Clinical trial results:
A Phase 3, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of Multiple Production LOTS and Dose Levels of The Vaccine Candidate BNT162b2 Against COVID-19 in Healthy Subjects 12 Through 50Years of Age and the Safety, Tolerability, and Immunogenicity of BNT162b2 RNA-Based COVID-19 Vaccine Candidates as a Booster Dose in Healthy Subjects 18 Through 50Years of Age

Summary

EudraCT number	2021-005903-11
Trial protocol	Outside EU/EEA
Global end of trial date	22 July 2021

Results information

Result version number	v1
This version publication date	06 February 2022
First version publication date	06 February 2022

Trial information

Trial identification

Sponsor protocol code	C4591017

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04713553
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 clinical trials patient information, BioNTech SE, +49 613190841919, patients@biontech.de
Scientific contact	BioNTech clinical trial information desk, BioNTech SE, +49 613190840, info@biontech.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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	06 January 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) To demonstrate that the immune responses induced by BNT162b2 are similar across the 3 US lots (Arms 1, 2, and 3) in subjects without evidence of SARS CoV-2 infection during the study. 2) To demonstrate that the immune response induced by the EU lot (Arm 4) of BNT162b2 is similar to the pooled US lots (Arms 1, 2, and 3) in subjects without evidence of SARS-CoV-2 infection during the study. 3) To demonstrate the noninferiority of the immune response to BNT162b2 in subjects receiving 20 mcg compared to subjects receiving the standard 30 mcg dose (prepared from the same manufacturing lot) without evidence of SARS-CoV-2 infection during the study. 4) To evaluate the safety of BNT162b2 when administered on a 2-dose schedule in healthy subjects 12 through 50 years of age.

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 Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 February 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1573
Worldwide total number of subjects	1573
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	445

Adults (18-64 years)	1128
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted in two parts: primary study and booster study.

Pre-assignment

Screening details:

Total number of subjects enrolled in study were 1574, however 1573 subjects received investigational product (1 subject was excluded for not meeting inclusion criteria). 1 subject randomised to US Lot 1(Arm 1) was administered US Lot 1 for Dose 1 and US Lot 3 for Dose 2, therefore, safety data was collected in both reporting group(Arm 1 and Arm 3).

Period 1

Period 1 title	Primary Study
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	BNT162b2; Arm 1 (US Lot 1)

Arm description:

Subjects were randomised to receive a single dose of 30 microgram (mcg) BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received BNT162b2 30 mcg single dose vaccine at Visit 1 and 2 separated by 21 days.

Arm title	BNT162b2; Arm 2 (US Lot 2)

Arm description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received BNT162b2 30 mcg single dose vaccine at Visit 1 and 2 separated by 21 days.

Arm title	BNT162b2; Arm 3 (US Lot 3)

Arm description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received BNT162b2 30 mcg single dose vaccine at Visit 1 and 2 separated by 21 days.

Arm title	BNT162b2; Arm 4 (EU Lot)

Arm description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received BNT162b2 30 mcg single dose vaccine at Visit 1 and 2 separated by 21 days.

Arm title	BNT162b2; Arm 5 (20 mcg)

Arm description:

Subjects were randomised to receive a single dose of 20 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received BNT162b2 20 mcg single dose vaccine at Visit 1 and 2 separated by 21 days.

Number of subjects in period 1	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)
Started	351	352	346
Completed	347	346	344
Not completed	4	6	2
Consent withdrawn by subject	2	3	-
Not specified	1	2	-
Lost to follow-up	1	1	2
Withdrawal by parent/guardian	-	-	-

Number of subjects in period 1	BNT162b2; Arm 4 (EU Lot)	BNT162b2; Arm 5 (20 mcg)
Started	173	351
Completed	171	349
Not completed	2	2

Consent withdrawn by subject	-	1
Not specified	-	1
Lost to follow-up	1	-
Withdrawal by parent/guardian	1	-

Period 2

Period 2 title	Booster Study
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	BNT162b2 (30 mcg)

Arm description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine by intramuscular injection at Visit 4 (3 months after Dose 2 in the primary study). Subjects participated in the study for 1 month with final visit at 1 month after Visit 4.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received BNT162b2 30 mcg single dose vaccine at Visit 4.

Arm title	BNT162b2.B.1.351 (30 mcg)

Arm description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2.B.1.351 vaccine by intramuscular injection at Visit 4 (3 months after Dose 2 in the primary study). Subjects participated in the study for 1 month with final visit at 1 month after Visit 4.

Arm type	Experimental
Investigational medicinal product name	BNT162b2.B.1.351
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received BNT162b2.B.1.351 30 mcg single dose vaccine at Visit 4.

Number of subjects in period 2	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)
Started	31	31
Completed	31	31

Baseline characteristics

Reporting groups	
Reporting group title	BNT162b2; Arm 1 (US Lot 1)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 microgram (mcg) BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 2 (US Lot 2)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 3 (US Lot 3)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 4 (EU Lot)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 5 (20 mcg)
Reporting group description:	
Subjects were randomised to receive a single dose of 20 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	

Reporting group values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)
Number of subjects	351	352	346
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	99	96	101
Adults (18-64 years)	252	256	245
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	28.0	27.8	27.5
standard deviation	± 11.66	± 11.76	± 11.54
Gender Categorical Units: Subjects			
Female	177	176	159
Male	174	176	187

Race Units: Subjects			
White	286	280	283
Asian	36	48	40
Black or African American	21	16	15
Multiracial	6	5	5
American Indian or Alaska Native	0	1	1
Native Hawaiian or other Pacific Islander	1	1	1
Not reported	1	1	1
Ethnicity Units: Subjects			
Hispanic/Latino	44	32	55
Non-Hispanic/non-Latino	306	319	291
Not reported	1	1	0

Reporting group values	BNT162b2; Arm 4 (EU Lot)	BNT162b2; Arm 5 (20 mcg)	Total
Number of subjects	173	351	1573
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	48	101	445
Adults (18-64 years)	125	250	1128
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	27.7	27.5	
standard deviation	± 11.40	± 11.71	-
Gender Categorical Units: Subjects			
Female	83	163	758
Male	90	188	815
Race Units: Subjects			
White	142	283	1274
Asian	24	44	192
Black or African American	2	14	68
Multiracial	4	5	25
American Indian or Alaska Native	0	3	5
Native Hawaiian or other Pacific Islander	0	2	5
Not reported	1	0	4
Ethnicity Units: Subjects			
Hispanic/Latino	22	42	195

Non-Hispanic/non-Latino	151	309	1376
Not reported	0	0	2

End points

End points reporting groups

Reporting group title	BNT162b2; Arm 1 (US Lot 1)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 microgram (mcg) BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 2 (US Lot 2)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 3 (US Lot 3)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 4 (EU Lot)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2; Arm 5 (20 mcg)
Reporting group description:	
Subjects were randomised to receive a single dose of 20 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Reporting group title	BNT162b2 (30 mcg)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine by intramuscular injection at Visit 4 (3 months after Dose 2 in the primary study). Subjects participated in the study for 1 month with final visit at 1 month after Visit 4.	
Reporting group title	BNT162b2.B.1.351 (30 mcg)
Reporting group description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2.B.1.351 vaccine by intramuscular injection at Visit 4 (3 months after Dose 2 in the primary study). Subjects participated in the study for 1 month with final visit at 1 month after Visit 4.	
Subject analysis set title	Pooled US Lots
Subject analysis set type	Per protocol
Subject analysis set description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine (in Arm 1, 2, and 3) intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.	
Subject analysis set title	BNT162b2; Arm 3 (US Lot 3)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2. 1 subject randomised to US Lot 1 (Arm 1) was administered US Lot 1 for Dose 1 and US Lot 3 for Dose 2, therefore, safety data was collected in both reporting groups (Arm 1 and Arm 3).	

Primary: Geometric Mean Ratios (GMRs) of Full-Length S-Binding IgG Concentrations Between Individual US Lots 1 Month After Dose 2: Primary Study

End point title	Geometric Mean Ratios (GMRs) of Full-Length S-Binding IgG Concentrations Between Individual US Lots 1 Month After Dose 2: Primary Study[1]

End point description:

GMRs were calculated as ratios of Geometric Mean Concentrations (GMCs) of individual US Lots. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomised with Dose 2 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 2, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody)during the study and had no other important protocol deviations as determined by the clinician. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 Month after Dose 2 (maximum up to 35 days after Dose 2)

Notes:

[1] - 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: The endpoint was planned to be analysed in specified arms only.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	324	311	310	
Units: Unit per milliliter				
geometric mean (confidence interval 95%)	6299.5 (5835.4 to 6800.5)	6231.9 (5763.7 to 6738.2)	6774.8 (6264.9 to 7326.1)	

Statistical analyses

Statistical analysis title	Geometric Mean Ratio (Arm 1/Arm 2)
Comparison groups	BNT162b2; Arm 1 (US Lot 1) v BNT162b2; Arm 2 (US Lot 2)
Number of subjects included in analysis	635
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Geometric mean ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.13

Statistical analysis title	Geometric Mean Ratio (Arm 1/Arm 3)
Comparison groups	BNT162b2; Arm 1 (US Lot 1) v BNT162b2; Arm 3 (US Lot 3)

Number of subjects included in analysis	634
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Geometric mean ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.04

Statistical analysis title	Geometric Mean Ratio (Arm 2/Arm 3)
Comparison groups	BNT162b2; Arm 2 (US Lot 2) v BNT162b2; Arm 3 (US Lot 3)
Number of subjects included in analysis	621
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Geometric mean ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.03

Primary: Geometric Mean Ratios (GMRs) of Full-Length S-Binding IgG Concentrations Between EU Lot and Pooled US Lots 1 Month After Dose 2: Primary Study

End point title	Geometric Mean Ratios (GMRs) of Full-Length S-Binding IgG Concentrations Between EU Lot and Pooled US Lots 1 Month After Dose 2: Primary Study[2]

End point description:

GMRs were calculated as ratios of GMCs of EU Lot (Arm 4) and pooled US Lots (Arm 1, 2, and 3). Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomised with Dose 2 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 2, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody)during the study and had no other important protocol deviations as determined by the clinician. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 Month after Dose 2 (maximum up to 35 days after Dose 2)

Notes:

[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: The endpoint was planned to be analysed in specified arms only.

End point values	BNT162b2; Arm 4 (EU Lot)	Pooled US Lots		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	160	945		
Units: Unit per milliliter				
geometric mean (confidence interval 95%)	6098.6 (5474.7 to 6793.7)	6428.8 (6149.5 to 6720.7)		

Statistical analyses

Statistical analysis title	Geometric Mean Ratio (Arm 4/Pooled US Lots)
Comparison groups	BNT162b2; Arm 4 (EU Lot) v Pooled US Lots
Number of subjects included in analysis	1105
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Geometric mean ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.07

Primary: Geometric Mean Ratios (GMRs) of SARS-CoV-2 Neutralizing Titers Between 20-microgram Dose and 30-microgram Dose 1 Month After Dose 2: Primary Study

End point title	Geometric Mean Ratios (GMRs) of SARS-CoV-2 Neutralizing Titers Between 20-microgram Dose and 30-microgram Dose 1 Month After Dose 2: Primary Study[3]

End point description:

GMRs were calculated by exponentiating the mean difference of logarithmically transformed assay results between 2 vaccine groups. Assay results below the lower limit of quantitation (LLOQ) were set to 0.5 × LLOQ. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomised with Dose 2 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 2, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody)during the study and had no other important protocol deviations as determined by the clinician.

End point type	Primary

End point timeframe:

1 Month after Dose 2 (maximum up to 35 days after Dose 2)

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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[4]	0[5]	0[6]	0[7]
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[4] - Data will be posted by 3rd Quarter of 2022 or sooner.

[5] - Data will be posted by 3rd Quarter of 2022 or sooner.

[6] - Data will be posted by 3rd Quarter of 2022 or sooner.

[7] - Data will be posted by 3rd Quarter of 2022 or sooner.

End point values	BNT162b2; Arm 5 (20 mcg)			
Subject group type	Reporting group			
Number of subjects analysed	0[8]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[8] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Dose 1 and 2: Primary Study

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Dose 1 and 2: Primary Study[9]

End point description:

Local reactions were collected by the subject using an electronic diary. Local reactions included Redness, Swelling, and Pain at Injection site (PAIS) for Dose 1 and 2. Redness, and swelling at any severity (>2.0 centimeters [cm]) were reported. Safety population included all randomised subjects who received at least 1 dose of study intervention. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint and 'Number Analysed (n)' signifies number of subjects evaluable for each specified row.

End point type	Primary

End point timeframe:

Within 7 days after Dose 1 and Dose 2

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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	351	352	345	173
Units: Percentage of subjects				
number (confidence interval 95%)				

Dose 1: Redness (n=351,352,345,173,351)	1.1 (0.3 to 2.9)	2.0 (0.8 to 4.1)	2.9 (1.4 to 5.3)	2.3 (0.6 to 5.8)
Dose1: Swelling (n=351,352,345,173,351)	2.0 (0.8 to 4.1)	3.7 (2.0 to 6.2)	3.8 (2.0 to 6.4)	2.9 (0.9 to 6.6)
Dose 1: PAIS(n=351,352,345,173,351)	82.9 (78.6 to 86.7)	79.3 (74.6 to 83.4)	84.6 (80.4 to 88.3)	86.1 (80.1 to 90.9)
Dose 2: Redness (n=349,350,343,172,348)	3.7 (2.0 to 6.3)	4.0 (2.2 to 6.6)	4.4 (2.5 to 7.1)	2.9 (1.0 to 6.7)
Dose 2: Swelling (n=349,350,343,172,348)	4.9 (2.9 to 7.7)	6.0 (3.8 to 9.0)	4.7 (2.7 to 7.5)	3.5 (1.3 to 7.4)
Dose 2: PAIS(n=349,350,343,172,348)	80.2 (75.7 to 84.3)	77.7 (73.0 to 82.0)	83.1 (78.7 to 86.9)	77.3 (70.3 to 83.4)

End point values	BNT162b2; Arm 5 (20 mcg)			
Subject group type	Reporting group			
Number of subjects analysed	351			
Units: Percentage of subjects				
number (confidence interval 95%)				
Dose 1: Redness (n=351,352,345,173,351)	2.0 (0.8 to 4.1)			
Dose1: Swelling (n=351,352,345,173,351)	3.4 (1.8 to 5.9)			
Dose 1: PAIS(n=351,352,345,173,351)	78.1 (73.4 to 82.3)			
Dose 2: Redness (n=349,350,343,172,348)	3.2 (1.6 to 5.6)			
Dose 2: Swelling (n=349,350,343,172,348)	3.7 (2.0 to 6.3)			
Dose 2: PAIS(n=349,350,343,172,348)	79.6 (75.0 to 83.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Local Reactions Within 7 Days After any Dose: Primary Study

End point title	Percentage of Subjects With Local Reactions Within 7 Days After any Dose: Primary Study[10][11]

End point description:

Local reactions were collected by the subject using an electronic diary. Local reactions included Redness, Swelling, and Pain at Injection site for "any dose". Redness, and swelling scaled at any severity (>2.0 cm) were reported. Safety population included all randomised subjects who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Within 7 days after any dose

Notes:

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

[11] - 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: The endpoint was planned to be analysed in specified arms only.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 4 (EU Lot)	BNT162b2; Arm 5 (20 mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	351	352	173	351
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness	4.6 (2.6 to 7.3)	5.4 (3.3 to 8.3)	4.6 (2.0 to 8.9)	4.6 (2.6 to 7.3)
Swelling	6.0 (3.7 to 9.0)	8.8 (6.1 to 12.3)	4.6 (2.0 to 8.9)	6.3 (4.0 to 9.3)
Pain at Injection Site	90.9 (87.4 to 93.7)	85.8 (81.7 to 89.3)	91.3 (86.1 to 95.1)	89.5 (85.8 to 92.5)

End point values	BNT162b2; Arm 3 (US Lot 3)			
Subject group type	Subject analysis set			
Number of subjects analysed	347			
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness	6.6 (4.2 to 9.8)			
Swelling	7.2 (4.7 to 10.5)			
Pain at Injection Site	91.1 (87.6 to 93.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Dose 3: Booster Study

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Dose 3: Booster Study[12]

End point description:

Local reactions were collected by the subject using an electronic diary. Local reactions included Redness, Swelling, and Pain at Injection site for Dose 3. Redness, and swelling scaled at any severity (>2.0 cm) were reported. Safety population included all randomised subjects who received dose 3. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after Dose 3

Notes:

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

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	31		
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness	9.7 (2.0 to 25.8)	3.2 (0.1 to 16.7)		
Swelling	6.5 (0.8 to 21.4)	6.5 (0.8 to 21.4)		
Pain at Injection site	90.3 (74.2 to 98.0)	93.5 (78.6 to 99.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After Dose 1 and 2: Primary Study

End point title	Percentage of Subjects With Systemic Events Within 7 Days After Dose 1 and 2: Primary Study[13]

End point description:

Systemic events were reported using an electronic diary for any dose. Fever scales (fever>=38.0-38.4 degree Celsius [C]; >38.4-38.9 C; >38.9-40.0 C; >40.0 C). Fatigue, headache, chills, new or worsened muscle pain, joint pain, vomiting (>2 times in 24 hours), diarrhea (6 or more loose stools in 24 hours) at any severity were included. Safety population included all randomised subjects who received at least 1 dose of study intervention. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint and 'Number Analysed (n)' signifies number of subjects evaluable for each specified row.

End point type	Primary

End point timeframe:

Within 7 days after Dose 1 and Dose 2

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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	351	352	345	173
Units: Percentage of subjects				
number (confidence interval 95%)				
Dose1:Fever>=38.0 C(n=351,352,345,173,351)	0.3 (0.0 to 1.6)	0 (0.0 to 1.0)	2.0 (0.8 to 4.1)	1.2 (0.1 to 4.1)
Dose1:Fever>=38.0C to 38.4C(n=351,352,345,173,351)	0.3 (0.0 to 1.6)	0 (0.0 to 1.0)	1.2 (0.3 to 2.9)	0.6 (0.0 to 3.2)
Dose1:Fever>38.4C to 38.9C(n=351,352,345,173,351)	0 (0.0 to 1.0)	0 (0.0 to 1.0)	0.6 (0.1 to 2.1)	0.6 (0.0 to 3.2)
Dose1:Fever>38.9C to 40.0C(n=351,352,345,173,351)	0 (0.0 to 1.0)	0 (0.0 to 1.0)	0.3 (0.0 to 1.6)	0 (0.0 to 2.1)
Dose1:Fever>40.0 C (n=351,352,345,173,351)	0 (0.0 to 1.0)	0 (0.0 to 1.0)	1 (0.0 to 1.1)	0 (0.0 to 2.1)

Dose 1:Fatigue(n=351,352,345,173,351)	53.3 (47.9 to 58.6)	45.5 (40.2 to 50.8)	50.7 (45.3 to 56.1)	49.1 (41.5 to 56.8)
Dose1:Headache(n=351,352,345,173,351)	36.2 (31.1 to 41.5)	32.7 (27.8 to 37.8)	33.3 (28.4 to 38.6)	38.7 (31.4 to 46.4)
Dose1:Chills (n=351,352,345,173,351)	8.5 (5.8 to 12.0)	7.7 (5.1 to 11.0)	10.1 (7.2 to 13.8)	8.1 (4.5 to 13.2)
Dose1:Vomiting (n=351,352,345,173,351)	0.6 (0.1 to 2.0)	0.6 (0.1 to 2.0)	1.2 (0.3 to 2.9)	0.6 (0.0 to 3.2)
Dose 1:Diarrhea (n=351,352,345,173,351)	9.7 (6.8 to 13.3)	8.0 (5.4 to 11.3)	7.8 (5.2 to 11.2)	9.2 (5.4 to 14.6)
Dose1:New/worsen musclepain(n=351,352,345,173,351)	14.5 (11.0 to 18.7)	13.1 (9.7 to 17.0)	16.5 (12.8 to 20.9)	17.3 (12.0 to 23.8)
Dose1:New/worsen joint pain(n=351,352,345,173,351)	6.8 (4.4 to 10.0)	6.5 (4.2 to 9.6)	7.0 (4.5 to 10.2)	7.5 (4.1 to 12.5)
Dose2:Fever>=38.0 C(n=349,350,343,172,348)	7.2 (4.7 to 10.4)	6.3 (4.0 to 9.4)	6.7 (4.3 to 9.9)	8.7 (5.0 to 14.0)
Dose2:Fever>=38.0C to 38.4C(n=349,350,343,172,348)	4.6 (2.6 to 7.3)	3.4 (1.8 to 5.9)	3.2 (1.6 to 5.7)	6.4 (3.2 to 11.2)
Dose2:Fever>38.4C to 38.9C(n=349,350,343,172,348)	2.0 (0.8 to 4.1)	2.0 (0.8 to 4.1)	2.3 (1.0 to 4.5)	1.2 (0.1 to 4.1)
Dose2:Fever>38.9C to 40.0C(n=349,350,343,172,348)	0.6 (0.1 to 2.1)	0.9 (0.2 to 2.5)	0.9 (0.2 to 2.5)	1.2 (0.1 to 4.1)
Dose 2:Fever >40.0 C (n=349,350,343,172,348)	0 (0.0 to 1.1)	0 (0.0 to 1.0)	0.3 (0.0 to 1.6)	0 (0.0 to 2.1)
Dose 2: Fatigue(n=349,350,343,172,348)	69.9 (64.8 to 74.7)	66.6 (61.4 to 71.5)	71.4 (66.3 to 76.2)	69.8 (62.3 to 76.5)
Dose 2: Headache(n=349,350,343,172,348)	57.0 (51.6 to 62.3)	56.6 (51.2 to 61.8)	56.9 (51.4 to 62.2)	56.4 (48.6 to 63.9)
Dose 2: Chills (n=349,350,343,172,348)	28.1 (23.4 to 33.1)	31.1 (26.3 to 36.3)	33.8 (28.8 to 39.1)	28.5 (21.9 to 35.9)
Dose 2:Vomiting (n=349,350,343,172,348)	2.3 (1.0 to 4.5)	1.4 (0.5 to 3.3)	2.3 (1.0 to 4.5)	1.7 (0.4 to 5.0)
Dose 2:Diarrhea (n=349,350,343,172,348)	8.3 (5.6 to 11.7)	9.1 (6.3 to 12.7)	7.9 (5.3 to 11.2)	9.3 (5.4 to 14.7)
Dose2:New/worsen musclepain(n=349,350,343,172,348)	32.7 (27.8 to 37.9)	38.6 (33.4 to 43.9)	35.6 (30.5 to 40.9)	36.0 (28.9 to 43.7)
Dose2:New/worsen joint pain(n=349,350,343,172,348)	19.2 (15.2 to 23.7)	24.6 (20.2 to 29.4)	19.2 (15.2 to 23.8)	19.2 (13.6 to 25.9)

End point values	BNT162b2; Arm 5 (20 mcg)			
Subject group type	Reporting group			
Number of subjects analysed	351			
Units: Percentage of subjects				
number (confidence interval 95%)				
Dose1:Fever>=38.0 C(n=351,352,345,173,351)	0 (0.0 to 1.0)			
Dose1:Fever>=38.0C to 38.4C(n=351,352,345,173,351)	0 (0.0 to 1.0)			
Dose1:Fever>38.4C to 38.9C(n=351,352,345,173,351)	0 (0.0 to 1.0)			
Dose1:Fever>38.9C to 40.0C(n=351,352,345,173,351)	0 (0.0 to 1.0)			
Dose1:Fever>40.0 C (n=351,352,345,173,351)	0 (0.0 to 1.0)			
Dose 1:Fatigue(n=351,352,345,173,351)	49.0 (43.7 to 54.4)			

Dose1:Headache(n=351,352,345,173,351)	35.6 (30.6 to 40.9)			
Dose1:Chills (n=351,352,345,173,351)	6.8 (4.4 to 10.0)			
Dose1:Vomiting (n=351,352,345,173,351)	0.9 (0.2 to 2.5)			
Dose 1:Diarrhea (n=351,352,345,173,351)	10.0 (7.0 to 13.6)			
Dose1:New/worsen musclepain(n=351,352,345,173,351)	16.2 (12.5 to 20.5)			
Dose1:New/worsen joint pain(n=351,352,345,173,351)	6.6 (4.2 to 9.7)			
Dose2:Fever>=38.0 C(n=349,350,343,172,348)	5.7 (3.5 to 8.7)			
Dose2:Fever>=38.0C to 38.4C(n=349,350,343,172,348)	4.3 (2.4 to 7.0)			
Dose2:Fever>38.4C to 38.9C(n=349,350,343,172,348)	1.4 (0.5 to 3.3)			
Dose2:Fever>38.9C to 40.0C(n=349,350,343,172,348)	0 (0.0 to 1.1)			
Dose 2:Fever >40.0 C (n=349,350,343,172,348)	0 (0.0 to 2.1)			
Dose 2: Fatigue(n=349,350,343,172,348)	66.7 (61.4 to 71.6)			
Dose 2: Headache(n=349,350,343,172,348)	50.6 (45.2 to 55.9)			
Dose 2: Chills (n=349,350,343,172,348)	23.6 (19.2 to 28.4)			
Dose 2:Vomiting (n=349,350,343,172,348)	1.4 (0.5 to 3.3)			
Dose 2:Diarrhea (n=349,350,343,172,348)	6.9 (4.5 to 10.1)			
Dose2:New/worsen musclepain(n=349,350,343,172,348)	35.6 (30.6 to 40.9)			
Dose2:New/worsen joint pain(n=349,350,343,172,348)	19.5 (15.5 to 24.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After any Dose: Primary Study

End point title	Percentage of Subjects With Systemic Events Within 7 Days After any Dose: Primary Study[14][15]

End point description:

Systemic events were reported using an electronic diary for any dose. Fever scales (fever>=38.0-38.4 C; >38.4-38.9 C; >38.9-40.0 C; >40.0 C). Fatigue, headache, chills, new or worsened muscle pain, joint pain, vomiting (>2 times in 24 hours), diarrhea (6 or more loose stools in 24 hours) at any severity were included. Safety population included all randomised subjects who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Within 7 days after any dose

Notes:

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

[15] - 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: The endpoint was planned to be analysed in specified arms only.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 4 (EU Lot)	BNT162b2; Arm 5 (20 mcg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	351	352	173	351
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever>=38.0 C	7.4 (4.9 to 10.7)	6.3 (4.0 to 9.3)	9.2 (5.4 to 14.6)	5.7 (3.5 to 8.7)
Fever>=38.0C to 38.4C	4.8 (2.8 to 7.6)	3.4 (1.8 to 5.9)	6.4 (3.2 to 11.1)	4.3 (2.4 to 7.0)
Fever>38.4C to 38.9C	2.0 (0.8 to 4.1)	2.0 (0.8 to 4.1)	1.7 (0.4 to 5.0)	1.4 (0.5 to 3.3)
Fever>38.9C to 40.0C	0.6 (0.1 to 2.0)	0.9 (0.2 to 2.5)	1.2 (0.1 to 4.1)	0 (0.0 to 1.0)
Fever >40.0 C	0 (0.0 to 1.0)	0 (0.0 to 1.0)	0 (0.0 to 2.1)	0 (0.0 to 1.0)
Fatigue	78.6 (74.0 to 82.8)	73.6 (68.6 to 78.1)	76.9 (69.9 to 82.9)	75.5 (70.7 to 79.9)
Headache	66.7 (61.5 to 71.6)	65.1 (59.8 to 70.0)	68.8 (61.3 to 75.6)	63.8 (58.5 to 68.9)
Chills	32.8 (27.9 to 37.9)	34.1 (29.1 to 39.3)	32.4 (25.5 to 39.9)	26.2 (21.7 to 31.1)
Vomiting	2.8 (1.4 to 5.2)	2.0 (0.8 to 4.1)	2.3 (0.6 to 5.8)	2.3 (1.0 to 4.4)
Diarrhea	16.2 (12.5 to 20.5)	14.2 (10.7 to 18.3)	15.0 (10.1 to 21.2)	15.4 (11.8 to 19.6)
New/worsen muscle pain	38.7 (33.6 to 44.1)	43.5 (38.2 to 48.8)	43.9 (36.4 to 51.7)	40.5 (35.3 to 45.8)
New/worsen joint pain	23.4 (19.0 to 28.1)	27.3 (22.7 to 32.2)	24.3 (18.1 to 31.4)	22.2 (18.0 to 26.9)

End point values	BNT162b2; Arm 3 (US Lot 3)			
Subject group type	Subject analysis set			
Number of subjects analysed	347			
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever>=38.0 C	8.4 (5.7 to 11.8)			
Fever>=38.0C to 38.4C	4.0 (2.2 to 6.7)			
Fever>38.4C to 38.9C	2.9 (1.4 to 5.2)			
Fever>38.9C to 40.0C	1.2 (0.3 to 2.9)			
Fever >40.0 C	0.3 (0.0 to 1.6)			
Fatigue	81.0 (76.4 to 85.0)			
Headache	64.3 (59.0 to 69.3)			

Chills	37.2 (32.1 to 42.5)			
Vomiting	3.5 (1.8 to 6.0)			
Diarrhea	13.8 (10.4 to 17.9)			
New/worsen muscle pain	43.2 (37.9 to 48.6)			
New/worsen joint pain	23.9 (19.5 to 28.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After Dose 3: Booster Study

End point title	Percentage of Subjects With Systemic Events Within 7 Days After Dose 3: Booster Study[16]

End point description:

Systemic events were reported using an electronic diary for any dose. Fever scales (fever>=38.0-38.4 C; >38.4-38.9 C; >38.9-40.0 C; >40.0 C). Fatigue, headache, chills, new or worsened muscle pain, joint pain, vomiting (>2 times in 24 hours), diarrhea (6 or more loose stools in 24 hours) at any severity were included. Safety population included all randomised subjects who received dose 3. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after Dose 3

Notes:

[16] - 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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	31		
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever>=38.0 C	3.2 (0.1 to 16.7)	6.5 (0.8 to 21.4)		
Fever>=38.0 C to 38.4 C	0 (0.0 to 11.2)	6.5 (0.8 to 21.4)		
Fever>38.4 C to 38.9 C	3.2 (0.1 to 16.7)	0 (0.0 to 11.2)		
Fever>38.9C to 40.0 C	0 (0.0 to 11.2)	0 (0.0 to 11.2)		
Fever >40.0 C	0 (0.0 to 11.2)	0 (0.0 to 11.2)		
Fatigue	67.7 (48.6 to 83.3)	83.9 (66.3 to 94.5)		
Headache	41.9 (24.5 to 60.9)	58.1 (39.1 to 75.5)		
Chills	25.8 (11.9 to 44.6)	19.4 (7.5 to 37.5)		
Vomiting	3.2 (0.1 to 16.7)	0 (0.0 to 11.2)		

Diarrhea	16.1 (5.5 to 33.7)	6.5 (0.8 to 21.4)		
New/worsened muscle pain	41.9 (24.5 to 60.9)	19.4 (7.5 to 37.5)		
New/worsened joint pain	12.9 (3.6 to 29.8)	12.9 (3.6 to 29.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) From Dose 1 to 1 Month After Dose 2: Primary Study

End point title	Percentage of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) From Dose 1 to 1 Month After Dose 2: Primary Study[17]

End point description:

An AE was any untoward medical occurrence in a subject who received investigational product without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalisation; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly or that was considered to be an important medical event. Safety population included all randomised subjects who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

From Dose 1 (Day 1 of vaccination) up to 1 Month after Dose 2 (maximum up to 35 days after Dose 2)

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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	351	352	346	173
Units: Percentage of subjects				
number (not applicable)				
AEs	5.4	6.0	5.2	10.4
SAEs	0	0	0.3	0.6

End point values	BNT162b2; Arm 5 (20 mcg)			
Subject group type	Reporting group			
Number of subjects analysed	351			
Units: Percentage of subjects				
number (not applicable)				
AEs	6.8			
SAEs	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) From Dose 3 to 1 Month After Dose 3: Booster Study

End point title	Percentage of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) From Dose 3 to 1 Month After Dose 3: Booster Study[18]

End point description:

An AE was any untoward medical occurrence in a subject who received investigational product without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalisation; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly or that was considered to be an important medical event. Safety population included all randomised subjects who received Dose 3 of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 1 Month after Dose 3 (maximum up to 35 days after Dose 3)

Notes:

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

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	31		
Units: Percentage of subjects				
number (not applicable)				
AEs	6.5	3.2		
SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) of SARS-CoV-2 Reference-strain at Baseline, 1 Month After Dose 2 and 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Geometric Mean Titers (GMTs) of SARS-CoV-2 Reference-strain at Baseline, 1 Month After Dose 2 and 1 Week After and 1 Month After Dose 3: Booster Study[19]

End point description:

End point type	Primary

End point timeframe:

Baseline, 1 Month after Dose 2 and 1 Week after and 1 Month after Dose 3

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: Only descriptive data was planned to be reported for this endpoint
Validation report
(Report created at 13:52:49 on 21-January-2022)
Download validation report
Expand all "More" links / Collapse all "Less" links

Trial information
No errors or warnings found.

Subject disposition
No errors or warnings found.

Baseline characteristics
No errors or warnings found.

End points
WARNING - End Point: Geometric Mean Ratios (GMRs) of SARS-CoV-2 Neutralizing Titers Between 20-microgra

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[20]	0[21]		
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[20] - Data will be posted by 3rd Quarter of 2022 or sooner.

[21] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) of SARS-CoV-2 B.1.351-strain at Baseline, 1 Month After Dose 2 and 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Geometric Mean Titers (GMTs) of SARS-CoV-2 B.1.351-strain at Baseline, 1 Month After Dose 2 and 1 Week After and 1 Month After Dose 3: Booster Study[22]

End point description:

End point type	Primary

End point timeframe:

Baseline, 1 Month after Dose 2 and 1 Week after and 1 Month after Dose 3

Notes:

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

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[23]	0[24]		
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[23] - Data will be posted by 3rd Quarter of 2022 or sooner.

[24] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentrations (GMCs) of Full-length S-binding IgG Levels at Baseline, 1 Month After Dose 2, and 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Geometric Mean Concentrations (GMCs) of Full-length S-binding IgG Levels at Baseline, 1 Month After Dose 2, and 1 Week After and 1 Month After Dose 3: Booster Study[25]

End point description:

GMCs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomized in the primary study with Dose 2 received within the predefined window, received Dose 3 to which they were randomized in the booster study with Dose 3 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 3, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody) during the primary and booster studies, and had no other important protocol deviations as determined by the clinician.

End point type	Primary

End point timeframe:

Baseline, 1 Month after Dose 2, and 1 Week after and 1 Month after Dose 3

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: Only descriptive data was planned to be reported for this endpoint

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[26]	0[27]		
Units: Unit per milliliter				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[26] - Data will be posted by 3rd Quarter of 2022 or sooner.

[27] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Fold Rises (GMFRs) in Full-length S-binding IgG Levels From 1 Month After Dose 2 to 1 Week After and 1 Month After Dose 3 and From

Before Dose 3 to 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Geometric Mean Fold Rises (GMFRs) in Full-length S-binding IgG Levels From 1 Month After Dose 2 to 1 Week After and 1 Month After Dose 3 and From Before Dose 3 to 1 Week After and 1 Month After Dose 3: Booster Study[28]

End point description:

GMFRs 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. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomized in the primary study with Dose 2 received within the predefined window, received Dose 3 to which they were randomized in the booster study with Dose 3 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 3, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody) during the primary and booster studies, and had no other important protocol deviations as determined by the clinician.

End point type	Primary

End point timeframe:

From 1 Month after Dose 2 to 1 Week after and 1 Month after Dose 3 and from before Dose 3 to 1 Week after and 1 Month after Dose 3

Notes:

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

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[29]	0[30]		
Units: Unit per milliliter				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[29] - Data will be posted by 3rd Quarter of 2022 or sooner.

[30] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Fold Rise (GMFRs) in SARS-CoV-2 Reference-strain From 1 Month After Dose 2 to 1 Week After and 1 Month After Dose 3 and From Before Dose 3 to 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Geometric Mean Fold Rise (GMFRs) in SARS-CoV-2 Reference-strain From 1 Month After Dose 2 to 1 Week After and 1 Month After Dose 3 and From Before Dose 3 to 1 Week After and 1 Month After Dose 3: Booster Study[31]

End point description:

GMFRs 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. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomized in the primary study with Dose 2 received within the predefined window, received Dose 3 to which they were randomized in the booster study with Dose 3 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 3, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody) during the primary and booster studies, and had no other important protocol deviations as determined by the clinician.

End point type	Primary

End point timeframe:

From 1 Month after Dose 2 to 1 Week after and 1 Month after Dose 3 and from before Dose 3 to 1 Week

after and 1 Month after Dose 3

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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[32]	0[33]		
Units: Unit per milliliter				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[32] - Data will be posted by 3rd Quarter of 2022 or sooner.

[33] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Fold Rise (GMFRs) in SARS-CoV-2 B.1.351-strain From 1 Month After Dose 2 to 1 Week After and 1 Month After Dose 3 and From Before Dose 3 to 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Geometric Mean Fold Rise (GMFRs) in SARS-CoV-2 B.1.351-strain From 1 Month After Dose 2 to 1 Week After and 1 Month After Dose 3 and From Before Dose 3 to 1 Week After and 1 Month After Dose 3: Booster Study[34]

End point description:

GMFRs 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. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomized in the primary study with Dose 2 received within the predefined window, received Dose 3 to which they were randomized in the booster study with Dose 3 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 3, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody) during the primary and booster studies, and had no other important protocol deviations as determined by the clinician.

End point type	Primary

End point timeframe:

From 1 Month after Dose 2 to 1 Week after and 1 Month after Dose 3 and from before Dose 3 to 1 Week after and 1 Month after Dose 3

Notes:

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

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[35]	0[36]		
Units: Unit per milliliter				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[35] - Data will be posted by 3rd Quarter of 2022 or sooner.

[36] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Seroresponse to B.1.351 Variant Strain at 1 Month After Dose 2, Before Dose 3, and 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Percentage of Subjects With Seroresponse to B.1.351 Variant Strain at 1 Month After Dose 2, Before Dose 3, and 1 Week After and 1 Month After Dose 3: Booster Study[37]

End point description:

Seroresponse was defined as ≥4-fold increase from baseline (before Dose 1) to the specified time point. If the baseline measurement was below LLOQ, a postvaccination measurement of ≥4 × LLOQ was considered a seroresponse. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomized in the primary study with Dose 2 received within the predefined window, received Dose 3 to which they were randomized in the booster study with Dose 3 received within the predefined window, had at least 1 valid and determinate immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 3 visit, were negative for SARS-CoV-2 infection during the primary and booster studies, and had no other important protocol deviations as determined by the clinician.

End point type	Primary

End point timeframe:

1 Month after Dose 2, before Dose 3, and 1 Week after and 1 Month after Dose 3

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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[38]	0[39]		
Units: Percentage of subjects				
number (not applicable)				

Notes:

[38] - Data will be posted by 3rd Quarter of 2022 or sooner.

[39] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Seroresponse to Reference Strain at 1 Month After Dose 2, Before Dose 3, and 1 Week After and 1 Month After Dose 3: Booster Study

End point title	Percentage of Subjects With Seroresponse to Reference Strain at 1 Month After Dose 2, Before Dose 3, and 1 Week After and 1 Month After Dose 3: Booster Study[40]

End point description:

Seroresponse was defined as greater than equal to (≥) 4-fold increase from baseline (before Dose 1) to the specified time point. If the baseline measurement was below LLOQ, a postvaccination measurement of ≥4 × LLOQ was considered a seroresponse. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomized in the primary study with Dose 2 received within the predefined window, received Dose 3 to which they were randomized in the booster study with Dose 3 received within the predefined window, had at least 1 valid and determinate immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 3 visit, were negative for SARS-CoV-2 infection during the primary and booster studies, and had no other important protocol deviations as determined by the clinician.

End point type	Primary

End point timeframe:

1 Month after Dose 2, before Dose 3, and 1 Week after and 1 Month after Dose 3

Notes:

[40] - 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: Only descriptive data was planned to be reported for this endpoint.

End point values	BNT162b2 (30 mcg)	BNT162b2.B.1.351 (30 mcg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[41]	0[42]		
Units: Percentage of subjects				
number (not applicable)				

Notes:

[41] - Data will be posted by 3rd Quarter of 2022 or sooner.

[42] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Full-Length S-Binding IgG Levels at Baseline and 1 Month After Dose 2: Primary Study

End point title	Geometric Mean Concentrations (GMCs) of Full-Length S-Binding IgG Levels at Baseline and 1 Month After Dose 2: Primary Study[43]

End point description:

GMCs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomised with Dose 2 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 2, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody)during the study and had no other important protocol deviations as determined by the clinician. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint and 'Number Analysed (n)' signifies number of subjects evaluable for each specified row.

End point type	Secondary

End point timeframe:

Baseline (before Dose 1), 1 Month after Dose 2 (maximum up to 35 days after Dose 2)

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: The endpoint was planned to be analysed in specified arms only.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	324	311	310	160
Units: Unit per milliliter				
geometric mean (confidence interval 95%)				
Baseline (n=323, 311, 310, 160)	3.1 (2.7 to 3.5)	2.6 (2.3 to 3.0)	2.6 (2.2 to 3.0)	2.6 (2.1 to 3.2)
1 Month After Dose 2 (n=324, 311, 310, 160)	6269.8 (5717.7 to 6875.2)	6222.3 (5721.5 to 6766.9)	6818.9 (6280.9 to 7403.1)	6098.9 (5446.0 to 6830.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rises (GMFRs) in Full-Length S-Binding IgG Levels From Baseline to 1 Month After Dose 2: Primary Study

End point title	Geometric Mean Fold Rises (GMFRs) in Full-Length S-Binding IgG Levels From Baseline to 1 Month After Dose 2: Primary Study[44]

End point description:

GMFRs 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. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomised with Dose 2 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 2, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody)during the study and had no other important protocol deviations as determined by the clinician. Here, 'Number of Subjects Analysed' signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From Baseline (before Dose 1) up to 1 Month after Dose 2 (maximum up to 35 days after Dose 2)

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: The endpoint was planned to be analysed in specified arms only.

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	323	311	310	160
Units: Unit per milliliter				
geometric mean (confidence interval 95%)	2036.6 (1744.5 to 2377.7)	2367.1 (2028.6 to 2762.2)	2645.2 (2271.2 to 3080.8)	2373.8 (1901.2 to 2963.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of SARS-CoV-2 Neutralizing Titers at Baseline and 1 Month After Dose 2: Primary Study

End point title	Geometric Mean Concentrations (GMCs) of SARS-CoV-2 Neutralizing Titers at Baseline and 1 Month After Dose 2: Primary Study

End point description:

GMCs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomised with Dose 2 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 2, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody)during the study and had no other important protocol deviations as determined by the

End point type	Secondary

End point timeframe:

Baseline (before Dose 1), 1 Month after Dose 2 (maximum up to 35 days after Dose 2)

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[45]	0[46]	0[47]	0[48]
Units: Titer				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[45] - Data will be posted by 3rd Quarter of 2022 or sooner.

[46] - Data will be posted by 3rd Quarter of 2022 or sooner.

[47] - Data will be posted by 3rd Quarter of 2022 or sooner.

[48] - Data will be posted by 3rd Quarter of 2022 or sooner.

End point values	BNT162b2; Arm 5 (20 mcg)			
Subject group type	Reporting group			
Number of subjects analysed	0[49]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[49] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rises (GMFRs) in SARS-CoV-2 Neutralizing Titers From Baseline to 1 Month After Dose 2: Primary Study

End point title	Geometric Mean Fold Rises (GMFRs) in SARS-CoV-2 Neutralizing Titers From Baseline to 1 Month After Dose 2: Primary Study

End point description:

GMFRs 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. Evaluable immunogenicity population included all eligible randomised subjects who received 2 doses of the vaccine to which they were randomised with Dose 2 received within the predefined window, had at least 1 valid immunogenicity result from the blood sample collected within an appropriate window at 1 month after the Dose 2, were negative for both SARS-CoV-2 test (RT-PCR and N-blinding antibody)during the study and had no other important protocol deviations as determined by the clinician.

End point type	Secondary

End point timeframe:

From Baseline (before Dose 1) up to 1 Month after Dose 2 (maximum up to 35 days after Dose 2)

End point values	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 3 (US Lot 3)	BNT162b2; Arm 4 (EU Lot)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[50]	0[51]	0[52]	0[53]
Units: Units per milliliter				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[50] - Data will be posted by 3rd Quarter of 2022 or sooner.

[51] - Data will be posted by 3rd Quarter of 2022 or sooner.

[52] - Data will be posted by 3rd Quarter of 2022 or sooner.

[53] - Data will be posted by 3rd Quarter of 2022 or sooner.

End point values	BNT162b2; Arm 5 (20 mcg)			
Subject group type	Reporting group			
Number of subjects analysed	0[54]			
Units: Units per milliliter				
geometric mean (confidence interval 95%)	(to)			

Notes:

[54] - Data will be posted by 3rd Quarter of 2022 or sooner.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs and SAEs (primary study): From Dose 1 to 1 Month after Dose 2 (up to 35 days after Dose 2); AEs and SAEs (booster study): From Dose 3 to 1 Month after Dose 3 (up to 35 days after Dose 3); Local reactions/systemic events: Within 7 days after each dose

Adverse event reporting additional description:

Safety populations: subjects who received at least 1 dose and had safety data available. SAEs and AEs were grouped by system organ class and summarized. AEs included events collected in electronic diary (local and systemic reactions; systematic assessment) and events collected on case report form at each visit (nonsystematic assessment).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	BNT162b2; Arm 1 (US Lot 1)

Reporting group description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Reporting group title	BNT162b2; Arm 2 (US Lot 2)

Reporting group description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Reporting group title	BNT162b2; Arm 4 (EU Lot)

Reporting group description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Reporting group title	BNT162b2; Arm 5 (20 mcg)

Reporting group description:

Subjects were randomised to receive a single dose of 20 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2.

Reporting group title	BNT162b2

Reporting group description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine by intramuscular injection at Visit 4 (3 months after Dose 2 in the primary study). Subjects participated in the study for 1 month with final visit at 1 month after Visit 4.

Reporting group title	BNT162b2.B.1.351

Reporting group description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2.B.1.351 vaccine by intramuscular injection at Visit 4 (3 months after Dose 2 in the primary study). Subjects participated in the study for 1 month with final visit at 1 month after Visit 4.

Reporting group title	BNT162b2; Arm 3 (US Lot)

Reporting group description:

Subjects were randomised to receive a single dose of 30 mcg BNT162b2 vaccine intramuscular injection at each vaccination visit (Visits 1 and 2) separated by 21 days. Subjects participated in the study for 2 months with final visit at 1 month after Visit 2. 1 subject randomised to US Lot 1 (Arm 1) was administered US Lot 1 for Dose 1 and US Lot 3 for Dose 2, therefore, safety data was collected in both reporting groups (Arm 1 and Arm 3).

Serious adverse events	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 4 (EU Lot)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 351 (0.00%)	0 / 352 (0.00%)	1 / 173 (0.58%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Migrainosus			
subjects affected / exposed	0 / 351 (0.00%)	0 / 352 (0.00%)	1 / 173 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 351 (0.00%)	0 / 352 (0.00%)	0 / 173 (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	BNT162b2; Arm 5 (20 mcg)	BNT162b2	BNT162b2.B.1.351
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 351 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Migrainosus			
subjects affected / exposed	0 / 351 (0.00%)	0 / 31 (0.00%)	0 / 31 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 351 (0.00%)	0 / 31 (0.00%)	0 / 31 (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	BNT162b2; Arm 3 (US Lot)		
Total subjects affected by serious			

adverse events			
subjects affected / exposed	1 / 347 (0.29%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Migrainosus			
subjects affected / exposed	0 / 347 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 347 (0.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	BNT162b2; Arm 1 (US Lot 1)	BNT162b2; Arm 2 (US Lot 2)	BNT162b2; Arm 4 (EU Lot)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	341 / 351 (97.15%)	336 / 352 (95.45%)	165 / 173 (95.38%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign abdominal neoplasm			
subjects affected / exposed	0 / 351 (0.00%)	0 / 352 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	234 / 351 (66.67%)	229 / 352 (65.06%)	119 / 173 (68.79%)
occurrences (all)	234	229	119
Syncope			
subjects affected / exposed	0 / 351 (0.00%)	0 / 352 (0.00%)	2 / 173 (1.16%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Chills			
alternative assessment type: Systematic			

subjects affected / exposed	115 / 351 (32.76%)	120 / 352 (34.09%)	56 / 173 (32.37%)
occurrences (all)	115	120	56
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	276 / 351 (78.63%)	259 / 352 (73.58%)	133 / 173 (76.88%)
occurrences (all)	276	259	133
Injection site erythema			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 351 (4.56%)	19 / 352 (5.40%)	8 / 173 (4.62%)
occurrences (all)	16	19	8
Injection site pain			
alternative assessment type: Systematic			
subjects affected / exposed	319 / 351 (90.88%)	302 / 352 (85.80%)	158 / 173 (91.33%)
occurrences (all)	319	302	158
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	21 / 351 (5.98%)	31 / 352 (8.81%)	8 / 173 (4.62%)
occurrences (all)	21	31	8
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	26 / 351 (7.41%)	22 / 352 (6.25%)	16 / 173 (9.25%)
occurrences (all)	26	22	16
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 351 (0.00%)	0 / 352 (0.00%)	0 / 173 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	57 / 351 (16.24%)	50 / 352 (14.20%)	26 / 173 (15.03%)
occurrences (all)	57	50	26
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 351 (2.85%)	7 / 352 (1.99%)	4 / 173 (2.31%)
occurrences (all)	10	7	4

Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 351 (0.00%)	1 / 352 (0.28%)	3 / 173 (1.73%)
occurrences (all)	0	1	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	82 / 351 (23.36%)	96 / 352 (27.27%)	42 / 173 (24.28%)
occurrences (all)	82	96	42
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	136 / 351 (38.75%)	153 / 352 (43.47%)	76 / 173 (43.93%)
occurrences (all)	136	153	76

Non-serious adverse events	BNT162b2; Arm 5 (20 mcg)	BNT162b2	BNT162b2.B.1.351
Total subjects affected by non-serious adverse events			
subjects affected / exposed	342 / 351 (97.44%)	30 / 31 (96.77%)	31 / 31 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign abdominal neoplasm			
subjects affected / exposed	0 / 351 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	224 / 351 (63.82%)	13 / 31 (41.94%)	18 / 31 (58.06%)
occurrences (all)	224	13	18
Syncope			
subjects affected / exposed	0 / 351 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
alternative assessment type: Systematic			
subjects affected / exposed	92 / 351 (26.21%)	8 / 31 (25.81%)	6 / 31 (19.35%)
occurrences (all)	92	8	6
Fatigue			
alternative assessment type: Systematic			

subjects affected / exposed	265 / 351 (75.50%)	21 / 31 (67.74%)	26 / 31 (83.87%)
occurrences (all)	265	21	26
Injection site erythema			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 351 (4.56%)	3 / 31 (9.68%)	1 / 31 (3.23%)
occurrences (all)	16	3	1
Injection site pain			
alternative assessment type: Systematic			
subjects affected / exposed	314 / 351 (89.46%)	28 / 31 (90.32%)	29 / 31 (93.55%)
occurrences (all)	314	28	29
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 351 (6.27%)	2 / 31 (6.45%)	2 / 31 (6.45%)
occurrences (all)	22	2	2
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	20 / 351 (5.70%)	1 / 31 (3.23%)	2 / 31 (6.45%)
occurrences (all)	20	1	2
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 351 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	54 / 351 (15.38%)	5 / 31 (16.13%)	2 / 31 (6.45%)
occurrences (all)	54	5	2
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 351 (2.28%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	8	1	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 351 (0.57%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	78 / 351 (22.22%)	4 / 31 (12.90%)	4 / 31 (12.90%)
occurrences (all)	78	4	4
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	142 / 351 (40.46%)	13 / 31 (41.94%)	6 / 31 (19.35%)
occurrences (all)	142	13	6

Non-serious adverse events	BNT162b2; Arm 3 (US Lot)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	335 / 347 (96.54%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign abdominal neoplasm			
subjects affected / exposed	0 / 347 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	223 / 347 (64.27%)		
occurrences (all)	223		
Syncope			
subjects affected / exposed	0 / 347 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chills			
alternative assessment type: Systematic			
subjects affected / exposed	129 / 347 (37.18%)		
occurrences (all)	129		
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	281 / 347 (80.98%)		
occurrences (all)	281		
Injection site erythema			
alternative assessment type: Systematic			

subjects affected / exposed	23 / 347 (6.63%)		
occurrences (all)	23		
Injection site pain			
alternative assessment type: Systematic			
subjects affected / exposed	316 / 347 (91.07%)		
occurrences (all)	316		
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	25 / 347 (7.20%)		
occurrences (all)	25		
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	29 / 347 (8.36%)		
occurrences (all)	29		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 347 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	48 / 347 (13.83%)		
occurrences (all)	48		
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	12 / 347 (3.46%)		
occurrences (all)	12		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 347 (0.29%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			

subjects affected / exposed	83 / 347 (23.92%)		
occurrences (all)	83		
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	150 / 347 (43.23%)		
occurrences (all)	150		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 May 2021	A booster study was added in which an additional dose of either BNT162b2 or BNT162b2.B.1.351 (beta variant of concern) was given to a subset of 60 subjects 18 through 50 yrs of age, 3 months after Dose 2, for assessment of safety and immunogenicity.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Data for neutralizing titers in the primary study and all immunogenicity data in the booster study will be posted in 3rd Quarter of 2022 or sooner when the data becomes available

Notes: