Clinical trial results:
A Phase II trial to evaluate the safety and immunogenicity of SARS-CoV-2 monovalent and multivalent RNA-based vaccines in healthy subjects

Summary

EudraCT number	2021-003458-22
Trial protocol	DE
Global end of trial date	04 October 2023

Results information

Result version number	v1 (current)
This version publication date	18 October 2024
First version publication date	18 October 2024

Trial information

Trial identification

Sponsor protocol code	BNT162-17

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05004181
WHO universal trial number (UTN)	-
Other trial identifiers	US IND: 19736

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech SE, BioNTech SE, +49 613190840, patients@biontech.de
Scientific contact	BioNTech SE, BioNTech SE, +49 613190840, patients@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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This trial consisted of Parts A, B, and C, and evaluated the safety and immunogenicity of a 3rd or 3rd and 4th doses of the multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), and one dose of the monovalent vaccines BNT162b2 (B.1.617.2), BNT162b2 (B.1.1.7) and BNT162b2, in participants who had received 2 doses of the parent vaccine BNT162b2 at 30 µg, at least 6 months after the 2nd dose of BNT162b2. It also evaluated the safety and immunogenicity of a 3-dose regimen of BNT162b2 (B.1.1.7 + B.1.617.2) in participants who had not received prior COVID-19 vaccination. In addition, the safety of BNT162b2 (B.1.1.529.1) or BNT162b2 given as a 3rd or 4th vaccine dose to RNA COVID-19 vaccine-experienced participants with history of SARSCoV-2 Omicron variant infection was evaluated and contrasted with the natural immune response reached after infection with the SARS-CoV-2 Omicron variant in RNA COVID-19 vaccine experienced participants.

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 participants were followed.

Background therapy:

Part A Cohorts 1-5 received BNT162b2 via either BNT162-02 / C4591001 (EudraCT number: 2020-002641-42) or by government available programs. Part B Cohorts 1 and 4 enrolled participants from the Phase III trial C4591001 (EudraCT number: 2020-002641-42) who had previously received two injections of 30 µg BNT162b2 (i.e., BNT162b2-experienced participants). Part C cohorts received mRNA COVID-19 vaccinations.

Evidence for comparator: -

Actual start date of recruitment	25 August 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 86
Country: Number of subjects enrolled	United States: 737
Country: Number of subjects enrolled	Türkiye: 137
Country: Number of subjects enrolled	South Africa: 420
Worldwide total number of subjects	1380
EEA total number of subjects	86

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)	0
Adults (18-64 years)	1219
From 65 to 84 years	160
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The first participant signed ICF on 25 Aug 2021 and the last participant completed the study on 04 Oct 2023. Participants were eligible if they had received 2 doses of the parent vaccine BNT162b2 at 30 µg, and the second dose of BNT162b2 was at least 6 months ago (Part A Cohorts 1 to 5, Part B Cohorts 1 and 4).

Pre-assignment

Screening details:

Participants were also eligible if they had not received prior Coronavirus Disease 2019 (COVID-19) vaccination (Part A Cohort 6, Part B Cohort 6) or had received 2 or 3 injections of any authorized COVID-19 RNA-based vaccine and were subsequently diagnosed with SARS-CoV-2 infection from Jan 2022 onwards.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Arm description:

Participants in Part A - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (B.1.1.7 + B.1.617.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Arm description:

Participants in Part A - Cohort 2 received 2 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection one on Day 1 and one on Day 56

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (B.1.1.7 + B.1.617.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The same arm may be used for both immunizations. The non-dominant arm was preferred.

Arm title	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)

Arm description:

Participants in Part A - Cohort 3 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.7) on Day 1

Arm type	Experimental

Investigational medicinal product name	BNT162b2 (B.1.1.7)
Investigational medicinal product code	
Other name	Alpha
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)

Arm description:

Participants in Part A - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (B.1.617.2)
Investigational medicinal product code	
Other name	Delta
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)

Arm description:

Participants in Part A - Cohort 5 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1.
21 participants assigned to Part B Cohort 4 actually received BNT162b2 (treatment of Part A Cohort 5) and therefore were included in the analyses of safety set of Part A Cohort 5 and excluded from Part B safety set. 1 participant from Part A - Cohort 6 also received BNT162b2 and was included in the Part A - Cohort 5 safety set.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Original Vaccine)
Investigational medicinal product code	
Other name	Comirnaty
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Arm description:

Participants in Part A - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (B.1.1.7 + B.1.617.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The same arm may be used for all immunizations. The non-dominant arm was preferred.

Arm title	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Arm description:

Participants in Part B - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1

Arm type	Experimental

Investigational medicinal product name	BNT162b2 (B.1.1.7 + B.1.617.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)

Arm description:

Participants in Part B - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (B.1.617.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Arm description:

Participants in Part B - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (B.1.1.7 + B.1.617.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The same arm may be used for all immunizations. The non-dominant arm was preferred.

Arm title	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)

Arm description:

Participants in Part C - Cohort 7 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.529.1) on Day 1

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (B.1.1.529.1)
Investigational medicinal product code	
Other name	Omicron
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular; upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)

Arm description:

Participants in Part C - Cohort 8 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1

Arm type	Experimental

Investigational medicinal product name	BNT162b2 (Original Vaccine)
Investigational medicinal product code	
Other name	Comirnaty
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	Part C - C9: No Vaccination

Arm description:

No vaccination was given to Part C - Cohort 9 participants within 3 months after Visit 1. After the 3-month follow-up period, participants in Cohort 9 were to be offered a BNT162b2 vaccination, depending on the epidemiological situation, local regulatory authority recommendations, and/or variant vaccine authorization status.
35 participants were randomized to Part C - Cohort 9. As per protocol, these participants did not receive treatment.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 +	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)
Started	21	20	20
Completed	14	10	15
Not completed	7	10	5
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	1
Physician decision	-	-	-
Lost to follow-up	2	4	2
Not further specified	1	-	-
Withdrawal by subject	2	3	2
Protocol deviation	2	3	-

Number of subjects in period 1	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Started	20	42	17
Completed	12	29	13
Not completed	8	13	4
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	3	3	-
Physician decision	-	-	-
Lost to follow-up	3	5	2
Not further specified	-	-	-
Withdrawal by subject	2	4	2
Protocol deviation	-	1	-

Number of subjects in period 1	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 +	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Started	349	352	361
Completed	280	291	299
Not completed	69	61	62
Adverse event, serious fatal	1	-	2
Consent withdrawn by subject	30	9	3
Physician decision	2	-	7
Lost to follow-up	15	12	38
Not further specified	1	-	2
Withdrawal by subject	4	22	8
Protocol deviation	16	18	2

Number of subjects in period 1	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part C - C9: No Vaccination
Started	72	71	35
Completed	60	55	30
Not completed	12	16	5
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	5	1
Physician decision	-	-	-
Lost to follow-up	6	6	-
Not further specified	1	-	1
Withdrawal by subject	1	3	2
Protocol deviation	2	2	1

Baseline characteristics

Reporting groups

Reporting group title	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1	
Reporting group title	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 2 received 2 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection one on Day 1 and one on Day 56	
Reporting group title	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)
Reporting group description:	
Participants in Part A - Cohort 3 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.7) on Day 1	
Reporting group title	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1	
Reporting group title	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)
Reporting group description:	
Participants in Part A - Cohort 5 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1. 21 participants assigned to Part B Cohort 4 actually received BNT162b2 (treatment of Part A Cohort 5) and therefore were included in the analyses of safety set of Part A Cohort 5 and excluded from Part B safety set. 1 participant from Part A - Cohort 6 also received BNT162b2 and was included in the Part A - Cohort 5 safety set.	
Reporting group title	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose	
Reporting group title	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part B - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1	
Reporting group title	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)
Reporting group description:	
Participants in Part B - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1	
Reporting group title	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part B - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose	
Reporting group title	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)
Reporting group description:	
Participants in Part C - Cohort 7 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.529.1) on Day 1	
Reporting group title	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)
Reporting group description:	
Participants in Part C - Cohort 8 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1	
Reporting group title	Part C - C9: No Vaccination
Reporting group description:	
No vaccination was given to Part C - Cohort 9 participants within 3 months after Visit 1. After the 3-month follow-up period, participants in Cohort 9 were to be offered a BNT162b2 vaccination, depending	

on the epidemiological situation, local regulatory authority recommendations, and/or variant vaccine authorization status.
35 participants were randomized to Part C - Cohort 9. As per protocol, these participants did not receive treatment.

Reporting group values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)
Number of subjects	21	20	20
Age categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
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)	0	0	0
Adults (18-64 years)	21	20	20
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: years			
arithmetic mean	35.4	38.7	36.0
standard deviation	± 11.13	± 9.79	± 11.89
Gender categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Female	11	12	10
Male	10	8	10
Race			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	1	1	0
Black or African American	0	0	0
White	20	18	19
Other	0	0	0
Multiracial	0	0	0
Not reported	0	0	0
Unknown	0	0	0
Region of Enrollment			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were			

randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Turkey	0	0	0
United States	21	20	20
South Africa	0	0	0
Germany	0	0	0
Ethnicity			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Hispanic or Latino	7	3	9
Not Hispanic or Latino	14	17	11
Not reported	0	0	0
Unknown	0	0	0
Body Mass Index (BMI)			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment. Measure Analysis Population Description: Height was missing for 1 participant in Part A - Cohort 6 and BMI could therefore not be calculated			
Units: kg/m^2			
arithmetic mean	27.54	27.97	30.09
standard deviation	± 5.508	± 6.840	± 6.509

Reporting group values	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Number of subjects	20	42	17
Age categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
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)	0	0	0
Adults (18-64 years)	20	37	17
From 65-84 years	0	5	0
85 years and over	0	0	0
Age continuous			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: years			
arithmetic mean	39.8	47.5	37.1
standard deviation	± 8.53	± 11.10	± 11.21
Gender categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Female	13	14	11

Male	7	28	6

Race			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	4	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	3	6
White	19	35	11
Other	0	0	0
Multiracial	0	0	0
Not reported	0	0	0
Unknown	0	0	0
Region of Enrollment			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Turkey	0	0	0
United States	20	42	17
South Africa	0	0	0
Germany	0	0	0
Ethnicity			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Hispanic or Latino	1	5	5
Not Hispanic or Latino	19	37	12
Not reported	0	0	0
Unknown	0	0	0
Body Mass Index (BMI)			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment. Measure Analysis Population Description: Height was missing for 1 participant in Part A - Cohort 6 and BMI could therefore not be calculated			
Units: kg/m^2			
arithmetic mean	29.72	29.83	30.82
standard deviation	± 6.287	± 6.722	± 8.394

Reporting group values	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Number of subjects	349	352	361
Age categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
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)	0	0	0
Adults (18-64 years)	304	279	336
From 65-84 years	45	73	25
85 years and over	0	0	0
Age continuous			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: years			
arithmetic mean	48.1	50.5	42.1
standard deviation	± 14.68	± 15.27	± 15.91
Gender categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Female	169	161	204
Male	180	191	157
Race			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
American Indian or Alaska Native	1	2	0
Asian	10	6	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	50	8	242
White	258	330	15
Other	0	3	63
Multiracial	30	3	41
Not reported	0	0	0
Unknown	0	0	0
Region of Enrollment			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Turkey	137	0	0
United States	134	284	23
South Africa	78	4	338
Germany	0	64	0
Ethnicity			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Hispanic or Latino	30	55	10
Not Hispanic or Latino	317	294	348
Not reported	2	2	0
Unknown	0	1	3
Body Mass Index (BMI)			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment. Measure Analysis Population Description: Height was missing for 1 participant in Part A - Cohort 6 and BMI could therefore not be calculated			

Units: kg/m^2			
arithmetic mean	28.29	28.78	26.30
standard deviation	± 6.012	± 6.202	± 8.413

Reporting group values	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part C - C9: No Vaccination
Number of subjects	72	71	35
Age categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
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)	0	0	0
Adults (18-64 years)	68	65	32
From 65-84 years	4	5	3
85 years and over	0	1	0
Age continuous			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: years			
arithmetic mean	41.9	43.5	44.5
standard deviation	± 12.14	± 13.57	± 11.5
Gender categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Female	42	43	25
Male	30	28	10
Race			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	4	4	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	7	2
White	62	59	31
Other	0	0	0
Multiracial	0	1	0
Not reported	1	0	0
Unknown	1	0	0
Region of Enrollment			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			

Turkey	0	0	0
United States	62	62	32
South Africa	0	0	0
Germany	10	9	3
Ethnicity			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Hispanic or Latino	12	5	5
Not Hispanic or Latino	59	66	30
Not reported	0	0	0
Unknown	1	0	0
Body Mass Index (BMI)			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment. Measure Analysis Population Description: Height was missing for 1 participant in Part A - Cohort 6 and BMI could therefore not be calculated			
Units: kg/m^2			
arithmetic mean	29.25	28.60	30.23
standard deviation	± 6.648	± 6.581	± 5.133

Reporting group values	Total		
Number of subjects	1380		
Age categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	1219		
From 65-84 years	160		
85 years and over	1		
Age continuous			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Female	715		
Male	665		
Race			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			

Units: Subjects			
American Indian or Alaska Native	4		
Asian	32		
Native Hawaiian or Other Pacific Islander	2		
Black or African American	322		
White	877		
Other	66		
Multiracial	75		
Not reported	1		
Unknown	1		
Region of Enrollment			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Turkey	137		
United States	737		
South Africa	420		
Germany	86		
Ethnicity			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment.			
Units: Subjects			
Hispanic or Latino	147		
Not Hispanic or Latino	1224		
Not reported	4		
Unknown	5		
Body Mass Index (BMI)			
Part A and B: Safety Set - All participants who received at least one dose in of IMP. 35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment. Measure Analysis Population Description: Height was missing for 1 participant in Part A - Cohort 6 and BMI could therefore not be calculated			
Units: kg/m^2			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1	
Reporting group title	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 2 received 2 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection one on Day 1 and one on Day 56	
Reporting group title	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)
Reporting group description:	
Participants in Part A - Cohort 3 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.7) on Day 1	
Reporting group title	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1	
Reporting group title	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)
Reporting group description:	
Participants in Part A - Cohort 5 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1. 21 participants assigned to Part B Cohort 4 actually received BNT162b2 (treatment of Part A Cohort 5) and therefore were included in the analyses of safety set of Part A Cohort 5 and excluded from Part B safety set. 1 participant from Part A - Cohort 6 also received BNT162b2 and was included in the Part A - Cohort 5 safety set.	
Reporting group title	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part A - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose	
Reporting group title	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part B - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1	
Reporting group title	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)
Reporting group description:	
Participants in Part B - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1	
Reporting group title	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Reporting group description:	
Participants in Part B - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose	
Reporting group title	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)
Reporting group description:	
Participants in Part C - Cohort 7 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.529.1) on Day 1	
Reporting group title	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)
Reporting group description:	
Participants in Part C - Cohort 8 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1	
Reporting group title	Part C - C9: No Vaccination
Reporting group description:	
No vaccination was given to Part C - Cohort 9 participants within 3 months after Visit 1. After the 3-month follow-up period, participants in Cohort 9 were to be offered a BNT162b2 vaccination, depending	

on the epidemiological situation, local regulatory authority recommendations, and/or variant vaccine authorization status.
35 participants were randomized to Part C - Cohort 9. As per protocol, these participants did not receive treatment.

Subject analysis set title	BNT162-17 Part B - C1 / C4591001
Subject analysis set type	Sub-group analysis

Subject analysis set description:

BNT162-17 Part B - Cohort 1 participants received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1 and C4591001 participants received 2 doses of BNT162b2 30 µg.
To evaluate the primary immunogenicity endpoints for Part B Cohort 1, 4 and 6, separate control groups, one for each cohort in Part B, were selected from the C4591001 trial who received 2 doses of BNT162b2 and had corresponding immune results at 1 month post 2nd dose

Subject analysis set title	BNT162-17 Part B - C4 / C4591001
Subject analysis set type	Sub-group analysis

Subject analysis set description:

BNT162-17 Part B - Cohort 4 participants received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) as a single injection on Day 1 and selected C4591001 participants received 2 doses of BNT162b2 30 µg.
To evaluate the primary immunogenicity endpoints for Part B Cohort 1, 4 and 6, separate control groups, one for each cohort in Part B, were selected from the C4591001 trial who received 2 doses of BNT162b2 and had corresponding immune results at 1 month post 2nd dose.

Subject analysis set title	BNT162-17 Part B - C6 / C4591001
Subject analysis set type	Sub-group analysis

Subject analysis set description:

BNT162-17 Part B - Cohort 6 participants received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose. C4591001 participants received 2 doses of BNT162b2 30 µg. Immunogenicity Analysis Set, i.e., all eligible randomized/assigned participants who received the trial intervention to which they were randomized or assigned, had a valid and determinate immunogenicity result from the blood sample collected within an appropriate window, and had no other important protocol deviations that could confound immunogenicity data. This set included 275 participants from the Phase III trial C4591001.

Subject analysis set title	Part C - Cohort 7: 1 Dose of 30 µg BNT162b2 / Cohort 8: 1 Dose
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Cohort 7 participants received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.529.1) on Day 1 and Cohort 8 participants received 1 dose of 30 µg BNT162b2 original vaccine on Day 1

Subject analysis set title	C4591001 BNT162b2 30 µg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants had previously received two injections of 30 µg BNT162b2 at least 6 months after the second BNT162b2 dose.

Subject analysis set title	Part B - C6: BNT162b2 With Evidence of Prior Infection
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose.

Subject analysis set title	Part B - C6: BNT162b2 Without Evidence of Infection
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose.

Subject analysis set title	Part B - C1: BNT162b2 Without Evidence of Infection
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1

Subject analysis set title	Part B - C6 With Prior Infection / C6 Without Prior Infection
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Cohort 6 with or without evidence of prior infection received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose.

Subject analysis set title	Part B - C6 With Prior Infection / C1 Without Prior Infection
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Cohort 6 with evidence of infection received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose. Participants in Cohort 1 without prior evidence of infection received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1

Primary: All Parts - Percentage of Participants Reporting Local Reactions at the Injection Site (Pain, Tenderness, Erythema/ Redness, Induration/Swelling)

End point title	All Parts - Percentage of Participants Reporting Local Reactions at the Injection Site (Pain, Tenderness, Erythema/ Redness, Induration/Swelling)[1]

End point description:

Local reactions of any grade are reported. Local reactions were graded using criteria based on the FDA Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials"; the guidance uses the Grades 1 (mild), 2 (moderate), 3 (severe), and 4 (potentially life-threatening). The reporting of systemic reactions was based on the participant's assessments collected in the electronic diary (e-diary) or mapped from the adverse event case report form from Day 1 to Day 7 after each IMP dose. For Erythema/redness and Induration/swelling, the reported size had to be at least 2.5 cm to be deemed as a local reaction. Local reactions with a size less than 2.5 cm were not included in the analysis. Per protocol, participants in C9 did not receive a vaccination and were not included in this analysis. Reactogenicity set, i.e., all participants included in the Safety Set with any reactogenicity data reported after IMP injection.

End point type	Primary

End point timeframe:

from Day 1 to Day 7 after each IMP dose

Notes:

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

End point values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	19	20
Units: Percentage of participants				
number (not applicable)				
Any local reaction - Overall	90.5	100	89.5	95.0
Pain at the injection site - Overall	81.0	95.0	73.7	85.0
Tenderness - Overall	85.7	100	89.5	90.0
Erythema/redness - Overall	4.8	15.0	5.3	5.0
Induration/swelling - Overall	4.8	15.0	5.3	10.0
Any local reaction - After IMP Dose 1	90.5	100	89.5	95.0
Pain at the injection site - After IMP Dose 1	81.0	95.0	73.7	85.0
Tenderness - After IMP Dose 1	85.7	100	89.5	90.0
Erythema/redness - After IMP Dose 1	4.8	15.0	5.3	5.0

Induration/swelling - After IMP Dose 1	4.8	15.0	5.3	10.0
Any local reaction - After IMP Dose 2	0	85.7	0	0
Pain at the injection site - After IMP Dose 2	0	78.6	0	0
Tenderness - After IMP Dose 2	0	64.3	0	0
Erythema/redness - After IMP Dose 2	0	0	0	0
Induration/swelling - After IMP Dose 2	0	7.1	0	0
Any local reaction - After IMP Dose 3	0	0	0	0
Pain at the injection site - After IMP Dose 3	0	0	0	0
Tenderness - After IMP Dose 3	0	0	0	0
Erythema/redness - After IMP Dose 3	0	0	0	0
Induration/swelling - After IMP Dose 3	0	0	0	0

End point values	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	17	341	348
Units: Percentage of participants				
number (not applicable)				
Any local reaction - Overall	92.5	88.2	85.0	89.1
Pain at the injection site - Overall	67.5	76.5	74.5	75.9
Tenderness - Overall	82.5	82.4	64.5	78.4
Erythema/redness - Overall	20.0	5.9	10.0	8.6
Induration/swelling - Overall	25.0	23.5	10.6	8.6
Any local reaction - After IMP Dose 1	92.5	75.0	85.0	89.1
Pain at the injection site - After IMP Dose 1	67.5	62.5	74.5	75.9
Tenderness - After IMP Dose 1	82.5	75.0	64.5	78.4
Erythema/redness - After IMP Dose 1	20.0	6.3	10.0	8.6
Induration/swelling - After IMP Dose 1	25.0	12.5	10.6	8.6
Any local reaction - After IMP Dose 2	0	71.4	0	0
Pain at the injection site - After IMP Dose 2	0	64.3	0	0
Tenderness - After IMP Dose 2	0	71.4	0	0
Erythema/redness - After IMP Dose 2	0	0	0	0
Induration/swelling - After IMP Dose 2	0	0	0	0
Any local reaction - After IMP Dose 3	0	80.0	0	0
Pain at the injection site - After IMP Dose 3	0	80.0	0	0
Tenderness - After IMP Dose 3	0	70.0	0	0
Erythema/redness - After IMP Dose 3	0	0	0	0
Induration/swelling - After IMP Dose 3	0	30.0	0	0

End point values	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.	Part C - C8: 1 Dose of 30 µg BNT162b2	Part C - C9: No Vaccination

	1.1.7 + B.1.617.2)	1.1.529.1)	(Original Vaccine)	
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	358	72	70	0[2]
Units: Percentage of participants				
number (not applicable)				
Any local reaction - Overall	72.9	87.5	87.1	
Pain at the injection site - Overall	69.0	79.2	74.3	
Tenderness - Overall	56.1	76.4	80.0	
Erythema/redness - Overall	13.1	15.3	10.0	
Induration/swelling - Overall	16.2	11.1	7.1	
Any local reaction - After IMP Dose 1	61.4	87.5	87.1	
Pain at the injection site - After IMP Dose 1	55.9	79.2	74.3	
Tenderness - After IMP Dose 1	38.3	76.4	80.0	
Erythema/redness - After IMP Dose 1	6.3	15.3	10.0	
Induration/swelling - After IMP Dose 1	10.4	11.1	7.1	
Any local reaction - After IMP Dose 2	47.7	0	0	
Pain at the injection site - After IMP Dose 2	44.2	0	0	
Tenderness - After IMP Dose 2	24.9	0	0	
Erythema/redness - After IMP Dose 2	5.0	0	0	
Induration/swelling - After IMP Dose 2	6.9	0	0	
Any local reaction - After IMP Dose 3	57.3	0	0	
Pain at the injection site - After IMP Dose 3	51.9	0	0	
Tenderness - After IMP Dose 3	41.7	0	0	
Erythema/redness - After IMP Dose 3	6.4	0	0	
Induration/swelling - After IMP Dose 3	6.4	0	0	

Notes:

[2] - As per protocol, these participants did not receive treatment and were therefore excluded

Statistical analyses

No statistical analyses for this end point

Primary: All Parts - Percentage of Participants Reporting Systemic Events (Fever, Fatigue, Headache, Chills, Vomiting, Nausea, Diarrhea, New or Worsened Muscle Pain, and New or Worsened Joint Pain)

End point title	All Parts - Percentage of Participants Reporting Systemic Events (Fever, Fatigue, Headache, Chills, Vomiting, Nausea, Diarrhea, New or Worsened Muscle Pain, and New or Worsened Joint Pain)[3]

End point description:

Systemic reactions of any grade are reported. Systemic reactions were graded using criteria based on the FDA Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials"; the guidance uses the Grades 1 (mild), 2 (moderate), 3 (severe), and 4 (potentially life-threatening). The reporting of systemic reactions was based on the participant's assessments collected in the e-diary or mapped from the adverse event case report form from Day 1 to Day 7 after each IMP dose. For Fever, the reported oral temperature had to be ≥38.0°C to be deemed as a systemic event. Oral temperature less than 38.0°C was not included in the analysis. Per protocol, participants in C9 did not receive a vaccination and were not included in this analysis. Reactogenicity set, i.e., all participants included in the Safety Set with any reactogenicity data reported after IMP injection.

End point type	Primary

End point timeframe:

from Day 1 to Day 7 after each IMP dose

Notes:

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

End point values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	19	20
Units: Percentage of participants				
number (not applicable)				
Any systemic event - Overall	81.0	100	78.9	80.0
Oral temperature of ≥ 38.0 °C – Overall	19.0	25.0	15.8	10.0
Nausea – Overall	9.5	45.0	21.1	35.0
Vomiting – Overall	0	15.0	0	5.0
Diarrhea – Overall	9.5	25.0	15.8	10.0
Headache – Overall	71.4	85.0	63.2	40.0
Fatigue – Overall	71.4	95.0	78.9	75.0
Chills – Overall	47.6	65.0	15.8	45.0
New or worsened muscle pain – Overall	47.6	70.0	52.6	40.0
New or worsened joint pain – Overall	28.6	35.0	21.1	20.0
Any systemic event – After IMP Dose 1	81.0	90.0	78.9	80.0
Oral temperature of ≥ 38.0 °C – After IMP Dose 1	19.0	20.0	15.8	10.0
Nausea – After IMP Dose 1	9.5	30.0	21.1	35.0
Vomiting – After IMP Dose 1	0	5.0	0	5.0
Diarrhea – After IMP Dose 1	9.5	20.0	15.8	10.0
Headache – After IMP Dose 1	71.4	80.0	63.2	40.0
Fatigue – After IMP Dose 1	71.4	85.0	78.9	75.0
Chills – After IMP Dose 1	47.6	45.0	15.8	45.0
New or worsened muscle pain – After IMP Dose 1	47.6	60.0	52.6	40.0
New or worsened joint pain – After IMP Dose 1	28.6	30.0	21.1	20.0
Any systemic event – After IMP Dose 2	0	93.3	0	0
Oral temperature of ≥ 38.0 °C – After IMP Dose 2	0	6.7	0	0
Nausea – After IMP Dose 2	0	33.3	0	0
Vomiting – After IMP Dose 2	0	13.3	0	0
Diarrhea – After IMP Dose 2	0	13.3	0	0
Headache – After IMP Dose 2	0	73.3	0	0
Fatigue – After IMP Dose 2	0	86.7	0	0
Chills – After IMP Dose 2	0	40.0	0	0
New or worsened muscle pain – After IMP Dose 2	0	60.0	0	0
New or worsened joint pain – After IMP Dose 2	0	20.0	0	0
Any systemic event – After IMP Dose 3	0	0	0	0
Oral temperature of ≥ 38.0 °C – After IMP Dose 3	0	0	0	0
Nausea – After IMP Dose 3	0	0	0	0

Vomiting – After IMP Dose 3	0	0	0	0
Diarrhea – After IMP Dose 3	0	0	0	0
Headache – After IMP Dose 3	0	0	0	0
Fatigue – After IMP Dose 3	0	0	0	0
Chills – After IMP Dose 3	0	0	0	0
New or worsened muscle pain – After IMP Dose 3	0	0	0	0
New or worsened joint pain – After IMP Dose 3	0	0	0	0

End point values	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	17	341	347
Units: Percentage of participants				
number (not applicable)				
Any systemic event - Overall	82.5	76.5	74.8	76.9
Oral temperature of ≥ 38.0 °C – Overall	0	5.9	9.4	9.8
Nausea – Overall	10.0	23.5	17.9	18.4
Vomiting – Overall	0	5.9	2.3	2.0
Diarrhea – Overall	15.0	23.5	5.6	11.2
Headache – Overall	55.0	58.8	46.9	51.3
Fatigue – Overall	75.0	52.9	64.2	63.4
Chills – Overall	32.5	41.2	26.7	33.1
New or worsened muscle pain – Overall	40.0	47.1	36.1	37.8
New or worsened joint pain – Overall	32.5	29.4	25.5	22.5
Any systemic event – After IMP Dose 1	82.5	68.8	74.8	76.9
Oral temperature of ≥ 38.0 °C – After IMP Dose 1	0	0	9.4	9.8
Nausea – After IMP Dose 1	10.0	18.8	17.9	18.4
Vomiting – After IMP Dose 1	0	6.3	2.3	2.0
Diarrhea – After IMP Dose 1	15.0	12.5	5.6	11.2
Headache – After IMP Dose 1	55.0	50.0	46.9	51.3
Fatigue – After IMP Dose 1	75.0	50.0	64.2	63.4
Chills – After IMP Dose 1	32.5	18.8	26.7	33.1
New or worsened muscle pain – After IMP Dose 1	40.0	37.5	36.1	37.8
New or worsened joint pain – After IMP Dose 1	32.5	18.8	25.5	22.5
Any systemic event – After IMP Dose 2	0	60.0	0	0
Oral temperature of ≥ 38.0 °C – After IMP Dose 2	0	6.7	0	0
Nausea – After IMP Dose 2	0	13.3	0	0
Vomiting – After IMP Dose 2	0	6.7	0	0
Diarrhea – After IMP Dose 2	0	13.3	0	0
Headache – After IMP Dose 2	0	40.0	0	0
Fatigue – After IMP Dose 2	0	40.0	0	0
Chills – After IMP Dose 2	0	20.0	0	0

New or worsened muscle pain – After IMP Dose 2	0	26.7	0	0
New or worsened joint pain – After IMP Dose 2	0	26.7	0	0
Any systemic event – After IMP Dose 3	0	60.0	0	0
Oral temperature of ≥ 38.0 °C – After IMP Dose 3	0	0	0	0
Nausea – After IMP Dose 3	0	10.0	0	0
Vomiting – After IMP Dose 3	0	0	0	0
Diarrhea – After IMP Dose 3	0	10.0	0	0
Headache – After IMP Dose 3	0	40.0	0	0
Fatigue – After IMP Dose 3	0	40.0	0	0
Chills – After IMP Dose 3	0	20.0	0	0
New or worsened muscle pain – After IMP Dose 3	0	40.0	0	0
New or worsened joint pain – After IMP Dose 3	0	20.0	0	0

End point values	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part C - C9: No Vaccination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	358	72	70	0[4]
Units: Percentage of participants				
number (not applicable)				
Any systemic event - Overall	70.7	72.2	78.6	
Oral temperature of ≥ 38.0 °C – Overall	9.5	1.4	4.3	
Nausea – Overall	26.0	12.5	21.4	
Vomiting – Overall	9.5	1.4	0	
Diarrhea – Overall	19.0	11.1	14.3	
Headache – Overall	53.1	44.4	50.0	
Fatigue – Overall	50.3	55.6	62.9	
Chills – Overall	21.5	15.3	20.0	
New or worsened muscle pain – Overall	39.9	27.8	27.1	
New or worsened joint pain – Overall	28.2	12.5	12.9	
Any systemic event – After IMP Dose 1	58.5	72.2	78.6	
Oral temperature of ≥ 38.0 °C – After IMP Dose 1	4.0	1.4	4.3	
Nausea – After IMP Dose 1	16.7	12.5	21.4	
Vomiting – After IMP Dose 1	6.3	1.4	0	
Diarrhea – After IMP Dose 1	12.7	11.1	14.3	
Headache – After IMP Dose 1	36.0	44.4	50.0	
Fatigue – After IMP Dose 1	34.3	55.6	62.9	
Chills – After IMP Dose 1	12.4	15.3	20.0	
New or worsened muscle pain – After IMP Dose 1	26.5	27.8	27.1	
New or worsened joint pain – After IMP Dose 1	19.6	12.5	12.9	
Any systemic event – After IMP Dose 2	43.0	0	0	
Oral temperature of ≥ 38.0 °C – After IMP Dose 2	3.7	0	0	

Nausea – After IMP Dose 2	8.7	0	0	
Vomiting – After IMP Dose 2	2.8	0	0	
Diarrhea – After IMP Dose 2	6.2	0	0	
Headache – After IMP Dose 2	27.2	0	0	
Fatigue – After IMP Dose 2	23.8	0	0	
Chills – After IMP Dose 2	9.0	0	0	
New or worsened muscle pain – After IMP Dose 2	18.9	0	0	
New or worsened joint pain – After IMP Dose 2	12.1	0	0	
Any systemic event – After IMP Dose 3	48.1	0	0	
Oral temperature of ≥ 38.0 °C – After IMP Dose 3	4.4	0	0	
Nausea – After IMP Dose 3	11.2	0	0	
Vomiting – After IMP Dose 3	4.1	0	0	
Diarrhea – After IMP Dose 3	7.5	0	0	
Headache – After IMP Dose 3	35.3	0	0	
Fatigue – After IMP Dose 3	29.5	0	0	
Chills – After IMP Dose 3	9.2	0	0	
New or worsened muscle pain – After IMP Dose 3	18.3	0	0	
New or worsened joint pain – After IMP Dose 3	9.5	0	0	

Notes:

[4] - As per protocol, these participants did not receive treatment and were therefore excluded

Statistical analyses

No statistical analyses for this end point

Primary: All Parts - Percentage of Participants Reporting Adverse Events (AEs)

End point title	All Parts - Percentage of Participants Reporting Adverse Events (AEs)[5]

End point description:

An AE is defined as TEAE if the event onset date and time is after the first IMP dose (if the event was absent before the first administration of the IMP) or worsened after the first IMP dose (if the event was present before the first administration of the IMP). In the event of an incomplete onset date, the event was considered as treatment-emergent unless the partial onset date information or complete or partial end date confirmed the onset date or the event end prior to the first dose of IMP. Percentages for dose 1, 2, 3 and overall summaries are based upon the number of participants who received the respective IMP dose. Safety set, i.e., all participants who received at least 1 dose of IMP. 21 participants assigned to Part B C4 actually received BNT162b2 (treatment of Part A C5) and therefore were included in the analyses of safety set of Part A C5 and excluded from Part B safety set. 1 participant from Part A C6 also received BNT162b2 and was included in the Part A C5 safety set.

End point type	Primary

End point timeframe:

Dose 1 up to 1 month after each dose (all parts)

Notes:

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

End point values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	20	20
Units: Percentage of participants				
number (not applicable)				
Any AE after IMP Dose 1	19.0	30.0	30.0	15.0
Any AE after IMP Dose 2	0	27.8	0	0
Any AE after IMP Dose 3	0	0	0	0

End point values	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	17	349	352
Units: Percentage of participants				
number (not applicable)				
Any AE after IMP Dose 1	66.7	29.4	14.6	13.1
Any AE after IMP Dose 2	0	17.6	0	0
Any AE after IMP Dose 3	0	20.0	0	0

End point values	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part C - C9: No Vaccination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	361	72	71	0[6]
Units: Percentage of participants				
number (not applicable)				
Any AE after IMP Dose 1	20.2	12.5	19.7	
Any AE after IMP Dose 2	15.7	0	0	
Any AE after IMP Dose 3	15.2	0	0	

Notes:

[6] - As per protocol, these participants did not receive treatment and were therefore excluded

Statistical analyses

No statistical analyses for this end point

Primary: All Parts - Percentage of Participants Reporting Serious Adverse Events (SAEs)

End point title	All Parts - Percentage of Participants Reporting Serious Adverse Events (SAEs)[7]

End point description:

An SAE was any untoward medical occurrence that, at any dose: resulted in death; was life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; resulted in persistent disability/ incapacity; was a congenital anomaly/birth defect and/or was another important medical event. SAEs from dose 1 up to 6 months post last IMP dose are presented. MedDRA (version 26.1) coding dictionary applied. An SAE was defined as TESAE if the event onset date and time was after the first IMP dose (if the event was absent before the first administration of the IMP) or worsened after the first IMP dose (if the event was present before the first administration of the IMP). In the event of an incomplete onset date, the event was considered as treatment-emergent unless the partial onset date information or complete or partial end date confirmed the onset date or the event end prior to the first dose of IMP. Safety set.

End point type	Primary

End point timeframe:

Dose 1 up to 6 months after the last dose

Notes:

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

End point values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	20	20
Units: Percentage of participants				
number (not applicable)				
Percentage of Participants Reporting SAEs	0	0	0	0

End point values	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	17	349	352
Units: Percentage of participants				
number (not applicable)				
Percentage of Participants Reporting SAEs	0	0	1.1	1.7

End point values	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part C - C9: No Vaccination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	361	72	71	0[8]
Units: Percentage of participants				
number (not applicable)				
Percentage of Participants Reporting SAEs	3.6	0	7.0	

Notes:

[8] - As per protocol, these participants did not receive treatment and were therefore excluded

Statistical analyses

No statistical analyses for this end point

Primary: Part B - GMR of B.1.1.7 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 (2020-002641-42) Trial

End point title	Part B - GMR of B.1.1.7 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 (2020-002641-42) Trial[9]

End point description:

GMRs and 2-sided 95% CIs were calculated by exponentiating the difference of least square means and corresponding CIs based on the analysis of logarithmically transformed neutralizing titers using a linear regression model with terms of age, sex, and vaccine group. The overall number of participants analyzed represents the number of participants with valid and determinate assay results for B.1.1.7 and reference strain respectively at the given dose/sampling time point within the specified window. Immunogenicity Analysis Set, i.e., all eligible randomized/assigned participants who received the trial intervention to which they were randomized or assigned, had a valid and determinate immunogenicity result from the blood sample collected within an appropriate window, and had no other important protocol deviations that could confound immunogenicity data.
GMR = Geometric mean ratio; NT = neutralizing titers

End point type	Primary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 (2020-002641-42) trial

Notes:

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

End point values	BNT162-17 Part B - C1 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	631[10]			
Units: Titer ratio				
geometric mean (confidence interval 95%)	8.81 (7.49 to 10.36)			

Notes:

[10] - Includes 299 participants from BNT162-17 and 332 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part B - GMR of B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial

End point title	Part B - GMR of B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial[11]

End point description:

GMRs and 2-sided 95% CIs were calculated by exponentiating the difference of least square means and corresponding CIs based on the analysis of logarithmically transformed neutralizing titers using a linear regression model with terms of age, sex, and group. The overall number of participants analyzed represents the number of participants with valid and determinate assay results for B.1.617.2 and reference strain respectively at the given dose/sampling time point within the specified window. Immunogenicity Analysis Set, i.e., all eligible randomized/assigned participants who received the trial intervention to which they were randomized or assigned, had a valid and determinate immunogenicity result from the blood sample collected within an appropriate window, and had no other important protocol deviations that could confound immunogenicity data.
GMR = Geometric mean ratio; NT = neutralizing titers

End point type	Primary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 (EudraCT number: 2020-002641-42) trial

Notes:

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

End point values	BNT162-17 Part B - C1 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	631[12]			
Units: Titer ratio				
geometric mean (confidence interval 95%)	4.88 (4.19 to 5.68)			

Notes:

[12] - Includes 299 participants from BNT162-17 and 332 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part B - GMR of B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial

End point title	Part B - GMR of B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial[13]

End point description:

GMRs and 2-sided 95% CIs were calculated by exponentiating the difference of least square means and corresponding CIs based on the analysis of logarithmically transformed neutralizing titers using a linear regression model with terms of age, sex, and group. The overall number of participants analyzed represents the number of participants with valid and determinate assay results for B.1.617.2 and reference strain respectively at the given dose/sampling time point within the specified window. Immunogenicity Analysis Set.

End point type	Primary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 (2020-002641-42) trial

Notes:

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

End point values	BNT162-17 Part B - C4 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	637[14]			
Units: Titer ratio				
geometric mean (confidence interval 95%)	6.40 (5.47 to 7.48)			

Notes:

[14] - Includes 317 participants from BNT162-17 and 320 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part B - Difference in Seroresponse (SR) to B.1.1.7 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From C4591001

End point title	Part B - Difference in Seroresponse (SR) to B.1.1.7 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From C4591001[15]

End point description:

Seroresponse was defined as a ≥4-fold rise in neutralizing titer from baseline. For subjects with a baseline titer less than the lower limit of quantitation (<LLOQ), seroresponse was defined as a post-vaccination titer of ≥4× LLOQ. Adjusted difference was estimated using minimum risk weights and stratified by sex and age group (18 to 55 years, 56 to 85 years), expressed as a percentage. Associated 2-sided 95% CI based on the Newcombe method with minimum risk weights for the difference in proportions. Immunogenicity Analysis Set.

End point type	Primary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 (2020-002641-42) trial

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: No statistical analysis was planned for this endpoint.

End point values	BNT162-17 Part B - C1 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	630[16]			
Units: Percentage difference				
number (confidence interval 95%)	0.25 (-4.86 to 5.26)			

Notes:

[16] - Includes 298 participants from BNT162-17 and 332 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part B - Difference in SR to B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2- experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From C4591001

End point title	Part B - Difference in SR to B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2- experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From C4591001[17]

End point description:

Seroresponse was defined as a ≥4-fold rise in neutralizing titer from baseline. For subjects with a baseline titer less than the lower limit of quantitation (<LLOQ), seroresponse was defined as a post-vaccination titer of ≥4× LLOQ. Adjusted difference was estimated using minimum risk weights and stratified by sex and age group (18 to 55 years, 56 to 85 years), expressed as a percentage. Associated 2-sided 95% CI based on the Newcombe method with minimum risk weights for the difference in proportions.

End point type	Primary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 (2020-002641-42) trial

Notes:

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

End point values	BNT162-17 Part B - C1 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	630[18]			
Units: Percentage difference				
number (confidence interval 95%)	-2.39 (-7.74 to 2.84)			

Notes:

[18] - Includes 298 participants from BNT162-17 and 332 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part B - Difference in SR to B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From C4591001 (2020-002641-42)

End point title	Part B - Difference in SR to B.1.617.2 NT 1 Month After 1 Dose of BNT162b2 (B.1.617.2) in BNT162b2-experienced Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From C4591001 (2020-002641-42)[19]

End point description:

Seroresponse was defined as a ≥4-fold rise in neutralizing titer from baseline. For subjects with a baseline titer less than the lower limit of quantitation (<LLOQ), seroresponse was defined as a post-vaccination titer of ≥4× LLOQ. Adjusted difference was estimated using minimum risk weights and stratified by sex and age group (18 to 55 years, 56 to 85 years), expressed as a percentage. Associated 2-sided 95% CI based on the Newcombe method with minimum risk weights for the difference in proportions. Immunogenicity Analysis Set.

End point type	Primary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 trial

Notes:

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

End point values	BNT162-17 Part B - C4 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	633[20]			
Units: Percentage difference				
number (confidence interval 95%)	9.70 (5.68 to 13.97)			

Notes:

[20] - Includes 313 participants from BNT162-17 and 320 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part B - GMR of B.1.1.7 NT 1 Month After 2 Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial

End point title	Part B - GMR of B.1.1.7 NT 1 Month After 2 Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial[21]

End point description:

In COVID-19 vaccine naïve individuals (Cohort B6) the aim was to generate data to support a 2-dose primary regimen of alpha-delta multivalent BNT162b2 vaccine in SARS-CoV-2 naïve, unvaccinated individuals. The population recruited in Cohort B6, while complying with the inclusion criterium of no known history SARS-CoV-2 infection, were retrospectively seropositive for SARS-CoV-2 by planned N-binding antibody assessment at baseline. While the cohort was COVID-19 vaccine-naïve, it was not SARS-CoV-2-naïve as needed to match the control population (C4591001). Procedurally, submission of a protocol amendment was not possible as the end of trial notification had been submitted in one country. However, the Statistical Analysis Plan was amended to describe that data analysis for the original primary immunogenicity endpoints for Cohort B6 could not be performed according to the protocol. Samples taken in Cohort B6 were used to address other primary, secondary and exploratory endpoints.

End point type	Primary

End point timeframe:

1 month

Notes:

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

End point values	BNT162-17 Part B - C6 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	0[22]			
Units: Titer ratio				
geometric mean (confidence interval 95%)	(to)			

Notes:

[22] - Data could not be collected as participants were not SARS-CoV-2 naïve

Statistical analyses

No statistical analyses for this end point

Primary: Part B - GMR of B.1.617.2 NT 1 Month After 2 Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial

End point title	Part B - GMR of B.1.617.2 NT 1 Month After 2 Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial[23][24]

End point description:

In COVID-19 vaccine naïve individuals (Cohort B6) the aim was to generate data to support a 2-dose primary regimen of alpha-delta multivalent BNT162b2 vaccine in SARS-CoV-2 naïve, unvaccinated individuals. The population recruited in Cohort B6, while complying with the inclusion criterium of no known history SARS-CoV-2 infection, were retrospectively seropositive for SARS-CoV-2 by planned N-binding antibody assessment at baseline. While the cohort was COVID-19 vaccine-naïve, it was not SARS-CoV-2-naïve as needed to match the control population (C4591001). Procedurally, submission of a protocol amendment was not possible as the end of trial notification had been submitted in one country. However, the Statistical Analysis Plan was amended to describe that data analysis for the original primary immunogenicity endpoints for Cohort B6 could not be performed according to the protocol. Samples taken in Cohort B6 were used to address other primary, secondary and exploratory endpoints.

End point type	Primary

End point timeframe:

1 month

Notes:

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

[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: This endpoint was meant to report only data relevant to Part B (Cohorts 1, 4, and 6). However, this data is not available for these cohorts.

End point values	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[25]	0[26]	0[27]	
Units: Titer ratio				
geometric mean (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[25] - Data could not be collected as participants were not SARS-CoV-2 naïve

[26] - Data could not be collected as participants were not SARS-CoV-2 naïve

[27] - Data could not be collected as participants were not SARS-CoV-2 naïve

Statistical analyses

No statistical analyses for this end point

Primary: Part B - The Difference in SR to B.1.1.7 NT 1 Month After 2 Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial

End point title	Part B - The Difference in SR to B.1.1.7 NT 1 Month After 2 Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial[28][29]

End point description:

In COVID-19 vaccine naïve individuals (Cohort B6) the aim was to generate data to support a 2-dose primary regimen of alpha-delta multivalent BNT162b2 vaccine in SARS-CoV-2 naïve, unvaccinated individuals. The population recruited in Cohort B6, while complying with the inclusion criterium of no known history SARS-CoV-2 infection, were retrospectively seropositive for SARS-CoV-2 by planned N-binding antibody assessment at baseline. While the cohort was COVID-19 vaccine-naïve, it was not SARS-CoV-2-naïve as needed to match the control population (C4591001). Procedurally, submission of a protocol amendment was not possible as the end of trial notification had been submitted in one country. However, the Statistical Analysis Plan was amended to describe that data analysis for the original primary immunogenicity endpoints for Cohort B6 could not be performed according to the protocol. Samples taken in Cohort B6 were used to address other primary, secondary and exploratory endpoints.

End point type	Primary

End point timeframe:

1 month

Notes:

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

[29] - 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: This endpoint was meant to report only data relevant to Part B (Cohorts 1 and 6). However, this data is not available for these cohorts.

End point values	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[30]	0[31]		
Units: Percentage difference				
number (confidence interval 95%)	(to)	(to)		

Notes:

[30] - Data could not be collected as participants were not SARS-CoV-2 naïve

[31] - Data could not be collected as participants were not SARS-CoV-2 naïve

Statistical analyses

No statistical analyses for this end point

Primary: Part B - The Difference in SR to B.1.617.2 NT 1 Month After 2 Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial

End point title	Part B - The Difference in SR to B.1.617.2 NT 1 Month After 2

	Doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 Vaccine-naïve Participants to the Reference Strain NT 1 Month After 2 Doses of BNT162b2 in Participants From the Phase III C4591001 Trial[32][33]

End point description:

In COVID-19 vaccine naïve individuals (Cohort B6) the aim was to generate data to support a 2-dose primary regimen of alpha-delta multivalent BNT162b2 vaccine in SARS-CoV-2 naïve, unvaccinated individuals. The population recruited in Cohort B6, while complying with the inclusion criterium of no known history SARS-CoV-2 infection, were retrospectively seropositive for SARS-CoV-2 by planned N-binding antibody assessment at baseline. While the cohort was COVID-19 vaccine-naïve, it was not SARS-CoV-2-naïve as needed to match the control population (C4591001). Procedurally, submission of a protocol amendment was not possible as the end of trial notification had been submitted in one country. However, the Statistical Analysis Plan was amended to describe that data analysis for the original primary immunogenicity endpoints for Cohort B6 could not be performed according to the protocol. Samples taken in Cohort B6 were used to address other primary, secondary and exploratory endpoints.

End point type	Primary

End point timeframe:

1 month

Notes:

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

[33] - 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: This endpoint was meant to report only data relevant to Part B (Cohorts 1, 4, and 6). However, this data is not available for these cohorts.

End point values	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[34]	0[35]	0[36]	
Units: Percentage difference				
number (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[34] - Data could not be collected as participants were not SARS-CoV-2 naïve

[35] - Data could not be collected as participants were not SARS-CoV-2 naïve

[36] - Data could not be collected as participants were not SARS-CoV-2 naïve

Statistical analyses

No statistical analyses for this end point

Primary: Part B - GMR of Reference Strain NT After One Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in Participants With Evidence of Prior Infection to the Reference Strain NT After 2 Doses of BNT162b2 in Participants Without Evidence of Infection

End point title	Part B - GMR of Reference Strain NT After One Dose of BNT162b2 (B.1.1.7 + B.1.617.2) in Participants With Evidence of Prior Infection to the Reference Strain NT After 2 Doses of BNT162b2 in Participants Without Evidence of Infection[37]

End point description:

GMR of reference strain NT 3 weeks after one dose of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 vaccine-naïve participants with evidence of prior infection and to the reference strain NT 1 month after two doses of BNT162b2 in participants without evidence of infection (COVID-19 Vaccine-naïve Participants) from the Phase III trial C4591001. GMRs and 2-sided 95% CIs were calculated by exponentiating the difference of LS means and corresponding CIs based on the analysis of logarithmically transformed neutralizing titers using a linear regression model with terms of age, sex,

and group. Assay results below the LLOQ were set to 0.5 × LLOQ. Immunogenicity Analysis Set.

End point type	Primary

End point timeframe:

3 weeks post Dose 1 in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 trial

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: No statistical analysis was planned for this endpoint.

End point values	BNT162-17 Part B - C6 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	537[38]			
Units: Titer ratio				
geometric mean (confidence interval 95%)	13.12 (11.14 to 15.45)			

Notes:

[38] - Includes 262 participants from BNT162-17 and 275 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part B - The Difference in SRs to the Reference Strain NT in Participants With Evidence of Prior Infection and to the Reference Strain NT in Participants Without Evidence of Infection (COVID-19 Vaccine-naïve Participants)

End point title	Part B - The Difference in SRs to the Reference Strain NT in Participants With Evidence of Prior Infection and to the Reference Strain NT in Participants Without Evidence of Infection (COVID-19 Vaccine-naïve Participants)[39]

End point description:

The difference in SRs to the reference strain NT 3 weeks after one dose of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 vaccine-naïve participants with evidence of prior infection to the reference strain NT 1 month after two doses of BNT162b2 in participants without evidence of infection (COVID-19 Vaccine-naïve Participants) from the Phase III trial C4591001. Seroresponse was defined as achieving a ≥4-fold rise from baseline. If the baseline measurement was below the LLOQ, a post-vaccination assay result ≥4 × LLOQ was considered a seroresponse. Adjusted difference in proportions was estimated using minimum risk weights and stratified by sex and age group (18 to 55 years, 56 to 85 years), expressed as a percentage 2-Sided CI based on the Newcombe method with minimum risk weights for the difference in proportions. Immunogenicity Analysis Set.

End point type	Primary

End point timeframe:

3 weeks post Dose 1 in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 trial

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: No statistical analysis was planned for this endpoint.

End point values	BNT162-17 Part B - C6 / C4591001			
Subject group type	Subject analysis set			
Number of subjects analysed	535[40]			
Units: Percentage difference				
number (confidence interval 95%)	-4.55 (-10.04 to 0.83)			

Notes:

[40] - Includes 260 participants from BNT162-17 and 275 participants from C4591001 (2020-002641-42).

Statistical analyses

No statistical analyses for this end point

Primary: Part C - GMR of B.1.1.529.1 NT 1 Month After One Dose of BNT162b2 (B.1.1.529.1) in RNA-based COVID-19 Vaccine experienced Participants With History of SARS-CoV-2 Infection to Those at 1 Month After One Dose of BNT162b2 for Cohorts 7 and 8

End point title	Part C - GMR of B.1.1.529.1 NT 1 Month After One Dose of BNT162b2 (B.1.1.529.1) in RNA-based COVID-19 Vaccine experienced Participants With History of SARS-CoV-2 Infection to Those at 1 Month After One Dose of BNT162b2 for Cohorts 7 and 8[41]

End point description:

GMRs and 2-sided 95% CIs were calculated by exponentiating the difference of least square means and corresponding CIs based on the analysis of logarithmically transformed neutralizing titers using a linear regression model with terms of age and number of prior doses. The overall number of participants analyzed represents the number of participants with valid and determinate assay results for B.1.1.529.1 at the given dose/sampling time point within the specified window. Immunogenicity Analysis Set.

End point type	Primary

End point timeframe:

1 month after 1 dose of BNT162b2 or BNT162b2 (B.1.1.529.1)

Notes:

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

End point values	Part C - Cohort 7: 1 Dose of 30 µg BNT162b2 / Cohort 8: 1 Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	121[42]			
Units: Titer ratio				
geometric mean (confidence interval 95%)	0.94 (0.61 to 1.44)			

Notes:

[42] - Includes 64 participants from Cohort 7 and 57 participants from Cohort 8.

Statistical analyses

No statistical analyses for this end point

Primary: Part C - The Difference in SR of B.1.1.529.1 NT 1 Month After One Dose of

BNT162b2 (B.1.1.529.1) in RNA-based COVID-19 Vaccine-experienced Participants With History of SARS-CoV-2 Infection to Those at 1 Month After One Dose of BNT162b2 for Cohorts 7 & 8

End point title	Part C - The Difference in SR of B.1.1.529.1 NT 1 Month After One Dose of BNT162b2 (B.1.1.529.1) in RNA-based COVID-19 Vaccine-experienced Participants With History of SARS-CoV-2 Infection to Those at 1 Month After One Dose of BNT162b2 for Cohorts 7 & 8[43]

End point description:

Seroresponse was defined as a ≥4-fold rise in neutralizing titer from baseline. For participants with a baseline titer less than the lower limit of quantitation (<LLOQ), seroresponse was defined as a post-vaccination titer of ≥4× LLOQ. Adjusted difference was estimated using minimum risk weights and stratified by sex and age group (18 to 55 years, 56 to 85 years), expressed as a percentage. Associated 2-sided 95% CI based on the Newcombe method with minimum risk weights for the difference in proportions. Immunogenicity Analysis Set.

End point type	Primary

End point timeframe:

1 month after 1 dose of BNT162b2 or BNT162b2 (B.1.1.529.1)

Notes:

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

End point values	Part C - Cohort 7: 1 Dose of 30 µg BNT162b2 / Cohort 8: 1 Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	121[44]			
Units: Percentage difference				
number (confidence interval 95%)	36.73 (19.21 to 51.17)			

Notes:

[44] - 64 participants from Cohort 7 and 57 participants from Cohort 8.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A - Geometric Mean Titer (GMT) at Each Timepoint

End point title	Part A - Geometric Mean Titer (GMT) at Each Timepoint[45]

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ and above the ULOQ were set to ULOQ.
Immunogenicity Analysis Set, i.e., all eligible randomized/assigned participants who received the trial intervention to which they were randomized or assigned, had a valid and determinate immunogenicity result from the blood sample collected within an appropriate window, and had no other important protocol deviations that could confound immunogenicity data.
999 = not applicable since Cohorts 1, 3, 4 and 5 received only 1 dose of IMP.
9999 = not applicable since Cohort 2 received dose 2 on Day 56 and did not receive dose 3.
99999 = not applicable since Cohort 6 received dose 2 on Day 21 and received dose 3 approximately 6 months after dose 2.

End point type	Secondary

End point timeframe:

Day 1 up to Day 421

Notes:

[45] - 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: This endpoint only reports data for Part A (Cohorts 1-6).

End point values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	20	20
Units: Titer				
geometric mean (confidence interval 95%)				
Pre IMP dose 1 - B.1.1.7	18.9 (9.0 to 39.7)	26.9 (14.5 to 49.9)	17.4 (9.0 to 33.8)	48.4 (20.0 to 117.0)
1-week post IMP dose 1 - B.1.1.7	1403.9 (817.9 to 2409.8)	1340.5 (731.0 to 2458.2)	1090.8 (701.7 to 1695.5)	557.2 (365.4 to 849.4)
3-weeks post IMP dose 1 - B.1.1.7	1035.7 (659.9 to 1625.5)	1168.4 (756.8 to 1803.9)	956.0 (657.3 to 1390.4)	493.5 (365.0 to 667.3)
1-month post IMP dose 1 - B.1.1.7	942.8 (552.6 to 1608.3)	1004.3 (705.3 to 1430.0)	1009.8 (697.8 to 1461.3)	468.5 (308.6 to 711.2)
6-months post IMP dose 1 - B.1.1.7	156.6 (62.5 to 392.2)	9999 (9999 to 9999)	352.3 (192.4 to 645.3)	151.5 (68.9 to 333.1)
12-months post IMP dose 1 - B.1.1.7	658.8 (385.8 to 1124.7)	9999 (9999 to 9999)	463.9 (180.0 to 1195.5)	241.0 (95.1 to 611.0)
Pre IMP dose 2 - B.1.1.7	999 (999 to 999)	151.0 (49.1 to 464.5)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 2 - B.1.1.7	999 (999 to 999)	987.0 (495.9 to 1964.4)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 2 - B.1.1.7	999 (999 to 999)	958.9 (586.3 to 1568.3)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	349.0 (166.5 to 731.6)	999 (999 to 999)	999 (999 to 999)
12-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	940.6 (480.4 to 1841.7)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2+pre IMP dose 3 - B.1.1.7	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 3 - B.1.1.7	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 3 - B.1.1.7	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
12-months post IMP dose 2 + 6-months post IMP dose	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
Pre IMP dose 1 - B.1.617.2	9.0 (4.8 to 16.7)	8.7 (5.1 to 15.0)	12.1 (6.4 to 22.8)	8.7 (6.0 to 12.6)
1-week post IMP dose 1 - B.1.617.2	526.6 (305.8 to 906.9)	385.0 (255.6 to 579.8)	517.1 (330.1 to 809.9)	359.2 (237.3 to 543.7)
3-weeks post IMP dose 1 - B.1.617.2	425.5 (283.1 to 723.5)	384.0 (251.0 to 587.6)	533.3 (368.0 to 772.7)	380.5 (265.8 to 544.8)
1-month post IMP dose 1 - B.1.617.2	369.1 (209.3 to 650.8)	303.8 (199.2 to 463.2)	486.8 (349.2 to 678.6)	288.4 (199.5 to 417.0)
6-months post IMP dose 1 - B.1.617.2	137.5 (51.6 to 366.1)	9999 (9999 to 9999)	217.7 (127.9 to 370.5)	123.9 (55.3 to 277.7)
12-months post IMP dose 1 - B.1.617.2	640.0 (293.4 to 1396.1)	9999 (9999 to 9999)	199.9 (87.3 to 458.1)	212.5 (78.3 to 576.2)
Pre IMP dose 2 - B.1.617.2	999 (999 to 999)	235.2 (144.0 to 384.1)	999 (999 to 999)	999 (999 to 999)

1-week post IMP dose 2 - B.1.617.2	999 (999 to 999)	515.4 (342.7 to 774.9)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 2 - B.1.617.2	999 (999 to 999)	517.8 (366.6 to 731.5)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	226.3 (114.9 to 445.6)	999 (999 to 999)	999 (999 to 999)
12-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	508.0 (288.7 to 893.9)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2+preIMP dose 3 - B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 3 - B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 3 - B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
12-mths post dose 2+6-mths post dose 3 – B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
Pre IMP dose 1 - Ref	14.9 (8.5 to 26.2)	18.7 (10.4 to 33.4)	18.3 (10.1 to 33.3)	27.8 (16.6 to 46.5)
1-week post IMP dose 1 - Ref	812.2 (474.1 to 1391.3)	519.8 (321.6 to 840.2)	640.0 (417.4 to 981.4)	702.0 (432.7 to 1138.7)
3-weeks post IMP dose 1 - Ref	678.1 (406.0 to 1132.3)	584.2 (357.5 to 954.8)	740.6 (495.0 to 1107.8)	748.0 (500.2 to 1118.6)
1-month post IMP dose 1 - Ref	589.9 (376.9 to 923.1)	452.5 (283.5 to 722.4)	688.4 (467.0 to 1014.9)	748.0 (469.3 to 1192.3)
6-months post IMP dose 1 - Ref	163.5 (72.7 to 367.7)	9999 (9999 to 9999)	244.4 (143.8 to 415.4)	101.4 (57.8 to 178.0)
12-months post IMP dose 1 - Ref	604.1 (311.3 to 1172.0)	9999 (9999 to 9999)	380.5 (164.8 to 878.9)	170.4 (67.6 to 429.5)
Pre IMP dose 2 - Ref	999 (999 to 999)	387.9 (227.7 to 660.9)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 2 - Ref	999 (999 to 999)	697.9 (453.5 to 1074.1)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 2 - Ref	999 (999 to 999)	665.1 (400.1 to 1105.6)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2 - Ref	999 (999 to 999)	334.2 (171.5 to 651.2)	999 (999 to 999)	999 (999 to 999)
12-months post IMP dose 2 - Ref	999 (999 to 999)	527.9 (263.8 to 1056.2)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2+pre IMP dose 3 - Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 3 - Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 3 - Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
12-mths post dose 2+6-mths post dose 3 – Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)

End point values	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	17		
Units: Titer				
geometric mean (confidence interval 95%)				

Pre IMP dose 1 - B.1.1.7	9.6 (5.2 to 17.8)	6.9 (4.6 to 10.5)		
1-week post IMP dose 1 - B.1.1.7	307.9 (209.1 to 453.5)	30.2 (6.8 to 133.1)		
3-weeks post IMP dose 1 - B.1.1.7	361.6 (223.9 to 584.2)	99999 (99999 to 99999)		
1-month post IMP dose 1 - B.1.1.7	314.5 (182.7 to 541.3)	99999 (99999 to 99999)		
6-months post IMP dose 1 - B.1.1.7	85.7 (36.9 to 199.3)	99999 (99999 to 99999)		
12-months post IMP dose 1 - B.1.1.7	463.9 (188.0 to 1144.8)	99999 (99999 to 99999)		
Pre IMP dose 2 - B.1.1.7	999 (999 to 999)	42.7 (12.5 to 145.9)		
1-week post IMP dose 2 - B.1.1.7	999 (999 to 999)	207.5 (104.3 to 413.0)		
1-month post IMP dose 2 - B.1.1.7	999 (999 to 999)	216.1 (101.7 to 459.0)		
6-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	99999 (99999 to 99999)		
12-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	99999 (99999 to 99999)		
6-months post IMP dose 2+pre IMP dose 3 - B.1.1.7	999 (999 to 999)	68.3 (21.7 to 215.2)		
1-week post IMP dose 3 - B.1.1.7	999 (999 to 999)	640.0 (379.2 to 1080.2)		
1-month post IMP dose 3 - B.1.1.7	999 (999 to 999)	562.0 (190.2 to 1660.6)		
12-months post IMP dose 2 + 6-months post IMP dose	999 (999 to 999)	351.7 (162.4 to 761.8)		
Pre IMP dose 1 - B.1.617.2	9.0 (5.2 to 15.8)	6.5 (4.7 to 9.0)		
1-week post IMP dose 1 - B.1.617.2	254 (162.5 to 369.9)	27.7 (6.6 to 115.4)		
3-weeks post IMP dose 1 - B.1.617.2	221.7 (123.0 to 399.6)	99999 (99999 to 99999)		
1-month post IMP dose 1 - B.1.617.2	207.5 (126.3 to 340.8)	99999 (99999 to 99999)		
6-months post IMP dose 1 - B.1.617.2	35.6 (17.5 to 72.7)	99999 (99999 to 99999)		
12-months post IMP dose 1 - B.1.617.2	226.3 (92.5 to 553.7)	99999 (99999 to 99999)		
Pre IMP dose 2 - B.1.617.2	999 (999 to 999)	60.4 (18.3 to 199.5)		
1-week post IMP dose 2 - B.1.617.2	999 (99 to 999)	216.7 (134.6 to 348.7)		
1-month post IMP dose 2 - B.1.617.2	999 (999 to 999)	320.0 (139.1 to 736.4)		
6-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	99999 (99999 to 99999)		
12-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	99999 (99999 to 99999)		
6-months post IMP dose 2+preIMP dose 3 - B.1.617.2	999 (999 to 999)	87.9 (26.2 to 294.9)		
1-week post IMP dose 3 - B.1.617.2	999 (999 to 999)	819.8 (353.1 to 1903.2)		
1-month post IMP dose 3 - B.1.617.2	999 (999 to 999)	640.0 (207.3 to 1976.3)		
12-mths post dose 2+6-mths post dose 3 – B.1.617.2	999 (999 to 999)	424.9 (213.3 to 846.5)		
Pre IMP dose 1 - Ref	14.1 (7.9 to 25.3)	6.8 (4.6 to 9.9)		

1-week post IMP dose 1 - Ref	352.3 (238.3 to 521.0)	25.4 (6.6 to 97.7)		
3-weeks post IMP dose 1 - Ref	408.7 (262.0 to 637.4)	99999 (99999 to 99999)		
1-month post IMP dose 1 - Ref	380.5 (232.0 to 624.3)	99999 (99999 to 99999)		
6-months post IMP dose 1 - Ref	78.2 (42.2 to 145.0)	99999 (99999 to 99999)		
12-months post IMP dose 1 - Ref	565.5 (244.1 to 1310.2)	99999 (99999 to 99999)		
Pre IMP dose 2 - Ref	999 (999 to 999)	37.5 (11.3 to 124.6)		
1-week post IMP dose 2 - Ref	999 (999 to 999)	95.1 (59.8 to 151.4)		
1-month post IMP dose 2 - Ref	999 (999 to 999)	136.1 (58.1 to 319.0)		
6-months post IMP dose 2 - Ref	999 (999 to 999)	99999 (99999 to 99999)		
12-months post IMP dose 2 - Ref	999 (999 to 999)	99999 (99999 to 99999)		
6-months post IMP dose 2+pre IMP dose 3 - Ref	999 (999 to 999)	53.1 (16.4 to 172.4)		
1-week post IMP dose 3 - Ref	999 (999 to 999)	551.7 (299.8 to 1015.1)		
1-month post IMP dose 3 - Ref	999 (999 to 999)	493.5 (195.5 to 1245.8)		
12-mths post dose 2+6-mths post dose 3 – Ref	999 (999 to 999)	205.9 (80.1 to 528.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A - Geometric Mean Fold Rises (GMFR) From Before Vaccination to Each Subsequent Time Point After Vaccination

End point title	Part A - Geometric Mean Fold Rises (GMFR) From Before Vaccination to Each Subsequent Time Point After Vaccination[46]

End point description:

GMFR is calculated as the mean of the difference of logarithmically transformed neutralization titers or antibody levels (later result minus earlier result) and exponentiating the mean. The associated 2-sided 95% CIs are obtained by constructing CIs using Student’s t-distribution for the mean difference on the natural log scale and exponentiating the confidence limits. Assay results below the LLOQ are set to 0.5 × LLOQ and above the ULOQ are set to ULOQ. Immunogenicity Analysis Set.
999 = not applicable since Cohorts 1, 3, 4 and 5 received only 1 dose of IMP.
9999 = not applicable since Cohort 2 received dose 2 on Day 56 and did not receive dose 3.
99999 = not applicable since Cohort 6 received dose 2 on Day 21 and received dose 3 approximately 6 months after dose 2.

End point type	Secondary

End point timeframe:

Day 1 to Day 421

Notes:

[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: This endpoint only reports data for Part A (Cohorts 1-6).

End point values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	20	20
Units: Fold rise				
geometric mean (confidence interval 95%)				
1-week post IMP dose 1 - B.1.1.7	68.6 (30.4 to 155.0)	78.8 (38.9 to 159.7)	95.5 (72.0 to 126.5)	13.0 (5.8 to 28.9)
3-weeks post IMP dose 1 - B.1.1.7	52.8 (28.4 to 98.2)	39.8 (23.3 to 68.0)	51.4 (30.3 to 87.3)	10.2 (4.8 to 21.9)
1-month post IMP dose 1 - B.1.1.7	48.1 (24.8 to 93.2)	37.4 (22.8 to 61.4)	54.3 (31.9 to 92.5)	9.7 (3.8 to 24.8)
6-months post IMP dose 1 - B.1.1.7	7.2 (2.9 to 18.0)	9999 (9999 to 9999)	18.7 (8.2 to 42.5)	2.9 (0.9 to 9.6)
12-months post IMP dose 1 - B.1.1.7	21.1 (4.6 to 96.4)	9999 (9999 to 9999)	20.5 (6.2 to 68.2)	4.0 (0.5 to 33.3)
Pre IMP dose 2 - B.1.1.7	999 (999 to 999)	6.2 (2.4 to 15.9)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 2 - B.1.1.7	999 (999 to 999)	64.0 (37.4 to 109.4)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 2 - B.1.1.7	999 (999 to 999)	39.5 (22.2 to 70.6)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	15.7 (7.4 to 33.2)	999 (999 to 999)	999 (999 to 999)
12-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	22.6 (6.7 to 76.7)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2+pre IMP dose 3 - B.1.1.7	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 3 - B.1.1.7	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 3 - B.1.1.7	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
12-mths post dose 2+6-mths post dose 3 – B.1.1.7	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 1 - B.1.617.2	52.7 (28.1 to 98.8)	64.0 (43.6 to 93.9)	73.1 (51.1 to 104.6)	35.9 (21.7 to 59.6)
3-weeks post IMP dose 1 - B.1.617.2	48.9 (28.4 to 84.2)	42.8 (27.6 to 66.5)	42.1 (26.2 to 67.6)	43.7 (27.1 to 70.6)
1-month post IMP dose 1 - B.1.617.2	40.9 (23.4 to 71.5)	34.9 (23.5 to 51.7)	38.4 (22.1 to 66.7)	33.1 (22.4 to 49.1)
6-months post IMP dose 1 - B.1.617.2	13.8 (5.3 to 35.6)	9999 (9999 to 9999)	16.3 (8.1 to 32.9)	14.3 (5.8 to 35.4)
12-months post IMP dose 1 - B.1.617.2	42.2 (10.5 to 169.8)	9999 (9999 to 9999)	12.8 (4.4 to 37.4)	21.9 (5.2 to 93.3)
Pre IMP dose 2 - B.1.617.2	999 (999 to 999)	27.4 (16.8 to 44.7)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 2 - B.1.617.2	999 (999 to 999)	86.7 (53.9 to 139.5)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 2 - B.1.617.2	999 (999 to 999)	60.4 (32.9 to 110.8)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	26.9 (11.7 to 62.0)	999 (999 to 999)	999 (999 to 999)
12-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	34.6 (8.1 to 146.7)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2+preIMP dose 3 - B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 3 - B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)

1-month post IMP dose 3 - B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
12-mths post dose 2+6-mths post dose 3 - B.1.617.2	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 1 - Ref	52.7 (33.3 to 83.2)	39.4 (21.6 to 71.9)	50.3 (38.7 to 65.4)	20.6 (11.0 to 38.7)
3-weeks post IMP dose 1 - Ref	46.1 (28.1 to 75.8)	29.2 (18.3 to 46.7)	37.7 (22.0 to 64.8)	26.9 (15.6 to 46.3)
1-month post IMP dose 1 - Ref	40.9 (26.8 to 62.3)	24.3 (15.0 to 39.1)	36.4 (20.8 to 63.7)	26.9 (15.9 to 45.6)
6-months post IMP dose 1 - Ref	10.5 (5.1 to 21.5)	9999 (9999 to 9999)	12.5 (6.1 to 25.4)	3.7 (1.8 to 7.5)
12-months post IMP dose 1 - Ref	29.9 (9.2 to 97.1)	9999 (9999 to 9999)	17.7 (6.6 to 47.4)	6.0 (1.4 to 25.1)
Pre IMP dose 2 - Ref	999 (999 to 999)	21.8 (12.8 to 37.2)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 2 - Ref	999 (999 to 999)	66.8 (27.7 to 161.5)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 2 - Ref	999 (999 to 999)	37.3 (21.6 to 64.6)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2 - Ref	999 (999 to 999)	18.6 (9.1 to 38.0)	999 (999 to 999)	999 (999 to 999)
12-months post IMP dose 2 - Ref	999 (999 to 999)	21.0 (5.3 to 83.5)	999 (999 to 999)	999 (999 to 999)
6-months post IMP dose 2+preIMP dose 3 - Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-week post IMP dose 3 - Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
1-month post IMP dose 3 - Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)
12-mths post dose 2+6-mths post dose 3 - Ref	999 (999 to 999)	9999 (9999 to 9999)	999 (999 to 999)	999 (999 to 999)

End point values	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	17		
Units: Fold rise				
geometric mean (confidence interval 95%)				
1-week post IMP dose 1 - B.1.1.7	31.4 (19.1 to 51.4)	4.8 (1.2 to 18.9)		
3-weeks post IMP dose 1 - B.1.1.7	35.7 (20.6 to 61.6)	99999 (99999 to 99999)		
1-month post IMP dose 1 - B.1.1.7	27.7 (14.0 to 55.2)	99999 (99999 to 99999)		
6-months post IMP dose 1 - B.1.1.7	9.0 (3.7 to 22.0)	99999 (99999 to 99999)		
12-months post IMP dose 1 - B.1.1.7	36.3 (13.8 to 95.5)	99999 (99999 to 99999)		
Pre IMP dose 2 - B.1.1.7	999 (999 to 999)	6.2 (2.2 to 17.4)		
1-week post IMP dose 2 - B.1.1.7	999 (999 to 999)	41.5 (20.9 to 82.6)		

1-month post IMP dose 2 - B.1.1.7	999 (999 to 999)	33.6 (17.9 to 63.3)		
6-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	99999 (99999 to 99999)		
12-months post IMP dose 2 - B.1.1.7	999 (999 to 999)	99999 (99999 to 99999)		
6-months post IMP dose 2+pre IMP dose 3 - B.1.1.7	999 (999 to 999)	12.4 (4.3 to 35.8)		
1-week post IMP dose 3 - B.1.1.7	999 (999 to 999)	105.0 (76.8 to 143.6)		
1-month post IMP dose 3 - B.1.1.7	999 (999 to 999)	82.0 (32.1 to 209.5)		
12-mths post dose 2+6-mths post dose 3 – B.1.1.7	999 (999 to 999)	53.8 (25.6 to 113.0)		
1-week post IMP dose 1 - B.1.617.2	27.2 (16.3 to 45.4)	4.9 (1.2 to 19.5)		
3-weeks post IMP dose 1 - B.1.617.2	22.6 (12.3 to 41.7)	99999 (99999 to 99999)		
1-month post IMP dose 1 - B.1.617.2	20.0 (11.7 to 34.2)	99999 (99999 to 99999)		
6-months post IMP dose 1 - B.1.617.2	4.4 (1.9 to 9.9)	99999 (99999 to 99999)		
12-months post IMP dose 1 - B.1.617.2	19.3 (6.9 to 54.0)	99999 (99999 to 99999)		
Pre IMP dose 2 - B.1.617.2	999 (999 to 999)	9.3 (3.2 to 27.5)		
1-week post IMP dose 2 - B.1.617.2	999 (999 to 999)	43.3 (26.9 to 69.7)		
1-month post IMP dose 2 - B.1.617.2	999 (999 to 999)	55.2 (24.0 to 126.9)		
6-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	99999 (99999 to 99999)		
12-months post IMP dose 2 - B.1.617.2	999 (999 to 999)	99999 (99999 to 99999)		
6-months post IMP dose 2+preIMP dose 3 - B.1.617.2	999 (999 to 999)	16.5 (5.0 to 54.5)		
1-week post IMP dose 3 - B.1.617.2	999 (999 to 999)	121.8 (63.4 to 233.9)		
1-month post IMP dose 3 - B.1.617.2	999 (999 to 999)	86.1 (28.2 to 263.2)		
12-mths post dose 2+6-mths post dose 3 - B.1.617.2	999 (999 to 999)	61.8 (30.8 to 124.0)		
1-week post IMP dose 1 - Ref	23.1 (15.8 to 33.8)	4.1 (1.3 to 13.3)		
3-weeks post IMP dose 1 - Ref	26.3 (16.5 to 42.0)	99999 (99999 to 99999)		
1-month post IMP dose 1 - Ref	23.1 (14.7 to 36.3)	99999 (99999 to 99999)		
6-months post IMP dose 1 - Ref	5.2 (2.9 to 9.2)	99999 (99999 to 99999)		
12-months post IMP dose 1 - Ref	26.5 (11.1 to 63.4)	99999 (99999 to 99999)		
Pre IMP dose 2 - Ref	999 (999 to 999)	5.5 (2.0 to 15.1)		
1-week post IMP dose 2 - Ref	999 (999 to 999)	19.0 (12.0 to 30.3)		
1-month post IMP dose 2 - Ref	999 (999 to 999)	21.5 (10.5 to 44.2)		
6-months post IMP dose 2 - Ref	999 (999 to 999)	99999 (99999 to 99999)		
12-months post IMP dose 2 - Ref	999 (999 to 999)	99999 (99999 to 99999)		

6-months post IMP dose 2+preIMP dose 3 - Ref	999 (999 to 999)	10.0 (3.3 to 30.2)		
1-week post IMP dose 3 - Ref	999 (999 to 999)	82.0 (52.7 to 127.6)		
1-month post IMP dose 3 - Ref	999 (999 to 999)	74.2 (34.7 to 158.7)		
12-mths post dose 2+6-mths post dose 3 - Ref	999 (999 to 999)	32.0 (10.8 to 95.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A - Percentage of participants achieving SR in Terms of NT at Each Post Vaccination Time Point

End point title	Part A - Percentage of participants achieving SR in Terms of NT at Each Post Vaccination Time Point[47]

End point description:

For BNT162b2-experienced participants (defined as participants who have previously received two injections of 30 µg BNT162b2). Reference and VOC specific NT.
SR is defined as a ≥4-fold rise in neutralizing titer from baseline (pre IMP dose 1). For participants with a baseline titer less than the LLOQ, SR is defined as a post-vaccination titer of ≥4 × LLOQ.
Pre IMP dose 2 is also 2 months post dose 1 for Cohort 2 and 3 weeks post dose 1 for Cohort 6.
Immunogenicity Analysis Set.
999 = not applicable since Cohorts 1, 3, 4 and 5 received only 1 dose of IMP.
9999 = not applicable since Cohort 2 received dose 2 on Day 56 and did not receive dose 3.
99999 = not applicable since Cohort 6 received dose 2 on Day 21 and received dose 3 approximately 6 months after dose 2.

End point type	Secondary

End point timeframe:

Day 1 to Day 421

Notes:

[47] - 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: This endpoint only reports data for Part A (Cohorts 1-6).

End point values	Part A - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	20	20	20
Units: Percentage of participants				
number (not applicable)				
1-week post IMP dose 1 - B.1.1.7	93.3	100	100	66.7
3-weeks post IMP dose 1 - B.1.1.7	94.4	94.7	94.7	65.0
1-month post IMP dose 1 - B.1.1.7	94.1	95.0	100	65.0
6-months post IMP dose 1 - B.1.1.7	64.3	9999	83.3	47.4
12-months post IMP dose 1 - B.1.1.7	80.0	9999	64.3	54.5
Pre IMP dose 2 - B.1.1.7	999	61.1	999	999
1-week post IMP dose 2 - B.1.1.7	999	100	999	999
1-month post IMP dose 2 - B.1.1.7	999	94.4	999	999

6-months post IMP dose 2+pre IMP dose 3 - B.1.1.7	999	9999	999	999
1-week post IMP dose 3 - B.1.1.7	999	9999	999	999
1-month post IMP dose 3 - B.1.1.7	999	9999	999	999
6-months post IMP dose 2 - B.1.1.7	999	87.5	999	999
12-mths post dose 2+6-mths post dose 3 – B.1.1.7	999	9999	999	999
12-months post IMP dose 2 - B.1.1.7	999	88.9	999	999
1-week post IMP dose 1 - B.1.617.2	93.8	100	100	100
3-weeks post IMP dose 1 - B.1.617.2	94.4	94.7	100	100
1-month post IMP dose 1 - B.1.617.2	100	95.0	94.7	100
6-months post IMP dose 1 - B.1.617.2	78.6	9999	88.9	73.7
12-months post IMP dose 1 - B.1.617.2	90.0	9999	57.1	81.1
Pre IMP dose 2 - B.1.617.2	999	94.4	999	999
1-week post IMP dose 2 - B.1.617.2	999	100	999	999
1-month post IMP dose 2 - B.1.617.2	999	94.4	999	999
6-months post IMP dose 2+preIMP dose 3 - B.1.617.2	999	9999	999	999
1-week post IMP dose 3 - B.1.617.2	999	9999	999	999
1-month post IMP dose 3 - B.1.617.2	999	9999	999	999
6-months post IMP dose 2 - B.1.617.2	999	81.3	999	999
12-mths post dose 2+6-mths post dose 3 – B.1.617.2	999	9999	999	999
12-months post IMP dose 2 - B.1.617.2	999	88.9	999	999
1-week post IMP dose 1 - Ref	100	100	100	86.7
3-weeks post IMP dose 1 - Ref	100	100	94.7	95.0
1-month post IMP dose 1 - Ref	100	95	94.7	95.0
6-months post IMP dose 1 - Ref	64.3	9999	83.3	36.8
12-months post IMP dose 1 - Ref	90.0	9999	85.7	54.5
Pre IMP dose 2 - Ref	999	94.4	999	999
1-week post IMP dose 2 - Ref	999	100	999	999
1-month post IMP dose 2 - Ref	999	100	999	999
6-months post IMP dose 2+pre IMP dose 3 - Ref	999	9999	999	999
1-week post IMP dose 3 - Ref	999	9999	999	999
1-month post IMP dose 3 - Ref	999	9999	999	999
6-months post IMP dose 2 - Ref	999	93.8	999	999
12-mths post dose 2+6-mths post dose 3 – Ref	999	9999	999	999
12-months post IMP dose 2 - Ref	999	88.9	999	999

End point values	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	17		
Units: Percentage of participants				
number (not applicable)				
1-week post IMP dose 1 - B.1.1.7	94.1	33.3		
3-weeks post IMP dose 1 - B.1.1.7	100	99999		

1-month post IMP dose 1 - B.1.1.7	88.2	99999		
6-months post IMP dose 1 - B.1.1.7	75.0	99999		
12-months post IMP dose 1 - B.1.1.7	90.9	99999		
Pre IMP dose 2 - B.1.1.7	999	43.8		
1-week post IMP dose 2 - B.1.1.7	999	100		
1-month post IMP dose 2 - B.1.1.7	999	92.9		
6-months post IMP dose 2+pre IMP dose 3 - B.1.1.7	999	63.6		
1-week post IMP dose 3 - B.1.1.7	999	100		
1-month post IMP dose 3 - B.1.1.7	999	100		
6-months post IMP dose 2 - B.1.1.7	999	99999		
12-mths post dose 2+6-mths post dose 3 – B.1.1.7	999	100		
12-months post IMP dose 2 - B.1.1.7	999	99999		
1-week post IMP dose 1 - B.1.617.2	88.2	33.3		
3-weeks post IMP dose 1 - B.1.617.2	93.8	99999		
1-month post IMP dose 1 - B.1.617.2	88.2	99999		
6-months post IMP dose 1 - B.1.617.2	58.3	99999		
12-months post IMP dose 1 - B.1.617.2	81.8	99999		
Pre IMP dose 2 - B.1.617.2	999	29.9		
1-week post IMP dose 2 - B.1.617.2	999	100		
1-month post IMP dose 2 - B.1.617.2	999	92.9		
6-months post IMP dose 2+preIMP dose 3 - B.1.617.2	999	72.7		
1-week post IMP dose 3 - B.1.617.2	999	100		
1-month post IMP dose 3 - B.1.617.2	999	100		
6-months post IMP dose 2 - B.1.617.2	999	99999		
12-mths post dose 2+6-mths post dose 3 – B.1.617.2	999	100		
12-months post IMP dose 2 - B.1.617.2	999	99999		
1-week post IMP dose 1 - Ref	94.1	33.3		
3-weeks post IMP dose 1 - Ref	100	99999		
1-month post IMP dose 1 - Ref	100	99999		
6-months post IMP dose 1 - Ref	58.3	99999		
12-months post IMP dose 1 - Ref	90.9	99999		
Pre IMP dose 2 - Ref	999	43.8		
1-week post IMP dose 2 - Ref	999	100		
1-month post IMP dose 2 - Ref	999	85.7		
6-months post IMP dose 2+pre IMP dose 3 - Ref	999	54.5		
1-week post IMP dose 3 - Ref	999	100		
1-month post IMP dose 3 - Ref	999	100		
6-months post IMP dose 2 - Ref	999	99999		
12-mths post dose 2+6-mths post dose 3 – Ref	999	100		
12-months post IMP dose 2 - Ref	999	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - GMT of VOCs and reference strains in Part B C1 and Control

End point title	Part B - GMT of VOCs and reference strains in Part B C1 and Control[48]

End point description:

GMTs of VOCs (B.1.1.7 and B.1.617.2) and reference strain 1 month after 1 dose of BNT162 (B.1.1.7+B.1.167.2) in participants from Part B Cohort 1 of the BNT162-17 trial (BNT162b2-experienced participants), and reference strain 1 month after 2 doses of BNT162b2 in selected participants from the Phase III C4591001 trial.
GMTs and 2-sided 95% CIs are calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ are set to 0.5 × LLOQ and above the ULOQ are set to ULOQ. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 trial

Notes:

[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: This endpoint only reports data for Part B - Cohort 1 and C4591001 BNT162b2 30 µg (control group).

End point values	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	C4591001 BNT162b2 30 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	299	332		
Units: Titer				
geometric mean (confidence interval 95%)				
B.1.1.7	996.5 (880.3 to 1128.0)	74.7 (66.1 to 84.3)		
B.1.617.2	552.4 (495.2 to 616.2)	65.2 (57.5 to 74.0)		
Reference strain	947.0 (846.4 to 1059.5)	113.3 (101.4 to 126.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - GMT of VOCs and reference strains in Part B C4 and Control

End point title	Part B - GMT of VOCs and reference strains in Part B C4 and Control[49]

End point description:

GMTs of VOCs (B.1.617.2) and reference strain 1 month after 1 dose of BNT162 (B.1.167.2) in participants from Part B Cohort 4 of the BNT162-17 trial (BNT162b2-experienced participants), and 1 month after 2 doses of BNT162b2 in selected participants from the Phase III C4591001 trial. GMTs and 2-sided 95% CIs are calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ are set to 0.5 × LLOQ and above the ULOQ are set to ULOQ. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

1 month after booster dose in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 trial

Notes:

[49] - 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: This endpoint only reports data for Part B - Cohort 4 and C4591001 BNT162b2 30 µg (control group).

End point values	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	C4591001 BNT162b2 30 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	317	320		
Units: Titer				
geometric mean (confidence interval 95%)				
B.1.1.7	972.8 (875.3 to 1081.3)	78.6 (69.6 to 88.8)		
B.1.617.2	730.5 (654.5 to 815.3)	71.2 (62.7 to 80.8)		
Reference strain	1005.3 (900.3 to 1122.5)	113.0 (100.5 to 127.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - GMT of VOCs and Reference Strain in Part B C6 1 Month After Dose 2 and 1 Month After Dose 3

End point title	Part B - GMT of VOCs and Reference Strain in Part B C6 1 Month After Dose 2 and 1 Month After Dose 3[50]

End point description:

GMTs of VOCs and reference strain NT 1 month after dose 2 and dose 3 of BNT162b2 (B.1.1.7 + B.1.617.2) (Part B - Cohort 6). GMTs and 2-sided 95% CIs are calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ are set to 0.5 × LLOQ and above the ULOQ are set to ULOQ. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

1 month after Dose 2 and 1 month after Dose 3

Notes:

[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: This endpoint only reports data for Part B - Cohort 6.

End point values	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)			
Subject group type	Reporting group			
Number of subjects analysed	359			
Units: Titer				
geometric mean (confidence interval 95%)				

1 month post IMP dose 2 - B.1.1.7	832.5 (718.2 to 965.0)			
1 month post IMP dose 3 - B.1.1.7	942.6 (836.4 to 1062.4)			
1 month post IMP dose 2 - B.1.617.2	1184.6 (1015.5 to 1381.9)			
1 month post IMP dose 3 - B.1.617.2	1270.9 (1130.2 to 1429.0)			
1 month post IMP dose 2 - Reference strain	697.5 (594.0 to 819.1)			
1 month post IMP dose 3 - Reference strain	830.5 (736.3 to 936.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - GMTs of VOC in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection in Part B C6 (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection in Part B C1 (1 Booster Dose)

End point title	Part B - GMTs of VOC in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection in Part B C6 (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection in Part B C1 (1 Booster Dose)

End point description:

GMTs of VOC specific NTs (B.1.1.7, B.1.617.2, B.1.1.529.5 [Omicron BA.5]) 3 weeks after one dose of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 vaccine-naïve participants with evidence of prior infection (Cohort 6), 1 month after two doses of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 vaccine-naïve participants without evidence of infection (Cohort 6), and 1 month after one booster dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced participants without evidence of infection (Cohort 1). GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ; assay results above the ULOQ were set to ULOQ. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

Day 1 up to 1 month after 1 booster dose in Part B Cohort 1 without evidence of infection, up to 1 month after 2 doses in Part B Cohort 6 without evidence of infection and up to 3 weeks after 1 dose in Part B Cohort 6 with evidence of prior infection

End point values	Part B - C6: BNT162b2 With Evidence of Prior Infection	Part B - C6: BNT162b2 Without Evidence of Infection	Part B - C1: BNT162b2 Without Evidence of Infection	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	142	17	136	
Units: Titer				
geometric mean (confidence interval 95%)				
SARS-CoV-2 neutralization assay – B.1.1.7	1045.3 (853.1 to 1280.8)	180.8 (91.8 to 356.3)	749.5 (621.1 to 904.6)	

SARS-CoV-2 neutralization assay – B.1.617.2	859.9 (693.4 to 1066.4)	62.6 (30.9 to 127.0)	466.6 (401.8 to 541.9)	
SARS-CoV-2 neutralization assay – B.1.1.529.5	229.3 (191.7 to 274.4)	10.2 (5.7 to 18.3)	80.8 (66.9 to 97.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - GMRs of VOC in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection (1 Booster Dose)

End point title	Part B - GMRs of VOC in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection (1 Booster Dose)

End point description:

GMR of VOC specific NTs (B.1.1.7, B.1.617.2, B.1.1.529.5 [Omicron BA.5]) 3 weeks after one dose of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 vaccine-naïve participants with evidence of prior infection (Cohort 6) to the VOCs NTs 1 month after two doses of BNT162b2 (B.1.1.7 + B.1.617.2) in participants without evidence of infection (Cohort 6), and to the VOCs NTs 1 month after one booster dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced participants without evidence of infection (Cohort 1). GMRs and 2-sided 95% CIs were calculated by exponentiating the difference of the LS means and corresponding CIs based on the analysis of logarithmically transformed neutralizing titers using a linear regression model with terms of age, sex, and group. A separate model was fit for each comparison. Assay results below the LLOQ were set to 0.5 × LLOQ; assay results above the ULOQ were set to ULOQ. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

Day 1 to Day 29

End point values	Part B - C6 With Prior Infection / C6 Without Prior Infection	Part B - C6 With Prior Infection / C1 Without Prior Infection		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	159	278		
Units: Titer ratio				
geometric mean (confidence interval 95%)				
SARS-CoV-2 neutralization assay – B.1.1.7	7.66 (4.09 to 14.33)	1.46 (1.10 to 1.93)		
SARS-CoV-2 neutralization assay – B.1.617.2	15.43 (7.87 to 30.28)	1.88 (1.44 to 2.45)		
SARS-CoV-2 neutralization assay – B.1.1.529.5	29.86 (17.31 to 51.49)	2.94 (2.26 to 3.82)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - Difference in SRs to VOCs in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection (1 Booster Dose)

End point title	Part B - Difference in SRs to VOCs in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection (1 Booster Dose)

End point description:

The difference in SRs to VOC specific NTs (B.1.1.7, B.1.617.2, B.1.1.529.5 [Omicron BA.5]) 3 weeks after one dose of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 vaccine-naïve participants with evidence of prior infection (Cohort 6) to those 1 month after two doses of BNT162b2 (B.1.1.7 + B.1.617.2) in participants without evidence of infection (Cohort 6), and to those 1 month after one booster dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced participants without evidence of infection (Cohort 1). Adjusted difference in proportions estimated using minimum risk weights and stratified by sex and age group (18 to 55 years, 56 to 85 years), expressed as a percentage. 2-Sided CI based on the Newcombe method stratified by sex and age group (18 to 55 years, 56 to 85 years) with minimum risk weights for the difference in proportions. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

Day 1 to Day 29

End point values	Part B - C6 With Prior Infection / C6 Without Prior Infection	Part B - C6 With Prior Infection / C1 Without Prior Infection		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	159	278		
Units: Percentage difference				
number (confidence interval 95%)				
SARS-CoV-2 neutralization assay – B.1.1.7	6.95 (-9.69 to 32.17)	-9.75 (-16.43 to -3.24)		
SARS-CoV-2 neutralization assay – B.1.617.2	20.90 (-0.62 to 46.52)	-6.56 (-13.03 to -0.37)		
SARS-CoV-2 neutralization assay – B.1.1.529.5	81.47 (54.28 to 90.07)	6.67 (-2.06 to 15.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - SR of VOC in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection (1 Booster Dose)

End point title	Part B - SR of VOC in COVID-19 Vaccine-naïve Participants With and Without Evidence of Prior Infection (1 and 2 primary doses respectively) and in BNT162b2-Experienced Participants Without Evidence of Infection (1 Booster Dose)

End point description:

SRs of VOC specific NTs (B.1.1.7, B.1.617.2, B.1.1.529.5 [Omicron BA.5]) 3 weeks after one dose of BNT162b2 (B.1.1.7 + B.1.617.2) in COVID-19 vaccine-naïve participants with evidence of prior infection (Cohort 6) 1 month after two doses of BNT162b2 (B.1.1.7 + B.1.617.2) in participants without evidence of infection (Cohort 6), and 1 month after one booster dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced participants without evidence of infection (Cohort 1). Seroresponse was defined as achieving a ≥4-fold rise from baseline. If the baseline measurement was below the LLOQ, a postvaccination assay result ≥4 × LLOQ was considered a seroresponse. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

3 weeks after one dose in participants with evidence of prior infection (Cohort 6), 1 month after two doses in participants without evidence of infection (Cohort 6), and 1 month after one booster dose (Cohort 1)

End point values	Part B - C6: BNT162b2 With Evidence of Prior Infection	Part B - C6: BNT162b2 Without Evidence of Infection	Part B - C1: BNT162b2 Without Evidence of Infection	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	142	17	136	
Units: Percentage of participants				
number (confidence interval 95%)				
SARS-CoV-2 neutralization assay – B.1.1.7	87.3 (80.7 to 92.3)	76.5 (50.1 to 93.2)	97.1 (92.6 to 99.2)	
SARS-CoV-2 neutralization assay – B.1.617.2	89.4 (83.2 to 94.0)	58.8 (32.9 to 81.6)	96.3 (91.6 to 98.8)	
SARS-CoV-2 neutralization assay – B.1.1.529.5	87.3 (80.7 to 92.3)	11.8 (1.5 to 36.4)	80.1 (72.4 to 86.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part C - GMT - B.1.1.529.1 in RNA Based COVID-19 Vaccine-experienced Participants With History of SARS-CoV-2 Infection

End point title	Part C - GMT - B.1.1.529.1 in RNA Based COVID-19 Vaccine-experienced Participants With History of SARS-CoV-2 Infection[51]

End point description:

VOC NT in RNA-based COVID-19 vaccine-experienced participants with history of SARS-CoV-2 infection at baseline and 7 days, 1 month, and 3 months after the trial start for Cohorts 7, 8, and 9, and 6 and 12 months after the trial start for Cohorts 7 and 8. GMTs and 2-sided 95% CIs are calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ are set to 0.5 × LLOQ and above the ULOQ are set to ULOQ. Number of subjects with valid and determinate assay results for the specified variant at the given dose/sampling time point. No vaccination was given to Cohort 9 participants within 3 months after Visit 1. The term "post IMP" does not apply for Cohort 9 since no IMP was given, but blood was collected at the same timepoints post randomization. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

Day 1 to Day 360

Notes:

[51] - 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: This endpoint only reports data for Part C (Cohorts 7, 8 and 9).

End point values	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part C - C9: No Vaccination	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	59	28	
Units: Titer				
geometric mean (confidence interval 95%)				
Baseline	169.2 (124.4 to 230.2)	388.5 (262.0 to 575.9)	164.0 (96.1 to 280.0)	
1-week post IMP Dose 1	751.7 (571.5 to 988.9)	768.9 (550.0 to 1074.9)	211.7 (122.5 to 365.9)	
1-month post IMP Dose 1	748.8 (572.0 to 980.3)	801.5 (569.8 to 1127.4)	180.4 (106.7 to 305.0)	
3-months post IMP Dose 1	590.3 (433.6 to 803.6)	571.5 (411.5 to 793.8)	143.3 (86.7 to 236.9)	
6-months post IMP Dose 1	289.6 (210.7 to 397.9)	356.8 (266.9 to 476.8)	999 (999 to 999)	
12-months post IMP Dose 1	197.0 (142.5 to 272.3)	180.5 (135.9 to 239.8)	999 (999 to 999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - SR of of VOCs and Reference Strains in Part B C1 and Control

End point title	Part B - SR of of VOCs and Reference Strains in Part B C1 and Control[52]

End point description:

Percentage of participants achieving SR at 1 month after 1 dose of BNT162b2 (B.1.1.7 + B.1.617.2) in BNT162b2-experienced participants (Cohort 1) and 1 month after 2 doses of BNT162b2 primary series (participants from C4591001). SR is defined as a ≥4-fold rise in neutralizing titer from baseline (pre IMP dose 1). For participants with a baseline titer less than the LLOQ, SR is defined as a post-vaccination titer of ≥4 × LLOQ. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

1 month after Dose 1 in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 (2020-002641-42) trial

Notes:

[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: This endpoint only reports data for Part B - Cohort 1 and C4591001 BNT162b2 30 µg (control group).

End point values	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	C4591001 BNT162b2 30 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	298	332		
Units: Percentage of participants				
number (confidence interval 95%)				
B.1.1.7	88.6 (84.4 to 92.0)	76.2 (71.3 to 80.7)		
B.1.617.2	85.9 (81.4 to 89.6)	74.4 (69.3 to 79.0)		
Reference strain	89.6 (85.6 to 92.8)	88.3 (84.3 to 91.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - SR of of VOCs and Reference Strains in Part B C4 and Control

End point title	Part B - SR of of VOCs and Reference Strains in Part B C4 and Control[53]

End point description:

Percentage of participants achieving SR at 1 month after 1 dose of BNT162b2 (B.1.617.2) in BNT162b2-experienced subjects (Part B - Cohort 4) and 1 month after 2 doses of BNT162b2 primary series (participants from C4591001). SR is defined as a ≥4-fold rise in neutralizing titer from baseline (pre IMP dose 1). For participants with a baseline titer less than the LLOQ, SR is defined as a post-vaccination titer of ≥4 × LLOQ. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

1 month after Dose 1 in BNT162-17 participants and 1 month post Dose 2 in participants from the C4591001 (2020-002641-42) trial

Notes:

[53] - 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: This endpoint only reports data for Part B - Cohort 4 and C4591001 BNT162b2 30 µg (control group).

End point values	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	C4591001 BNT162b2 30 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	313	320		
Units: Percentage of participants				
number (confidence interval 95%)				
B.1.1.7	96.5 (93.8 to 98.2)	78.4 (73.5 to 82.8)		
B.1.617.2	97.4 (95.0 to 98.9)	77.5 (72.5 to 82.0)		
Reference strain	98.1 (95.9 to 99.3)	87.5 (83.4 to 90.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B - C6 - Percentages with SRs to VOCs (B.1.1.7, B.1.617.2) and reference strain

End point title	Part B - C6 - Percentages with SRs to VOCs (B.1.1.7, B.1.617.2) and reference strain[54]

End point description:

Percentage of participants achieving SR to VOCs (B.1.1.7, B.1.617.2) and reference strain at 1 month after dose 2 and dose 3 of BNT162b2 (B.1.1.7 + B.1.617.2) (Part B - Cohort 6).
SR is defined as a ≥4-fold rise in neutralizing titer from baseline (pre IMP dose 1). For participants with a baseline titer less than the LLOQ, SR is defined as a post vaccination titer of ≥4 × LLOQ. Pre IMP dose 2 is also 3 weeks post dose 1 for Cohort 6. Immunogenicity Analysis Set.

End point type	Secondary

End point timeframe:

1 month after Dose 2 and 1 month after Dose 3

Notes:

[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: This endpoint only reports data for Part B - Cohort 6.

End point values	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)			
Subject group type	Reporting group			
Number of subjects analysed	359			
Units: Percentage of participants				
number (confidence interval 95%)				
1 month post IMP dose 2 - B.1.1.7	86.8 (82.2 to 90.5)			
1 month post IMP dose 3 - B.1.1.7	83.6 (78.8 to 87.7)			
1 month post IMP dose 2 - B.1.617.2	88.9 (84.7 to 92.4)			
1 month post IMP dose 3 - B.1.617.2	87.1 (82.7 to 90.8)			
1 month post IMP dose 2 - Reference strain	87.5 (83.0 to 91.1)			
1 month post IMP dose 3 - Reference strain	89.5 (85.4 to 92.8)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs: From Dose 1 to 1 Month after each dose; SAEs: From Dose 1 up to end of study, i.e., up to 18 months.

Adverse event reporting additional description:

35 participants were randomized to Part C - Cohort 9 but, as per protocol, these participants did not receive treatment and therefore adverse event data were not collected for these participants.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Part A - C1: 1 Dose of 30 µg BNT162b2 (B.1.1.7 + B.1.617)

Reporting group description:

Participants in Part A - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1

Reporting group title	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Reporting group description:

Participants in Part A - Cohort 2 received 2 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection one on Day 1 and one on Day 56

Reporting group title	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)

Reporting group description:

Participants in Part A - Cohort 3 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.7) on Day 1

Reporting group title	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)

Reporting group description:

Participants in Part A - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1

Reporting group title	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)

Reporting group description:

Participants in Part A - Cohort 5 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1. 21 subjects assigned to Part B Cohort 4 actually received BNT162b2 (treatment of Part A Cohort 5) and therefore were included in the analyses of safety set of Part A Cohort 5 and excluded from Part B safety set

Reporting group title	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Reporting group description:

Participants in Part A - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose

Reporting group title	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Reporting group description:

Participants in Part B - Cohort 1 received 1 dose of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2) as a single injection on Day 1

Reporting group title	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)

Reporting group description:

Participants in Part B - Cohort 4 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.617.2) on Day 1

Reporting group title	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)

Reporting group description:

Participants in Part B - Cohort 6 received 3 doses of 30 µg multivalent vaccine BNT162b2 (B.1.1.7 + B.1.617.2), as a single injection one on Day 1, one on Day 21 and one approximately 6 months after the second dose

Reporting group title	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)

Reporting group description:

Participants in Part C - Cohort 7 received 1 dose of 30 µg monovalent vaccine BNT162b2 (B.1.1.529.1) on Day 1

Reporting group title	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)

Reporting group description:

Participants in Part C - Cohort 8 received 1 dose of 30 µg BNT162b2 original vaccine on Day 1

Serious adverse events	Part A - C1: 1 Dose of 30 µg BNT162b2 (B.1.1.7 + B.1.617)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
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)			
Breast cancer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Lipoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Papillary thyroid cancer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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 cancer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Pyrexia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Social circumstances			
Physical assault			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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			
Ankle fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Fall			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Fibula fracture			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Lower limb fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Stab wound			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Subdural haematoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Tibia fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Cor pulmonale			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Myocarditis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Epilepsy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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			
Inguinal hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Cholelithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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

Hepatitis acute			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 20 (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			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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			
Mobility decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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			
Appendicitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Diverticulitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Epiglottitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Localized infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Pulmonary tuberculosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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
Sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (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	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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)			
Breast cancer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Lipoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Papillary thyroid cancer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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 cancer			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Chest pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Pyrexia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Social circumstances			
Physical assault			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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			
Ankle fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Fall			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Fibula fracture			

subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Lower limb fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Stab wound			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Subdural haematoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Tibia fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Cor pulmonale			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Myocardial infarction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Myocarditis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Epilepsy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Seizure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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			
Inguinal hernia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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			
Cholecystitis acute			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Cholelithiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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

Hepatitis acute			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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			
Acute kidney injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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			
Mobility decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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			
Appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Diverticulitis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Epiglottitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Localized infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Pulmonary tuberculosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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
Sepsis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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 / 20 (0.00%)	0 / 42 (0.00%)	0 / 17 (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	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 +	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 349 (1.72%)	9 / 352 (2.56%)	13 / 361 (3.60%)
number of deaths (all causes)	1	0	2
number of deaths resulting from adverse events	1	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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
Lipoma			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Papillary thyroid cancer			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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 cancer			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Chest pain			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Pyrexia			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Social circumstances			
Physical assault			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 349 (0.00%)	2 / 352 (0.57%)	0 / 361 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Fibula fracture			

subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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
Lower limb fracture			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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
Stab wound			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Tibia fracture			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Cor pulmonale			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial infarction			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Myocarditis			

subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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
Seizure			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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			
Inguinal hernia			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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			
Cholecystitis acute			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatitis acute			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (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			
Acute kidney injury			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Urinary retention			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
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			
Mobility decreased			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Rhabdomyolysis			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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			
Appendicitis			
subjects affected / exposed	0 / 349 (0.00%)	1 / 352 (0.28%)	0 / 361 (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
Cellulitis			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Epiglottitis			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localized infection			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Pneumonia bacterial			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sepsis			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	0 / 361 (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
Urinary tract infection			
subjects affected / exposed	1 / 349 (0.29%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 2	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 / 349 (0.00%)	0 / 352 (0.00%)	1 / 361 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 72 (0.00%)	5 / 71 (7.04%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			

subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Physical assault			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			

subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stab wound			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			

subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 72 (0.00%)	1 / 71 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hepatitis acute			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Mobility decreased			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			

subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localized infection			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			

subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Part A - C1: 1 Dose of 30 µg BNT162b2 (B.1.1.7 + B.1.617)	Part A - C2: 2 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)	Part A - C3: 1 Dose of 30 µg BNT162b2 (B.1.1.7)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 21 (9.52%)	7 / 20 (35.00%)	4 / 20 (20.00%)
Injury, poisoning and procedural complications			
Product administration error			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	1	1	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 21 (4.76%)	4 / 20 (20.00%)	2 / 20 (10.00%)
occurrences (all)	1	7	2
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A - C4: 1 Dose of 30 µg BNT162b2 (B.1.617.2)	Part A - C5: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	Part A - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	27 / 42 (64.29%)	6 / 17 (35.29%)
Injury, poisoning and procedural complications			

Product administration error			
subjects affected / exposed	0 / 20 (0.00%)	22 / 42 (52.38%)	0 / 17 (0.00%)
occurrences (all)	0	22	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Anosmia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 20 (0.00%)	1 / 42 (2.38%)	3 / 17 (17.65%)
occurrences (all)	1	1	4
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 20 (0.00%)	1 / 42 (2.38%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 20 (0.00%)	2 / 42 (4.76%)	2 / 17 (11.76%)
occurrences (all)	0	2	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 20 (0.00%)	1 / 42 (2.38%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Oropharyngeal pain			

subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 42 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Non-serious adverse events	Part B - C1: 1 Dose 30 µg BNT162b2 (B.1.1.7 +	Part B - C4: 1 Dose 30 µg BNT162b2 (B.1.617.2)	Part B - C6: 3 Doses of 30 µg BNT162b2 (B.1.1.7 + B.1.617.2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 349 (7.45%)	0 / 352 (0.00%)	39 / 361 (10.80%)
Injury, poisoning and procedural complications			
Product administration error			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Lymphadenopathy			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	26 / 349 (7.45%)	0 / 352 (0.00%)	39 / 361 (10.80%)
occurrences (all)	26	0	42
Upper respiratory tract infection			

subjects affected / exposed	0 / 349 (0.00%)	0 / 352 (0.00%)	0 / 361 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part C - C7: 1 Dose of 30 µg BNT162b2 (B.1.1.529.1)	Part C - C8: 1 Dose of 30 µg BNT162b2 (Original Vaccine)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 72 (5.56%)	5 / 71 (7.04%)	
Injury, poisoning and procedural complications			
Product administration error			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Anosmia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 72 (0.00%)	4 / 71 (5.63%)	
occurrences (all)	0	4	
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	4 / 72 (5.56%)	1 / 71 (1.41%)	
occurrences (all)	4	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 72 (0.00%)	0 / 71 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 August 2021	The amendment implemented updates in response to Center for Biologics Evaluation and Research (CBER) comments (dated 07 AUG 2021) on protocol version 1.0.
05 November 2021	The amendment implemented updates for clarification, updates reflecting the decision to perform SAR-CoV-2 viral genome sequencing for all participants (and not just if triggered), and adaptions to the statistical analysis reflecting discussion of booster data analysis with the FDA which requires the exclusion of certain protocol deviations from the primary analysis and thereby makes the Per Protocol Set redundant.
24 February 2022	This amendment implemented three additional cohorts (Cohorts 7, 8, and 9) within Part C, comprising an additional ~410 participants who: • have received two or three doses of any authorized COVID-19 RNA-based vaccine, e.g., 30 µg BNT162b2 (Comirnaty) or the Moderna vaccine (Spikevax), and • had a breakthrough SARS-CoV-2 infection from January 2022 on (limited to a period when there was a high prevalence of SARS-CoV-2 Omicron infections). Participants in Part C will receive either 30 µg of the monovalent BNT162b2 (B.1.1.529) as a third or fourth dose, 30 µg BNT162b2 as a third or fourth dose, or no vaccination within 3 months of Visit 1. In addition, a third dose of the multivariant vaccine has been added for Cohort 6, Parts A and B comprising BNT162b2-naïve participants, with planned visits at pre-Dose 3, 1-week post-Dose 3, and 1-month post-Dose 3. For participants who receive non-trial SARS-CoV-2 vaccinations, blood samples for humoral immunogenicity and T-cell and B-cell response assessments will not be collected, and they will be discontinued from the BNT162-17 trial. The amendment also includes updates for clarification and an updated Table 8, which following the request of the IEC in Germany now includes information on the SARS-CoV-2 Omicron variant.
01 August 2022	This update implemented a change in eligibility criteria for Part C. Eligibility criteria were updated to correspond to the existing regulatory guidance, clarifying the required time frame between the last dose of the COVID-19 RNA-based vaccine and first IMP dose. The two-month window between the documented SARS-CoV-2 infection and trial IMP administration was implemented to reduce heterogeneity in baseline VNT levels which may affect immune responses after trial vaccine administration. The mandatory NAAT test as a confirmation of prior SARS-CoV-2 infection was adjusted according to suggested updated algorithms for SARS-CoV-2 infection diagnostics. In addition, based on the recent immunogenicity data from the BNT162b2 Omicron variant vaccine in the BNT162-16 trial, the sample size and expected GMR were adjusted accordingly.
04 August 2022	This update implemented a correction, specifically the insertion of Table 5.

28 June 2023	This amendment implemented updates in response to FDA comments (dated 08 JUN 2023) and the decision to include additional immunogenicity analyses in the primary objectives and secondary objectives for COVID-19 vaccine-naïve participants (Cohort 6) in Part B. * Several sections were Updated to reflect the additional immunogenicity analyses * Updates to clarify that the original Omicron strain B.1.1.529 has since been renamed B.1.1.529.1 (known as Omicron BA.1), with the Omicron lineage having expanded into multiple sublineages. * The sponsors medical representative was updated. The document history was updated to reflect this update. * Trial rationale was updated to reflect the current BNt162b2 authorization status. Updates to clarify that the original Omicron strain B.1.1.529 has since been renamed B.1.1.529.1 (known as Omicron BA.1), with the Omicron lineage having expanded into multiple sublineages. Updates to explain how the data from Part B of the trial will be used. * Objectives and endpoints were updated to add clarification, to reflect the additional immunogenicity analyses, and corrections. This included the addition of two Primary objectives (Immunogenicity) and two secondary objectives for Part B. * Sections "Trial design" and "Overall design": Updated to reflect addition of new analyses. * Schedule of activities section updated to reflect change from “BNT162-naïve participants” to “COVID-19 vaccine-naïve participants” * Updates to reflect the current disease status. * Risk assessment was updated to add data cutoff dates. * Section "Measures to minimize bias randomization and blinding": Text updated for clarification. * Section "Regulatory reporting requirements for SAEs": Text updated for clarify where to find reference safety information in the current BNT162 IB. * Section "Reporting of SAEs and AESIs": Updates for clarifications on the new e-mail addresses and fax number for safety reporting.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported