.7 to 2053.0)
Reference(n=105,102,99,99,100,100,99,102,95)	12103.8 (9992.0 to 14662.0)	6913.9 (5690.4 to 8400.5)	14685.8 (12301.1 to 17532.8)	7128.6 (5954.4 to 8534.3)

End point values	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 60mcg):C4591031 SSE			
Subject group type	Subject analysis set			
Number of subjects analysed	100			
Units: Titer				
geometric mean (confidence interval 95%)				

OMI BA.4/BA.5(n=105,102,99,100,100,100,100,102,95)	1520.9 (1196.0 to 1934.0)			
OMI BA.1(n=105,101,99,100,99,100,100,102,95)	1936.9 (1489.4 to 2518.8)			
Reference(n=105,102,99,99,100,100,99,102,95)	11106.5 (8956.8 to 13772.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination

End point title	Cohort 2: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination[49][50]

End point description:

GMFR from before the study vaccination to 1 month after the study vaccination for each strain-specific neutralising titer 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. This endpoint was planned to be analysed in participants from Cohort 2 and control arms of BNT162b2 experienced participants 12-17 years of age, 18-55 years of age and >55 years of age from study C4591031 substudy E. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. Here, "Number of Participants Analysed" signifies participants evaluable for this endpoint and ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

From before the study vaccination to 1 month after the study vaccination

Notes:

[49] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	105	102	98	95
Units: Fold rise				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	7.6 (6.0 to 9.6)	9.0 (6.9 to 11.8)	9.3 (6.8 to 12.8)	8.4 (6.3 to 11.1)

OMI BA.1(n=105,101,96,100,97,100,97,102,	5.6 (4.6 to 6.9)	6.3 (4.9 to 8.2)	7.3 (5.4 to 9.7)	7.0 (5.3 to 9.1)
Reference(n=105,101,98,99,100,100,99,101,95)	3.4 (2.9 to 4.1)	4.3 (3.4 to 5.5)	5.4 (4.0 to 7.1)	5.1 (3.9 to 6.6)

End point values	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)	18-55 Years (BNT162b2 Bivalent(WT/OMI BA.1)30mcg):C4591031 SSE	18-55 Years(BNT162b2 Bivalent[WT/OMI BA.1] 60mcg):C4591	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30mcg):C4591031 SSE
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	102	100	100	100
Units: Fold rise				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	10.0 (7.5 to 13.3)	7.1 (5.7 to 8.9)	6.0 (4.7 to 7.7)	4.2 (3.4 to 5.2)
OMI BA.1(n=105,101,96,100,97,100,97,102,	7.3 (5.6 to 9.5)	9.3 (7.3 to 12.0)	6.4 (4.9 to 8.3)	5.1 (3.9 to 6.6)
Reference(n=105,101,98,99,100,100,99,101,95)	4.6 (3.7 to 5.8)	5.2 (4.3 to 6.3)	3.7 (3.0 to 4.6)	3.6 (2.9 to 4.4)

End point values	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 60mcg):C4591031 SSE			
Subject group type	Subject analysis set			
Number of subjects analysed	100			
Units: Fold rise				
geometric mean (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	6.1 (4.7 to 7.9)			
OMI BA.1(n=105,101,96,100,97,100,97,102,	6.8 (5.1 to 9.1)			
Reference(n=105,101,98,99,100,100,99,101,95)	4.4 (3.5 to 5.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and Reference Strain– NTs at 1 Month After Study Vaccination

End point title	Cohort 2: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.1 and BA.4/BA.5) and

	Reference Strain– NTs at 1 Month After Study Vaccination[51][52]

End point description:

Seroresponse: achieving >= 4-fold rise in NTs from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination measure of >= 4*LLOQ was considered a seroresponse. Percentage of participants with seroresponse to OMI BA.4/BA.5 for BNT162b2 Bivalent 30 and 60 mcg in Study C4591044 [NCT05472038] Cohort 2 and BNT162b2 30 mcg in Study C4591031 [NCT04955626] Substudy E among participants 12-17 years of age, 18-55 and >55 years of age are presented as descriptive data. This endpoint was planned to be analysed in participants from Cohort 2 and control arms of BNT162b2 experienced participants 18-55 years of age and >55 years of age from study C4591031 substudy E. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. Here, "Number of Participants Analysed" signifies participants evaluable for this endpoint and ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the study vaccination

Notes:

[51] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2 reporting groups only.

End point values	C2 G1:12-17 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)	C2G3: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60mcg)	C2 G5: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 60 mcg)	C2G2: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	105	102	98	95
Units: Percentage of participants				
number (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	66.3 (56.4 to 75.3)	66.7 (56.6 to 75.7)	63.3 (52.9 to 72.8)	64.2 (53.7 to 73.8)
OMI BA.1(n=105,101,96,100,97,100,97,102,	63.8 (53.9 to 73.0)	60.4 (50.2 to 70.0)	65.6 (55.2 to 75.0)	54.7 (44.2 to 65.0)
Reference(n=105,101,98,99,100,100,99,101,95)	41.0 (31.5 to 51.0)	51.5 (41.3 to 61.6)	55.1 (44.7 to 65.2)	49.5 (39.1 to 59.9)

End point values	C2 G4: >55 Years (BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30 mcg)	18-55 Years (BNT162b2 Bivalent(WT/OMI BA.1)30mcg):C4591031 SSE	18-55 Years(BNT162b2 Bivalent[WT/OMI BA.1] 60mcg):C4591	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30mcg):C4591031 SSE
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	102	100	100	100
Units: Percentage of participants				
number (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	71.3 (61.4 to 79.9)	62.0 (51.7 to 71.5)	59.0 (48.7 to 68.7)	37.4 (27.9 to 47.7)
OMI BA.1(n=105,101,96,100,97,100,97,102,	63.7 (53.6 to 73.0)	75.0 (65.3 to 83.1)	56.7 (46.3 to 66.7)	52.0 (41.8 to 62.1)

Reference(n=105,101,98,99,100,100,99,101,95)	50.5 (40.4 to 60.0)	59.6 (49.3 to 69.3)	41.0 (31.3 to 51.3)	41.0 (31.3 to 51.3)

End point values	>55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 60mcg):C4591031 SSE			
Subject group type	Subject analysis set			
Number of subjects analysed	100			
Units: Percentage of participants				
number (confidence interval 95%)				
OMI BA.4/BA.5(n=104,102,98,100,100,99,1	53.0 (42.8 to 63.1)			
OMI BA.1(n=105,101,96,100,97,100,97,102,	58.8 (48.3 to 68.7)			
Reference(n=105,101,98,99,100,100,99,101,95)	44.4 (34.5 to 54.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination

End point title	Cohort 4: Percentage of Participants Reporting Local Reactions Within 7 Days After Study Vaccination[53][54]

End point description:

Local reactions were recorded by participants in e-diary. Local reactions: redness, swelling, pain at injection site. Redness and swelling were graded as mild: > 2.0-5.0 cm, moderate: >5.0-10.0 cm, severe: >10.0 cm, grade 4: necrosis or exfoliative dermatitis (redness), necrosis (swelling). Pain at injection site was graded as mild: did not interfere with daily activity, moderate: interfered with daily activity, severe: prevented daily activity, grade 4: ER visit or hospitalisation. Grade 4 reactions (potentially life threatening) were classified by investigator/medically qualified person. Local reactions reported as AEs in CRF within 7 days after study vaccination were reported. Safety population: all participants receiving study intervention and obtaining informed consent. Here, "Number of Participants Analysed"= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after study vaccination

Notes:

[53] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	61	60	60
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	4.8 (1.0 to 13.5)	3.3 (0.4 to 11.3)	5.0 (1.0 to 13.9)	1.7 (0.0 to 8.9)
Redness: Mild	3.2 (0.4 to 11.2)	3.3 (0.4 to 11.3)	5.0 (1.0 to 13.9)	1.7 (0.0 to 8.9)
Redness: Moderate	1.6 (0.0 to 8.7)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Redness: Severe	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Redness: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Swelling: Any	1.6 (0.0 to 8.7)	3.3 (0.4 to 11.3)	6.7 (1.8 to 16.2)	3.3 (0.4 to 11.5)
Swelling: Mild	0 (0.0 to 5.8)	0 (0.0 to 5.9)	6.7 (1.8 to 16.2)	3.3 (0.4 to 11.5)
Swelling: Moderate	1.6 (0.0 to 8.7)	3.3 (0.4 to 11.3)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Swelling: Severe	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Swelling: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Pain at injection site: Any	85.5 (74.2 to 93.1)	88.5 (77.8 to 95.3)	76.7 (64.0 to 86.6)	76.7 (64.0 to 86.6)
Pain at injection site: Mild	64.5 (51.3 to 76.3)	65.6 (52.3 to 77.3)	68.3 (55.0 to 79.7)	61.7 (48.2 to 73.9)
Pain at injection site: Moderate	21.0 (11.7 to 33.2)	21.3 (11.9 to 33.7)	8.3 (2.8 to 18.4)	15.0 (7.1 to 26.6)
Pain at injection site: Severe	0 (0.0 to 5.8)	1.6 (0.0 to 8.8)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Pain at injection site: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	63			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	1.6 (0.0 to 8.5)			
Redness: Mild	1.6 (0.0 to 8.5)			
Redness: Moderate	0 (0.0 to 5.7)			
Redness: Severe	0 (0.0 to 5.7)			
Redness: Grade 4	0 (0.0 to 5.7)			
Swelling: Any	3.2 (0.4 to 11.0)			
Swelling: Mild	3.2 (0.4 to 11.0)			
Swelling: Moderate	0 (0.0 to 5.7)			

Swelling: Severe	0 (0.0 to 5.7)			
Swelling: Grade 4	0 (0.0 to 5.7)			
Pain at injection site: Any	84.1 (72.7 to 92.1)			
Pain at injection site: Mild	68.3 (55.3 to 79.4)			
Pain at injection site: Moderate	15.9 (7.9 to 27.3)			
Pain at injection site: Severe	0 (0.0 to 5.7)			
Pain at injection site: Grade 4	0 (0.0 to 5.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination

End point title	Cohort 4: Percentage of Participants Reporting Systemic Events Within 7 Days After Study Vaccination[55][56]

End point description:

Systemic events were recorded by participants in e-diary. Fever: oral temperature >= 38 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 or worsened muscle pain and new or 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 IV 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, Grade 4= ER visit or hospitalisation. Grade 4 events were classified by investigator or medically qualified person. Systemic events reported as AEs in CRF within 7 days after vaccination are included. Safety population= participants receiving study intervention and obtaining informed consent. "Number of Participants Analysed"= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after study vaccination

Notes:

[55] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	61	60	60
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	6.5 (1.8 to 15.7)	6.6 (1.8 to 15.9)	10.0 (3.8 to 20.5)	5.0 (1.0 to 13.9)

Fever: >=38.0 deg C to 38.4 deg C	3.2 (0.4 to 11.2)	6.6 (1.8 to 15.9)	5.0 (1.0 to 13.9)	5.0 (1.0 to 13.9)
Fever: >38.4 deg C to 38.9 deg C	3.2 (0.4 to 11.2)	0 (0.0 to 5.9)	3.3 (0.4 to 11.5)	0 (0.0 to 6.0)
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 5.8)	0 (0.0 to 5.9)	1.7 (0.0 to 8.9)	0 (0.0 to 6.0)
Fever: >40.0 deg C	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Fatigue: Any	61.3 (48.1 to 73.4)	63.9 (50.6 to 75.8)	73.3 (60.3 to 83.9)	66.7 (53.3 to 78.3)
Fatigue: Mild	25.8 (15.5 to 38.5)	29.5 (18.5 to 42.6)	38.3 (26.1 to 51.8)	35.0 (23.1 to 48.4)
Fatigue: Moderate	35.5 (23.7 to 48.7)	34.4 (22.7 to 47.7)	33.3 (21.7 to 46.7)	30.0 (18.8 to 43.2)
Fatigue: Severe	0 (0.0 to 5.8)	0 (0.0 to 5.9)	1.7 (0.0 to 8.9)	1.7 (0.0 to 8.9)
Fatigue: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Headache: Any	59.7 (46.4 to 71.9)	36.1 (24.2 to 49.4)	41.7 (29.1 to 55.1)	46.7 (33.7 to 60.0)
Headache: Mild	38.7 (26.6 to 51.9)	16.4 (8.2 to 28.1)	23.3 (13.4 to 36.0)	23.3 (13.4 to 36.0)
Headache: Moderate	17.7 (9.2 to 29.5)	19.7 (10.6 to 31.8)	18.3 (9.5 to 30.4)	21.7 (12.1 to 34.2)
Headache: Severe	3.2 (0.4 to 11.2)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	1.7 (0.0 to 8.9)
Headache: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Chills: Any	22.6 (12.9 to 35.0)	18.0 (9.4 to 30.0)	28.3 (17.5 to 41.4)	13.3 (5.9 to 24.6)
Chills: Mild	11.3 (4.7 to 21.9)	11.5 (4.7 to 22.2)	18.3 (9.5 to 30.4)	8.3 (2.8 to 18.4)
Chills: Moderate	11.3 (4.7 to 21.9)	6.6 (1.8 to 15.9)	10.0 (3.8 to 20.5)	5.0 (1.0 to 13.9)
Chills: Severe	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Chills: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Vomiting: Any	0 (0.0 to 5.8)	1.6 (0.0 to 8.8)	3.3 (0.4 to 11.5)	5.0 (1.0 to 13.9)
Vomiting: Mild	0 (0.0 to 5.8)	0 (0.0 to 5.9)	3.3 (0.4 to 11.5)	1.7 (0.0 to 8.9)
Vomiting: Moderate	0 (0.0 to 5.8)	1.6 (0.0 to 8.8)	0 (0.0 to 6.0)	3.3 (0.4 to 11.5)
Vomiting: Severe	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Vomiting: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Diarrhea: Any	12.9 (5.7 to 23.9)	6.6 (1.8 to 15.9)	16.7 (8.3 to 28.5)	16.7 (8.3 to 28.5)
Diarrhea: Mild	9.7 (3.6 to 19.9)	6.6 (1.8 to 15.9)	15.0 (7.1 to 26.6)	13.3 (5.9 to 24.6)
Diarrhea: Moderate	3.2 (0.4 to 11.2)	0 (0.0 to 5.9)	1.7 (0.0 to 8.9)	3.3 (0.4 to 11.5)
Diarrhea: Severe	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
Diarrhea: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
New or worsened muscle pain: Any	25.8 (15.5 to 38.5)	21.3 (11.9 to 33.7)	45.0 (32.1 to 58.4)	30.0 (18.8 to 43.2)
New or worsened muscle pain: Mild	19.4 (10.4 to 31.4)	8.2 (2.7 to 18.1)	23.3 (13.4 to 36.0)	11.7 (4.8 to 22.6)
New or worsened muscle pain: Moderate	6.5 (1.8 to 15.7)	11.5 (4.7 to 22.2)	21.7 (12.1 to 34.2)	18.3 (9.5 to 30.4)
New or worsened muscle pain: Severe	0 (0.0 to 5.8)	1.6 (0.0 to 8.8)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
New or worsened muscle pain: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
New or worsened joint pain: Any	14.5 (6.9 to 25.8)	14.8 (7.0 to 26.2)	5.0 (1.0 to 13.9)	13.3 (5.9 to 24.6)
New or worsened joint pain: Mild	9.7 (3.6 to 19.9)	6.6 (1.8 to 15.9)	0 (0.0 to 6.0)	3.3 (0.4 to 11.5)

New or worsened joint pain: Moderate	4.8 (1.0 to 13.5)	8.2 (2.7 to 18.1)	5.0 (1.0 to 13.9)	10.0 (3.8 to 20.5)
New or worsened joint pain: Severe	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)
New or worsened joint pain: Grade 4	0 (0.0 to 5.8)	0 (0.0 to 5.9)	0 (0.0 to 6.0)	0 (0.0 to 6.0)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	63			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	9.5 (3.6 to 19.6)			
Fever: >=38.0 deg C to 38.4 deg C	4.8 (1.0 to 13.3)			
Fever: >38.4 deg C to 38.9 deg C	1.6 (0.0 to 8.5)			
Fever: >38.9 deg C to 40.0 deg C	3.2 (0.4 to 11.0)			
Fever: >40.0 deg C	0 (0.0 to 5.7)			
Fatigue: Any	54.0 (40.9 to 66.6)			
Fatigue: Mild	17.5 (9.1 to 29.1)			
Fatigue: Moderate	34.9 (23.3 to 48.0)			
Fatigue: Severe	1.6 (0.0 to 8.5)			
Fatigue: Grade 4	0 (0.0 to 5.7)			
Headache: Any	39.7 (27.6 to 52.8)			
Headache: Mild	22.2 (12.7 to 34.5)			
Headache: Moderate	17.5 (9.1 to 29.1)			
Headache: Severe	0 (0.0 to 5.7)			
Headache: Grade 4	0 (0.0 to 5.7)			
Chills: Any	19.0 (10.2 to 30.9)			
Chills: Mild	12.7 (5.6 to 23.5)			
Chills: Moderate	6.3 (1.8 to 15.5)			
Chills: Severe	0 (0.0 to 5.7)			
Chills: Grade 4	0 (0.0 to 5.7)			
Vomiting: Any	1.6 (0.0 to 8.5)			
Vomiting: Mild	1.6 (0.0 to 8.5)			
Vomiting: Moderate	0 (0.0 to 5.7)			
Vomiting: Severe	0 (0.0 to 5.7)			
Vomiting: Grade 4	0 (0.0 to 5.7)			
Diarrhea: Any	12.7 (5.6 to 23.5)			

Diarrhea: Mild	11.1 (4.6 to 21.6)			
Diarrhea: Moderate	1.6 (0.0 to 8.5)			
Diarrhea: Severe	0 (0.0 to 5.7)			
Diarrhea: Grade 4	0 (0.0 to 5.7)			
New or worsened muscle pain: Any	27.0 (16.6 to 39.7)			
New or worsened muscle pain: Mild	12.7 (5.6 to 23.5)			
New or worsened muscle pain: Moderate	14.3 (6.7 to 25.4)			
New or worsened muscle pain: Severe	0 (0.0 to 5.7)			
New or worsened muscle pain: Grade 4	0 (0.0 to 5.7)			
New or worsened joint pain: Any	17.5 (9.1 to 29.1)			
New or worsened joint pain: Mild	7.9 (2.6 to 17.6)			
New or worsened joint pain: Moderate	9.5 (3.6 to 19.6)			
New or worsened joint pain: Severe	0 (0.0 to 5.7)			
New or worsened joint pain: Grade 4	0 (0.0 to 5.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: Percentage of Participants With AEs From Study Vaccination Through 1 Month After Study Vaccination

End point title	Cohort 4: Percentage of Participants With AEs From Study Vaccination Through 1 Month After Study Vaccination[57][58]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. Results excluded local reactions and systemic events data. Safety population included all participants who received the study intervention and where appropriate informed consent was obtained.

End point type	Primary

End point timeframe:

From study vaccination through 1 month after study vaccination

Notes:

[57] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	62	60	60

Units: Percentage of participants				
number (confidence interval 95%)	8.1 (2.7 to 17.8)	9.7 (3.6 to 19.9)	1.7 (0.0 to 8.9)	1.7 (0.0 to 8.9)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	63			
Units: Percentage of participants				
number (confidence interval 95%)	1.6 (0.0 to 8.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: Percentage of Participants With SAEs From Study Vaccination Through 6 Months After Study Vaccination

End point title	Cohort 4: Percentage of Participants With SAEs From Study Vaccination Through 6 Months After Study Vaccination[59][60]

End point description:

An AE was any untoward medical occurrence in a participant temporally associated with the use of study intervention, whether or not considered related to the study intervention. An SAE was an AE that 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 the study intervention and where appropriate informed consent was obtained.

End point type	Primary

End point timeframe:

From study vaccination through 6 months after study vaccination

Notes:

[59] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	62	60	60
Units: Percentage of participants				
number (confidence interval 95%)	1.6 (0.0 to 8.7)	0 (0.0 to 5.8)	0 (0.0 to 6.0)	0 (0.0 to 6.0)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	63			
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 5.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: GMT of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain NTs at 1 Month- Participants With or Without Evidence of Infection

End point title	Cohort 4: GMT of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain NTs at 1 Month- Participants With or Without Evidence of Infection[61][62]

End point description:

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). Evaluable immunogenicity population included all eligible randomised/assigned participants who received the study intervention to which they were randomised/assigned, had at least 1 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. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the study vaccination

Notes:

[61] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	61	57	56
Units: Titer				
geometric mean (confidence interval 95%)				

Omicron BA.4/BA.5 (n=61,61,57,56,61)	4850.5 (3677.1 to 6398.3)	4854.3 (3713.9 to 6344.9)	4944.6 (3620.3 to 6753.1)	5180.6 (3724.6 to 7205.8)
Reference strain (n=61,61,57,56,61)	10455.0 (8150.7 to 13410.8)	11360.0 (9408.3 to 13716.6)	10840.2 (8475.3 to 13865.0)	12303.8 (9728.6 to 15560.5)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.4/BA.5 (n=61,61,57,56,61)	5455.6 (4214.2 to 7062.8)			
Reference strain (n=61,61,57,56,61)	11164.3 (8729.0 to 14279.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: GMT of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain NTs at Baseline

End point title	Cohort 4: GMT of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain NTs at Baseline[63][64]

End point description:

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). Evaluable immunogenicity population included all eligible randomised/assigned participants who received the study intervention to which they were randomised/assigned, had at least 1 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. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

At baseline (before study vaccination)

Notes:

[63] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	61	57	56
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.4/BA.5 (n= 61,61,57,56,61)	1332.5 (909.2 to 1953.0)	1313.6 (922.6 to 1870.2)	1352.0 (876.0 to 2086.8)	1320.1 (869.8 to 2003.6)
Reference strain (n= 61,61,57,56,61)	3445.5 (2465.4 to 4815.3)	4907.1 (3753.0 to 6416.1)	4613.6 (3474.3 to 6126.4)	4395.7 (3244.1 to 5956.3)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.4/BA.5 (n= 61,61,57,56,61)	1203.9 (796.5 to 1819.6)			
Reference strain (n= 61,61,57,56,61)	4318.6 (3196.1 to 5835.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: GMFR of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination- Participants With or Without Evidence of Infection

End point title	Cohort 4: GMFR of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination- Participants With or Without Evidence of Infection[65][66]

End point description:

GMFR from before study vaccination to 1 month after study vaccination for each strain-specific neutralising titer was reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating mean logarithm of fold rises and corresponding CIs (based on student-t distribution). Assay results below LLOQ were set to 0.5*LLOQ in analysis. EIP included all eligible randomised/assigned participants who received study intervention to which they were randomised/assigned, had at least 1 valid and determinate immunogenicity result from blood sample collected within 28-42 days after study vaccination, and had no other important protocol deviations as determined by clinician. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after study vaccination

Notes:

[65] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	61	57	56
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron BA.4/BA.5 (n=61,61,57,56,61)	3.6 (2.7 to 4.8)	3.7 (2.7 to 5.0)	3.7 (2.8 to 4.7)	3.9 (2.9 to 5.3)
Reference strain (n=61,61,57,56,61)	3.0 (2.3 to 4.0)	2.3 (1.8 to 3.0)	2.3 (1.9 to 2.8)	2.8 (2.1 to 3.7)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron BA.4/BA.5 (n=61,61,57,56,61)	4.5 (3.3 to 6.2)			
Reference strain (n=61,61,57,56,61)	2.6 (2.1 to 3.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 4: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs at 1 Month After Study Vaccination- Participants With or Without Evidence of Infection

End point title	Cohort 4: Percentage of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs at 1 Month After Study Vaccination- Participants With or Without Evidence of Infection[67][68]

End point description:

Seroresponse was defined as achieving >= 4-fold rise in NTs from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination measure of >= 4*LLOQ was considered a seroresponse. Percentage of participants with seroresponse to OMI BA.4/BA.5, XBB.1.5 and reference strain NTs at 1 month after study vaccination are presented as descriptive data. EIP included all eligible randomised/assigned participants who received study intervention to which they were randomised/assigned, had at least 1 valid and determinate immunogenicity result from blood sample collected within 28-42 days after study vaccination, and had no other important protocol deviations as determined by clinician. Analysis was performed in participants with or without evidence of infection up to 1 month post study vaccination. Here, ''n'' signifies participants evaluable for specified rows.

End point type	Primary

End point timeframe:

1 month after the study vaccination

Notes:

[67] - 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: Per protocol, only descriptive data was planned to be analysed for this endpoint.

[68] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 4 reporting groups only.

End point values	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	61	57	56
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron BA.4/BA.5 (n=61,61,57,56,61)	42.6 (30.0 to 55.9)	41.0 (28.6 to 54.3)	42.1 (29.1 to 55.9)	39.3 (26.5 to 53.2)
Reference strain (n=61,61,57,56,61)	37.7 (25.6 to 51.0)	27.9 (17.1 to 40.8)	22.8 (12.7 to 35.8)	26.8 (15.8 to 40.3)

End point values	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30			
Subject group type	Reporting group			
Number of subjects analysed	61			
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron BA.4/BA.5 (n=61,61,57,56,61)	44.3 (31.5 to 57.6)			
Reference strain (n=61,61,57,56,61)	29.5 (18.5 to 42.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: GMR of the Reference-Strain– NTs of BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg Cohort 2 (Group 4)/ Cohort 3 (Group 2) Combined in C4591044 Compared to NT of BNT162b2 30mcg in C4591031 >55 Years of age– 1 Month After Vaccination

End point title	GMR of the Reference-Strain– NTs of BNT162b2 Bivalent [WT/OMI BA.4/BA.5] 30mcg Cohort 2 (Group 4)/ Cohort 3 (Group 2) Combined in C4591044 Compared to NT of BNT162b2 30mcg in C4591031 >55 Years of age– 1 Month After Vaccination[69]

End point description:

Model based GMT of reference strain NTs induced by BNT Bivalent 30mcg groups of study C4591044 [NCT05472038] Cohort 2/3 combined; BNT 30mcg of study C4591031 [NCT04955626] Substudy E in participants >55 years presented as descriptive data. GMT and 2-sided 95% CI calculated by exponentiating LS means and corresponding CI based on analysis of logarithmically transformed NT using linear regression model with terms of baseline NT (log scale) and vaccine group. Assay results below LLOQ=0.5*LLOQ. Model based GMR: OMI BA.4/BA.5 NTs induced 1 month after BNT Bivalent vaccination in study C4591044 to 1 month after BNT vaccination in study C4591031 in participants >55 years reported in statistical section. Endpoint was planned per protocol to analyse in participants from C2 G4+C3 G2 and BNT experienced participants >55 years from study C4591031 Substudy E (control arm). Analysis= EIP with/without evidence of infection up to 1 month post vaccination. "N"= participants evaluable for endpoint.

End point type	Secondary

End point timeframe:

1 month after study vaccination

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m	BNT162b2 30 mcg: C4591031 Substudy E		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	284	287		
Units: Titer				
geometric mean (confidence interval 95%)	15361.6 (14082.9 to 16756.5)	11117.2 (10196.4 to 12121.1)		

Statistical analyses

Statistical analysis title	C2 (G2)+C3 (G1) Vs C4591031 Sub study E

Statistical analysis description:

Noninferiority based on model-based GMR was declared if the lower limit of the 2-sided 95% CI for the model-based GMR is greater than 0.67.

Comparison groups	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30mcg) v BNT162b2 30 mcg: C4591031 Substudy E

Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Model-Based GMR
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.22
upper limit	1.56

Secondary: Cohort 2/Group 2 + Cohort 3/Group 1 Combined and Cohort 2/Group 4 + Cohort 3/Group 2 Combined: GMT of SARS-CoV-2 Omicron BA.4/BA.5 and Reference Strain NT at Baseline and 1 Month After the Study Vaccination

End point title	Cohort 2/Group 2 + Cohort 3/Group 1 Combined and Cohort 2/Group 4 + Cohort 3/Group 2 Combined: GMT of SARS-CoV-2 Omicron BA.4/BA.5 and Reference Strain NT at Baseline and 1 Month After the Study Vaccination[70]

End point description:

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). This endpoint was planned per protocol to be analysed in participants from Cohort 2 Group 2 + Cohort 3 Group 1, Cohort 2 Group 4 + Cohort 3 Group 2 and control arm of BNT162b2 experienced participants >55 years of age from study C4591031 Substudy E. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. Here, "Number of Participants Analysed": participants evaluable for this endpoint and ''n'' signifies participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

At baseline and 1 month after study vaccination

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m	BNT162b2 30 mcg: C4591031 Substudy E	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	297	286	289	
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron BA.4/BA.5 at baseline(n=294,284,278)	569.6 (471.4 to 688.2)	458.2 (365.2 to 574.8)	205.4 (170.3 to 247.7)	
Omicron BA.4/BA.5 at 1 Month(n=297,284,282)	4455.9 (3851.7 to 5154.8)	4158.1 (3554.8 to 4863.8)	938.9 (802.3 to 1098.8)	
Reference strain at baseline(n=296,284,287)	4017.3 (3430.7 to 4704.1)	3690.6 (3082.2 to 4419.0)	2699.9 (2291.7 to 3180.9)	

Reference strain at 1 Month(n=296,286,289)	16323.3 (14686.5 to 18142.6)	16250.1 (14499.2 to 18212.4)	10415.5 (9366.7 to 11581.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2/Group 2 + Cohort 3/Group 1 Combined and Cohort 2/Group 4 + Cohort 3/Group 2 Combined: Percentages of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs at 1 Month After the Study Vaccination

End point title	Cohort 2/Group 2 + Cohort 3/Group 1 Combined and Cohort 2/Group 4 + Cohort 3/Group 2 Combined: Percentages of Participants With Seroresponse to SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs at 1 Month After the Study Vaccination[71]

End point description:

Seroresponse was defined as achieving >= 4-fold rise in NTs from baseline (before study vaccination). If baseline measurement was below LLOQ, postvaccination measure of >= 4*LLOQ was considered seroresponse. Percentage of participants with seroresponse to OMI BA.4/BA.5 for BNT162b2 Bivalent 30 mcg in Study C4591044 [NCT05472038] Cohort 2/3 combined and BNT162b2 30 mcg in Study C4591031 [NCT04955626] Substudy E among participants >55 years of age are presented as descriptive data. This endpoint was planned per protocol to be analysed in participants from Cohort 2 Group 2 + Cohort 3 Group 1, Cohort 2 Group 4 + Cohort 3 Group 2 and control arm of BNT162b2 experienced participants >55 years of age from study C4591031 Substudy E. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. "Number of Participants Analysed" signifies participants evaluable for this endpoint and ''n'' signifies participants evaluable for the specified rows.

End point type	Secondary

End point timeframe:

1 month after the study vaccination

Notes:

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m	BNT162b2 30 mcg: C4591031 Substudy E	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	295	284	287	
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron BA.4/BA.5(n=294,282,273)	61.2 (55.4 to 66.8)	66.7 (60.8 to 72.1)	46.5 (40.5 to 52.6)	
Reference strain(n=295,284,287)	44.1 (38.3 to 49.9)	45.8 (39.9 to 51.8)	48.1 (42.2 to 54.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2/Group 2 + Cohort 3/Group 1 Combined and Cohort 2/Group 4 + Cohort 3/Group 2 Combined: GMFR of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination

End point title	Cohort 2/Group 2 + Cohort 3/Group 1 Combined and Cohort 2/Group 4 + Cohort 3/Group 2 Combined: GMFR of SARS-CoV-2 Omicron Strain (BA.4/BA.5) and Reference Strain– NTs From Before the Study Vaccination to 1 Month After the Study Vaccination[72]

End point description:

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. GMFR from before the study vaccination to 1 month after study vaccination for Omicron BA.4/BA.5 and reference strain neutralising titer was reported in this endpoint. This endpoint was planned per protocol to be analysed in participants from Cohort 2 Group 2 + Cohort 3 Group 1, Cohort 2 Group 4 + Cohort 3 Group 2 and control arm of BNT162b2 experienced participants >55 years of age from study C4591031 Substudy E. Analysis was performed in EIP with or without evidence of infection up to 1 month post study vaccination. Here, "Number of Participants Analysed" signifies participants evaluable for this endpoint and ''n'' signifies participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

From before the study vaccination to 1 month after study vaccination

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, this analysis was planned to be analysed in Cohort 2+3 reporting groups only.

End point values	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI	C2G4+C3G2:>55 Years(BNT162b2 Bivalent [WT/OMI BA.4/BA.5]30m	BNT162b2 30 mcg: C4591031 Substudy E	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	295	284	287	
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron BA.4/BA.5 (n=294,282,273)	7.8 (6.7 to 9.2)	8.9 (7.5 to 10.6)	4.6 (4.0 to 5.2)	
Reference strain (n=295,284,287)	4.1 (3.6 to 4.6)	4.4 (3.8 to 5.1)	3.9 (3.4 to 4.4)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Local reactions and systemic events: From Day 1 to Day 7 after study vaccination; AE: From study vaccination on Day 1 through 1 month after study vaccination, SAE and Death: From study vaccination on Day 1 through 6 months after study vaccination

Adverse event reporting additional description:

Same event may appear as non-SAE and SAE, what is presented are distinct. Event may be categorised as serious in 1 and non-serious in other, or participant may experience both SAE and non-SAE. Safety population. Per analysis planned, data is summarised and combined for C2/C3 30mcg groups per age category. MedDRA for C1/C4: v27.0; for C2/C3: v26.0.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	C 2 G 1: 12-17 Years (BNT162b2 [WT/OMI BA.4/BA.5] 30 mcg)

Reporting group description:

Participants aged 12-17 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C 2 G 3: 18-55 Years (BNT162b2 [WT/OMI BA.4/BA.5] 60 mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C2G4+C3G2:>55 Years (BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)

Reporting group description:

Participants aged more than (>) 55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C 2 G 5: >55 Years (BNT162b2 [WT/OMI BA.4/BA.5] 60 mcg)

Reporting group description:

Participants aged >55 years received BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 60 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b5 Bivalent (WT/OMI BA.2) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b6 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b2 Bivalent (WT/OMI BA.1) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b2 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b5 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b7 Bivalent (Original/OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Reporting group title	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)

Reporting group description:

Participants aged 18-55 years received BNT162b7 Monovalent (OMI BA.4/BA.5) 30 mcg intramuscularly at Visit 1 (Day 1).

Serious adverse events	C 2 G 1: 12-17 Years (BNT162b2 [WT/OMI BA.4/BA.5] 30 mcg)	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)	C 2 G 3: 18-55 Years (BNT162b2 [WT/OMI BA.4/BA.5] 60 mcg)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 107 (0.93%)	2 / 313 (0.64%)	1 / 110 (0.91%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Leukaemia			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Testicular germ cell cancer			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	1 / 110 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 107 (0.00%)	1 / 313 (0.32%)	0 / 110 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	1 / 107 (0.93%)	0 / 313 (0.00%)	0 / 110 (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
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	1 / 107 (0.93%)	0 / 313 (0.00%)	0 / 110 (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
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Left ventricular failure			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Blood and lymphatic system disorders			
Normocytic anaemia			

subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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			
Pancreatitis acute			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Renal and urinary disorders			
Urinary tract obstruction			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Acute kidney injury			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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			
Diverticulitis			

subjects affected / exposed	0 / 107 (0.00%)	1 / 313 (0.32%)	0 / 110 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Gastroenteritis			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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			
Hypoglycaemia			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Hypokalaemia			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (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	C2G4+C3G2:>55 Years (BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)	C 2 G 5: >55 Years (BNT162b2 [WT/OMI BA.4/BA.5] 60 mcg)	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 306 (3.27%)	0 / 102 (0.00%)	1 / 104 (0.96%)
number of deaths (all causes)	1	0	0

number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Leukaemia			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Testicular germ cell cancer			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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
Prostate cancer			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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			
Suicidal ideation			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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
Cardiac disorders			

Arrhythmia			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Left ventricular failure			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Blood and lymphatic system disorders			
Normocytic anaemia			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	1 / 104 (0.96%)
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			
Pancreatitis acute			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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
Renal and urinary disorders			
Urinary tract obstruction			

subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Acute kidney injury			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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
Post procedural infection			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Gastroenteritis			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (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			
Hypoglycaemia			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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

Hypokalaemia			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (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

Serious adverse events	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 60 (0.00%)	2 / 102 (1.96%)	1 / 62 (1.61%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Leukaemia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Testicular germ cell cancer			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Prostate cancer			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Vascular disorders			
Hypotension			

subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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			
Suicidal ideation			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Left ventricular failure			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Blood and lymphatic system disorders			
Normocytic anaemia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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			
Pancreatitis acute			

subjects affected / exposed	0 / 60 (0.00%)	1 / 102 (0.98%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 60 (0.00%)	1 / 102 (0.98%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 60 (0.00%)	1 / 102 (0.98%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary tract obstruction			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Acute kidney injury			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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			
Diverticulitis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Post procedural infection			

subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Gastroenteritis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	1 / 62 (1.61%)
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			
Hypoglycaemia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Hypokalaemia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (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	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			

subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Leukaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Testicular germ cell cancer			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Prostate cancer			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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			
Suicidal ideation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Cardiac disorders			
Arrhythmia			

subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Left ventricular failure			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Blood and lymphatic system disorders			
Normocytic anaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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			
Pancreatitis acute			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Renal and urinary disorders			
Urinary tract obstruction			

subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Acute kidney injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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			
Diverticulitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Post procedural infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Gastroenteritis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Enterocolitis infectious			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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			
Hypoglycaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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

Hypokalaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (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

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

Non-serious adverse events	C 2 G 1: 12-17 Years (BNT162b2 [WT/OMI BA.4/BA.5] 30 mcg)	C2G2+C3G1:18-55Years(BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)	C 2 G 3: 18-55 Years (BNT162b2 [WT/OMI BA.4/BA.5] 60 mcg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	96 / 107 (89.72%)	269 / 313 (85.94%)	106 / 110 (96.36%)
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	54 / 107 (50.47%)	144 / 313 (46.01%)	50 / 110 (45.45%)
occurrences (all)	54	144	50
Bell's palsy			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Lymphadenopathy			
subjects affected / exposed	0 / 107 (0.00%)	6 / 313 (1.92%)	1 / 110 (0.91%)
occurrences (all)	0	6	1
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	25 / 107 (23.36%)	68 / 313 (21.73%)	30 / 110 (27.27%)
occurrences (all)	25	68	30
Fatigue			
subjects affected / exposed	3 / 107 (2.80%)	2 / 313 (0.64%)	1 / 110 (0.91%)
occurrences (all)	3	2	1
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 107 (7.48%)	22 / 313 (7.03%)	17 / 110 (15.45%)
occurrences (all)	8	22	17
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	75 / 107 (70.09%)	235 / 313 (75.08%)	103 / 110 (93.64%)
occurrences (all)	75	235	103
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 107 (5.61%)	20 / 313 (6.39%)	12 / 110 (10.91%)
occurrences (all)	6	20	12
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	72 / 107 (67.29%)	189 / 313 (60.38%)	76 / 110 (69.09%)
occurrences (all)	72	189	76
Injection site pain			
subjects affected / exposed	2 / 107 (1.87%)	2 / 313 (0.64%)	0 / 110 (0.00%)
occurrences (all)	2	2	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 107 (9.35%)	15 / 313 (4.79%)	13 / 110 (11.82%)
occurrences (all)	10	15	13
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 107 (2.80%)	6 / 313 (1.92%)	2 / 110 (1.82%)
occurrences (all)	3	6	2
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 107 (6.54%)	33 / 313 (10.54%)	14 / 110 (12.73%)
occurrences (all)	7	33	14
Diarrhoea			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 107 (12.15%)	46 / 313 (14.70%)	27 / 110 (24.55%)
occurrences (all)	13	46	27
Myalgia			
subjects affected / exposed	2 / 107 (1.87%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	2	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	28 / 107 (26.17%)	94 / 313 (30.03%)	46 / 110 (41.82%)
occurrences (all)	28	94	46
Back pain			

subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Sinusitis			
subjects affected / exposed	2 / 107 (1.87%)	1 / 313 (0.32%)	0 / 110 (0.00%)
occurrences (all)	2	1	0
COVID-19			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Joint abscess			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 107 (0.00%)	0 / 313 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	C2G4+C3G2:>55 Years (BNT162b2 Bivalent[WT/OMI BA.4/BA.5]30mcg)	C 2 G 5: >55 Years (BNT162b2 [WT/OMI BA.4/BA.5] 60 mcg)	Cohort 1: 18-55 Years (BNT162b5 Bivalent [WT/OMI BA.2] 30 mcg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	210 / 306 (68.63%)	82 / 102 (80.39%)	97 / 104 (93.27%)
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	92 / 306 (30.07%)	36 / 102 (35.29%)	55 / 104 (52.88%)
occurrences (all)	92	36	55
Bell's palsy			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	36 / 306 (11.76%)	23 / 102 (22.55%)	22 / 104 (21.15%)
occurrences (all)	36	23	22
Fatigue			
subjects affected / exposed	1 / 306 (0.33%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	1	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 306 (2.61%)	9 / 102 (8.82%)	11 / 104 (10.58%)
occurrences (all)	8	9	11
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	171 / 306 (55.88%)	71 / 102 (69.61%)	86 / 104 (82.69%)
occurrences (all)	171	71	86
Injection site erythema (REDNESS)			

alternative assessment type: Systematic			
subjects affected / exposed	11 / 306 (3.59%)	7 / 102 (6.86%)	6 / 104 (5.77%)
occurrences (all)	11	7	6
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	115 / 306 (37.58%)	54 / 102 (52.94%)	76 / 104 (73.08%)
occurrences (all)	115	54	76
Injection site pain			
subjects affected / exposed	1 / 306 (0.33%)	1 / 102 (0.98%)	0 / 104 (0.00%)
occurrences (all)	1	1	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 306 (4.25%)	14 / 102 (13.73%)	2 / 104 (1.92%)
occurrences (all)	13	14	2
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 306 (0.65%)	3 / 102 (2.94%)	1 / 104 (0.96%)
occurrences (all)	2	3	1
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	28 / 306 (9.15%)	7 / 102 (6.86%)	15 / 104 (14.42%)
occurrences (all)	28	7	15
Diarrhoea			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Vulvovaginal pruritus			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	36 / 306 (11.76%)	15 / 102 (14.71%)	19 / 104 (18.27%)
occurrences (all)	36	15	19
Myalgia			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	54 / 306 (17.65%)	23 / 102 (22.55%)	37 / 104 (35.58%)
occurrences (all)	54	23	37
Back pain			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Sinusitis			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	3 / 104 (2.88%)
occurrences (all)	0	0	3
Joint abscess			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			

subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 306 (0.00%)	0 / 102 (0.00%)	0 / 104 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	C4:18-55 Years(BNT162b6 Bivalent[Original/OMI BA.4/BA.5]30mcg)	Cohort 1: 18-55 Years (BNT162b2 Bivalent [WT/OMI BA.1] 30 mcg)	C4:18-55 Years(BNT162b2 Bivalent[Original/OMI BA.4/BA.5]30mcg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 60 (86.67%)	91 / 102 (89.22%)	55 / 62 (88.71%)
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	25 / 60 (41.67%)	47 / 102 (46.08%)	37 / 62 (59.68%)
occurrences (all)	25	47	37
Bell's palsy			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 60 (28.33%)	20 / 102 (19.61%)	14 / 62 (22.58%)
occurrences (all)	17	20	14
Fatigue			
subjects affected / exposed	1 / 60 (1.67%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	1	0	1
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 60 (6.67%)	11 / 102 (10.78%)	1 / 62 (1.61%)
occurrences (all)	4	11	1
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	45 / 60 (75.00%)	83 / 102 (81.37%)	52 / 62 (83.87%)
occurrences (all)	45	83	52
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 60 (5.00%)	6 / 102 (5.88%)	3 / 62 (4.84%)
occurrences (all)	3	6	3
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	44 / 60 (73.33%)	64 / 102 (62.75%)	38 / 62 (61.29%)
occurrences (all)	44	64	38
Injection site pain			
subjects affected / exposed	2 / 60 (3.33%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	2	0	1
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 60 (10.00%)	6 / 102 (5.88%)	4 / 62 (6.45%)
occurrences (all)	6	6	4
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1

Gastrointestinal disorders			
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 60 (3.33%)	2 / 102 (1.96%)	0 / 62 (0.00%)
occurrences (all)	2	2	0
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 60 (16.67%)	20 / 102 (19.61%)	8 / 62 (12.90%)
occurrences (all)	10	20	8
Diarrhoea			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 60 (5.00%)	18 / 102 (17.65%)	9 / 62 (14.52%)
occurrences (all)	3	18	9
Myalgia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	27 / 60 (45.00%)	39 / 102 (38.24%)	16 / 62 (25.81%)
occurrences (all)	27	39	16
Back pain			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Sinusitis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 60 (0.00%)	4 / 102 (3.92%)	0 / 62 (0.00%)
occurrences (all)	0	4	0
Joint abscess			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	1 / 60 (1.67%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 102 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1

Non-serious adverse events	C4:18-55 Years(BNT162b5 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4:18-55 Years(BNT162b7 Bivalent[Original/OMI BA.4/BA.5]30mcg)	C4: 18-55 Years (BNT162b7 Monovalent [OMI BA.4/BA.5] 30 mcg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 62 (90.32%)	53 / 60 (88.33%)	56 / 63 (88.89%)
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			

Thermal burn			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 62 (35.48%)	28 / 60 (46.67%)	25 / 63 (39.68%)
occurrences (all)	22	28	25
Bell's palsy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 62 (17.74%)	8 / 60 (13.33%)	12 / 63 (19.05%)
occurrences (all)	11	8	12
Fatigue			
subjects affected / exposed	1 / 62 (1.61%)	1 / 60 (1.67%)	0 / 63 (0.00%)
occurrences (all)	1	1	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 62 (3.23%)	2 / 60 (3.33%)	2 / 63 (3.17%)
occurrences (all)	2	2	2
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	54 / 62 (87.10%)	46 / 60 (76.67%)	52 / 63 (82.54%)
occurrences (all)	54	46	52
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			

subjects affected / exposed	2 / 62 (3.23%)	1 / 60 (1.67%)	1 / 63 (1.59%)
occurrences (all)	2	1	1
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	39 / 62 (62.90%)	39 / 60 (65.00%)	34 / 63 (53.97%)
occurrences (all)	39	39	34
Injection site pain			
subjects affected / exposed	3 / 62 (4.84%)	1 / 60 (1.67%)	3 / 63 (4.76%)
occurrences (all)	3	1	3
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 62 (6.45%)	3 / 60 (5.00%)	6 / 63 (9.52%)
occurrences (all)	4	3	6
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 62 (1.61%)	3 / 60 (5.00%)	1 / 63 (1.59%)
occurrences (all)	1	3	1
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 62 (6.45%)	10 / 60 (16.67%)	8 / 63 (12.70%)
occurrences (all)	4	10	8
Diarrhoea			
subjects affected / exposed	0 / 62 (0.00%)	1 / 60 (1.67%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 62 (0.00%)	1 / 60 (1.67%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			

subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 62 (14.52%)	8 / 60 (13.33%)	11 / 63 (17.46%)
occurrences (all)	9	8	11
Myalgia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 60 (1.67%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 62 (20.97%)	17 / 60 (28.33%)	17 / 63 (26.98%)
occurrences (all)	13	17	17
Back pain			
subjects affected / exposed	0 / 62 (0.00%)	1 / 60 (1.67%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Sinusitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Joint abscess			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			

subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 60 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 July 2022	Inclusion of a second cohort to describe the immune response to BNT162b2 Bivalent (WT/OMI BA.4/BA.5) at 30 mcg in individuals >=12 years of age and at 60 mcg in adults >=18 years of age. Added corresponding objectives, estimands, and endpoints and details in the statistical methods sections. Study intervention details and background information supporting inclusion of this cohort were added. Inclusion of prospective capture of confirmed COVID-19 cases for both Cohorts 1 and 2 with active COVID-19 surveillance and convalescent visits.
24 August 2022	Inclusion of a third cohort to allow for a sufficiently powered evaluation of BNT162b2 Bivalent (WT/OMI BA.4/BA.5) 30 mcg as a second booster dose in BNT162b2-experienced participants >=18 years of age. Added corresponding objectives, estimands, and endpoints and details in the statistical methods sections. Study intervention details and background information supporting inclusion of this cohort were added.
26 May 2023	Inclusion of a fourth cohort to describe the immune response to authorised and new 30 mcg Bivalent and Monovalent Omicron BA.4/BA.5–modified BNT162b vaccines: 1. BNT162b2 Bivalent (Original/OMI BA.4/BA.5) 2. BNT162b5 Bivalent (Original/OMI BA.4/BA.5) 3. BNT162b7 Bivalent (Original/OMI BA.4/BA.5) 4. BNT162b7 Monovalent (OMI BA.4/BA.5) given to mRNA COVID-19 vaccine–experienced participants 18 through 55 years of age. Added corresponding objectives, estimands, and endpoints and details in the statistical methods sections. Study intervention details and background information supporting the inclusion of this cohort were also added.
27 July 2023	Addition of BNT162b6 vaccine into Cohort 4 to describe the immune response to this new 30 mcg Bivalent Omicron BA.4/BA.5–modified BNT162b vaccine: BNT162b6 Bivalent (Original/OMI BA.4/BA.5) given to mRNA COVID 19 vaccine–experienced participants 18 through 55 years of age. Updated corresponding objectives and details in the statistical methods sections. Study intervention details and background information supporting the inclusion of this vaccine were also added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported