Clinical trial results:
A Phase II, open-label, rollover trial to evaluate the safety and immunogenicity of one or two boosting doses of Comirnaty or one dose of BNT162b2s01 in BNT162-01 trial subjects, or two boosting doses of Comirnaty in BNT162-04 trial subjects

Summary

EudraCT number	2021-002387-50
Trial protocol	DE
Global end of trial date	16 September 2022

Results information

Result version number	v2 (current)
This version publication date	18 April 2025
First version publication date	01 October 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	BNT162-14

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04949490
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech clinical trials patient information, BioNTech SE, 0049 613190840, patients@biontech.de
Scientific contact	BioNTech clinical trials patient information, BioNTech SE, 0049 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	04 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the safety and tolerability of one or two boosting doses of Comirnaty or one dose of BNT162b2s01 in BNT162-01 trial subjects, or two boosting doses of Comirnaty in BNT162-04 trial subjects.

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: -

Evidence for comparator: -

Actual start date of recruitment	26 July 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: 137
Worldwide total number of subjects	137
EEA total number of subjects	137

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)	106
From 65 to 84 years	31
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This rollover study (BNT162-14) has enrolled BNT162-01 (EudraCT number 2020-001038-36) or BNT162-04 (EudraCT number 2020-003267-26) study participants meeting all inclusion/exclusion criteria defined in the study protocol.
The first participant was enrolled on 26 JUL 2021. The last visit of the last participant was on 16 SEP 2022.

Pre-assignment

Screening details:

All enrolled participants were allocated to treatment.
Participants of the Group B immunology subset are also included in the respective Group B arms. Overall a total of 137 participants were enrolled into this study (including the Group B immunology subset participants).

Period 1

Period 1 title	Group A and B
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Group A study participants were randomized 2:1 to BNT162b2s01:Comirnaty. Group B study participants were allocated to study treatment without active randomization and selected participants were asked to participate in the detailed immunogenicity assessment based on their parent study cohort.

Arms

Are arms mutually exclusive?	No
Arm title	Group A Comirnaty

Arm description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2 (Comirnaty) on Day 1.

BNT162b2: intramuscular (IM) injection

Arm type	Experimental
Investigational medicinal product name	BNT162b2
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	Group A BNT162b2s01

Arm description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2s01 on Day 1.

BNT162b2s01: IM injection

Arm type	Experimental

Investigational medicinal product name	BNT162b2s01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

Arm title	Group B Non-transplant Participants

Arm description:

Study participants in either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Arm type	Experimental
Investigational medicinal product name	BNT162b2
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	Group B Transplant Participants

Arm description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).

BNT162b2: IM injection

Arm type	Experimental
Investigational medicinal product name	BNT162b2
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.

Number of subjects in period 1	Group A Comirnaty	Group A BNT162b2s01	Group B Non-transplant Participants
Started	21	44	61
Completed	21	44	60
Not completed	0	0	1
Consent withdrawn by subject	-	-	1
Non-study SARS-COV-2 vaccination	-	-	-

Number of subjects in period 1	Group B Transplant Participants
Started	11

Completed	9
Not completed	2
Consent withdrawn by subject	-
Non-study SARS-COV-2 vaccination	2

Period 2

Period 2 title	Subset Group B Immunogenicity Evaluation
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Group B study participants were allocated to study treatment without active randomization and selected participants were asked to participate in the detailed immunogenicity assessment based on their parent study cohort.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group B Immunology Subset Non-transplant Participants

Arm description:

Study participants in either the study BNT162-01 (excluding transplant study participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Arm type	Experimental
Investigational medicinal product name	BNT162b2
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	Group B Immunology Subset Transplant Participants

Arm description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).

BNT162b2: IM injection

Arm type	Experimental
Investigational medicinal product name	BNT162b2
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.

Number of subjects in period 2	Group B Immunology Subset Non-transplant Participants	Group B Immunology Subset Transplant Participants
Started	22	11
Completed	21	9
Not completed	1	2
Consent withdrawn by subject	1	-
Non-study SARS-COV-2 vaccination	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Group A Comirnaty

Reporting group description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2 (Comirnaty) on Day 1.

BNT162b2: intramuscular (IM) injection

Reporting group title	Group A BNT162b2s01

Reporting group description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2s01 on Day 1.

BNT162b2s01: IM injection

Reporting group title	Group B Non-transplant Participants

Reporting group description:

Study participants in either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Reporting group title	Group B Transplant Participants

Reporting group description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).

BNT162b2: IM injection

Reporting group values	Group A Comirnaty	Group A BNT162b2s01	Group B Non-transplant Participants
Number of subjects	21	44	61
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	17	28	50
From 65-84 years	4	16	11
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	53.91	55.81	49.17
standard deviation	± 15.13	± 15.20	± 16.72

Gender categorical Units: Subjects			
Female	9	20	29
Male	12	24	32
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	20	44	61
Race Units: Subjects			
Asian	0	1	0
Black or African American	0	1	0
White	21	42	61
Weight Units: kg			
arithmetic mean	76.76	76.73	76.79
standard deviation	± 10.80	± 13.45	± 13.86

Reporting group values	Group B Transplant Participants	Total	
Number of subjects	11	137	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	11	106	
From 65-84 years	0	31	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	50.88		
standard deviation	± 11.92	-	
Gender categorical Units: Subjects			
Female	5	63	
Male	6	74	
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	
Not Hispanic or Latino	11	136	
Race Units: Subjects			
Asian	0	1	
Black or African American	0	1	
White	11	135	

Weight			
Units: kg			
arithmetic mean	74.14		
standard deviation	± 10.93	-	

End points

End points reporting groups

Reporting group title	Group A Comirnaty

Reporting group description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2 (Comirnaty) on Day 1.

BNT162b2: intramuscular (IM) injection

Reporting group title	Group A BNT162b2s01

Reporting group description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2s01 on Day 1.

BNT162b2s01: IM injection

Reporting group title	Group B Non-transplant Participants

Reporting group description:

Study participants in either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Reporting group title	Group B Transplant Participants

Reporting group description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).

BNT162b2: IM injection

Reporting group title	Group B Immunology Subset Non-transplant Participants

Reporting group description:

Study participants in either the study BNT162-01 (excluding transplant study participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Reporting group title	Group B Immunology Subset Transplant Participants

Reporting group description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).

BNT162b2: IM injection

Subject analysis set title	Group B Immunology Subset Non-transplant Participants
Subject analysis set type	Safety analysis

Subject analysis set description:

Study participants in either the study BNT162-01 (excluding transplant study participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Subject analysis set title	Group B Immunology Subset Transplant Participants
Subject analysis set type	Safety analysis

Subject analysis set description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).

BNT162b2: IM injection

Subject analysis set title	Group B Immunology Subset Total
Subject analysis set type	Safety analysis

Subject analysis set description:

All Group B immunology subset study participants, i.e., transplant study participants from Cohort 13 of the study BNT162-01 who received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which was followed 3 to 7 months afterward by a second injection of 30 µg BNT162b2, and non-transplant study participants from either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 were offered two injections of 30 µg BNT162b2 as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Subject analysis set title	Group A Total
Subject analysis set type	Safety analysis

Subject analysis set description:

All Group A study participants, i.e., study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty), received one booster injection of BNT162b2s01 or BNT162b2 on Day 1.
BNT162b2s01 and BNT162b2: IM injection

Subject analysis set title	Group B Total
Subject analysis set type	Safety analysis

Subject analysis set description:

All Group B study participants, i.e., transplant study participants from Cohort 13 of the study BNT162-01 who received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which was followed 3 to 7 months afterward by a second injection of 30 µg BNT162b2, and non-transplant study participants from either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 were offered two injections of 30 µg BNT162b2 as per the conditional marketing authorization on Day 1 and Day 21.
BNT162b2: IM injection

Primary: The Number of Participants in Each Treatment Group With at Least One Serious Adverse Event (SAE) or Adverse Events of Special Interest (AESIs)

End point title	The Number of Participants in Each Treatment Group With at Least One Serious Adverse Event (SAE) or Adverse Events of Special Interest (AESIs)[1]

End point description:

For treatment-emergent SAEs and AESIs (TESAEs, TEAESIs), the data refers to the interval "Dose 1 up to 28 days after Dose 1". For other SAEs and AESIs, the data refers to the interval "Dose 1 up to 26 weeks after Dose 1".
A TESAE/TEAESI is defined as any SAE/AESI with an onset after the first IMP dose or worsened after the first IMP dose (if the SAE/AESI was present before the first administration of IMP). SAEs/AESIs with an onset date more than 28 days after the last administration of IMP will be considered as TESAE/TEAESI only if assessed as related to IMP by the investigator.
Participants of the Group B immunology subset are also included in the respective Group B arms and therefore counted in more than one arm/group. Overall a total of 137 participants were enrolled into this study (including the Group B immunology subset participants).

End point type	Primary

End point timeframe:

Up to 26 weeks after the first IMP injection

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 analyses were planned for this primary endpoint.

End point values	Group A Comirnaty	Group A BNT162b2s01	Group B Non-transplant Participants	Group B Transplant Participants
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	44	61	11
Units: Participants				
Any SAE	0	2	1	4
Any related SAE	0	0	0	0
Any TESAE	0	1	0	1
Any related TESAE	0	0	0	0
Any AESI	0	0	0	0
Any related AESI	0	0	0	0
Any TEAESI	0	0	0	0

End point values	Group B Immunology Subset Non-transplant Participants	Group B Immunology Subset Transplant Participants	Group B Immunology Subset Total	Group A Total
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	11	33	65
Units: Participants				
Any SAE	0	4	4	2
Any related SAE	0	0	0	0
Any TESAE	0	0	0	1
Any related TESAE	0	0	0	0
Any AESI	0	0	0	0
Any related AESI	0	0	0	0
Any TEAESI	0	0	0	0

End point values	Group B Total			
Subject group type	Subject analysis set			
Number of subjects analysed	72			
Units: Participants				
Any SAE	5			
Any related SAE	0			
Any TESAE	1			
Any related TESAE	0			
Any AESI	0			
Any related AESI	0			
Any TEAESI	0			

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants With Solicited Local Reactions at the Injection Site Recorded up to 7 Days After Each IMP Injection for Group A and for a Selected Subset (Immunology Subset) of Group B Participants

End point title	The Number of Participants With Solicited Local Reactions at the Injection Site Recorded up to 7 Days After Each IMP Injection for Group A and for a Selected Subset (Immunology Subset) of Group B Participants[2][3]

End point description:

Local reactions (pain, tenderness, erythema/redness, induration/swelling) were graded using criteria based on the guidance given in US 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 local reactions was based on the participant's assessments via daily solicited reports in the participant diaries. Participants of the Group B immunology subset are part of the Group B. The 'Total' arms include all participants from the respective Group A and Group B immunology subset arms presented.
99999 indicates not applicable since Group A only received 1 dose.

End point type	Primary

End point timeframe:

Group A: From Day 1 to Day 8; For Group B (except transplant participants): From Day 1 to Day 8 for Dose 1, and from Day 22 to Day 29 for Dose 2. For Group B transplant participants: From Day 1 to Day 8 for Dose 1, and up to 7 days after Dose 2.

Notes:

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

[3] - 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: As per protocol, the results for Group B Immunology Subset participants are presented and not for all Group B participants.

End point values	Group A Comirnaty	Group A BNT162b2s01	Group B Immunology Subset Non-transplant Participants	Group B Immunology Subset Transplant Participants
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	21	44	22	11
Units: Participants				
Dose 1 up to Day 8: any local reaction	20	41	21	10
Dose 1 up to Day 8: any grade >=3 local reaction	1	2	3	1
Dose 2 up to Day 8: any local reaction	99999	99999	20	5
Dose 2 up to Day 8: any grade >=3 local reaction	99999	99999	4	0

End point values	Group B Immunology Subset Total	Group A Total		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	65		
Units: Participants				
Dose 1 up to Day 8: any local reaction	31	61		
Dose 1 up to Day 8: any grade >=3 local reaction	4	3		
Dose 2 up to Day 8: any local reaction	25	99999		
Dose 2 up to Day 8: any grade >=3 local reaction	4	99999		

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants With Solicited Systemic Reactions Recorded up to 7 Days After Each IMP Injection for Group A and for a Selected Subset (Immunology Subset) of Group B Participants

End point title	The Number of Participants With Solicited Systemic Reactions Recorded up to 7 Days After Each IMP Injection for Group A and for a Selected Subset (Immunology Subset) of Group B Participants[4][5]

End point description:

Systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills and fever) were graded using criteria based on the guidance given in US 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 via daily solicited reports in the participant diaries.
Participants of the Group B immunology subset are part of the Group B. The 'Total' arms include all participants from the respective Group A and Group B immunology subset arms presented.
99999 indicates not applicable since Group A only received 1 dose.

End point type	Primary

End point timeframe:

Group A: From Day 1 to Day 8; For Group B (except transplant participants): From Day 1 to Day 8 for Dose 1, and from Day 22 to Day 29 for Dose 2. For Group B transplant participants: From Day 1 to Day 8 for Dose 1, and up to 7 days after Dose 2.

Notes:

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

[5] - 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: As per protocol, the results for Group B Immunology Subset participants are presented and not for all Group B participants.

End point values	Group A Comirnaty	Group A BNT162b2s01	Group B Immunology Subset Non-transplant Participants	Group B Immunology Subset Transplant Participants
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	21	44	22	11
Units: Participants				
number (not applicable)				
Dose 1 to Day 8: any systemic reaction	18	33	20	8
Dose 1 to Day 8: any grade >=3 systemic reaction	4	9	2	0
Dose 2 to Day 8: any systemic reaction	99999	99999	17	4
Dose 2 to Day 8: any grade >=3 systemic reaction	99999	99999	7	0

End point values	Group B Immunology Subset Total	Group A Total		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	65		
Units: Participants				
number (not applicable)				
Dose 1 to Day 8: any systemic reaction	28	51		
Dose 1 to Day 8: any grade >=3 systemic reaction	2	13		
Dose 2 to Day 8: any systemic reaction	21	99999		
Dose 2 to Day 8: any grade >=3 systemic reaction	7	99999		

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants With at Least One Unsolicited TEAE Occurring up to 28 Days After IMP Injection in Each Treatment Group for Group A and for a Selected Subset (Immunology Subset) of Group B Participants

End point title	The Number of Participants With at Least One Unsolicited TEAE Occurring up to 28 Days After IMP Injection in Each Treatment Group for Group A and for a Selected Subset (Immunology Subset) of Group B Participants[6][7]

End point description:

A TEAE is defined as any AE with an onset after the first IMP injection or worsened after the first IMP injection (if the AE was present before the first administration of IMP). AEs with an onset date more than 28 days after the last administration of IMP will be considered as treatment-emergent only if assessed as related to IMP by the investigator.
Participants of the Group B immunology subset are part of the Group B. The 'Total' arms include all participants from the respective Group A and Group B immunology subset arms presented.
99999 indicates not applicable since Group A only received 1 dose.

End point type	Primary

End point timeframe:

Up to 28 days after Dose 1 and up to 28 days after Dose 2

Notes:

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

[7] - 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: As per protocol, the results for Group B Immunology Subset participants are presented and not for all Group B participants.

End point values	Group A Comirnaty	Group A BNT162b2s01	Group B Immunology Subset Non-transplant Participants	Group B Immunology Subset Transplant Participants
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	21	44	22	11
Units: Participants				
Dose 1 up to Day 29: any TEAE	8	14	5	6
Dose 1 up to Day 29: any grade >=3 TEAE	1	1	0	0
Dose 2 up to Day 29: any TEAE	99999	99999	5	2
Dose 2 up to Day 29: any grade >=3 TEAE	99999	99999	0	0

End point values	Group B Immunology Subset Total	Group A Total		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	65		
Units: Participants				
Dose 1 up to Day 29: any TEAE	11	22		
Dose 1 up to Day 29: any grade >=3 TEAE	0	2		
Dose 2 up to Day 29: any TEAE	7	99999		
Dose 2 up to Day 29: any grade >=3 TEAE	0	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Neutralizing Antibody Titers From Reference Strain and SARS-CoV-2 Variant B.1.351

End point title	Neutralizing Antibody Titers From Reference Strain and SARS-CoV-2 Variant B.1.351[8]

End point description:

For Group A participants and Group B participants (except transplant participants). Non-transplant participants of the Group B immunology subset are also part of the respective Group B arm and therefore occurring in more than one arm/group. The 'Total' arm for Group A includes all participants from the Group A arms/groups.
Response neutralizing antibody titers from reference (ref.) strain and SARS-CoV-2 variant B.1.351 (variant).
9999 indicates data not collected per protocol.
99999 indicates titers were below lower limit of detection and confidence intervals were not computable.

End point type	Secondary

End point timeframe:

Group A: At baseline (Day 1) and Day 8 and at Week 4 Day 29), Week 12 (Day 85), and Week 26 (Day 182). Group B: At baseline (Day 1) and Day 8 and at Week 3 (Day 22), Week 4 (Day 29), Week 7 (Day 50), Week 12 (Day 85), and Week 26 (Day 182).

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per protocol, the results for Group B Non-transplant Participants are presented.

End point values	Group A Comirnaty	Group A BNT162b2s01	Group B Non-transplant Participants	Group B Immunology Subset Non-transplant Participants
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	21	44	61	22
Units: Titer				
geometric mean (confidence interval 95%)				
Neutralizing antibody titers ref. strain - Day 1	21.4 (13.2 to 34.5)	21.3 (15.3 to 29.6)	15.6 (11.5 to 21.0)	13.3 (8.3 to 21.3)
Neutralizing antibody titers variant - Day 1	99999 (-99999 to 99999)	99999 (-99999 to 99999)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Neutralizing antibody titers ref. strain - Day 8	640.0 (376.6 to 1087.7)	349.0 (254.5 to 478.6)	729.3 (485.4 to 1095.8)	1093.4 (719.8 to 1661.0)
Neutralizing antibody titers variant - Day 8	285.1 (164.2 to 495.0)	330.2 (232.3 to 469.5)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Neutralizing antibody titers ref. strain - Day 22	9999 (-9999 to 9999)	9999 (-9999 to 9999)	1085.6 (775.5 to 1519.5)	1183.0 (738.2 to 1896.0)
Neutralizing antibody titers ref. strain - Day 29	570.2 (309.3 to 1051.1)	509.3 (372.4 to 696.6)	1789.7 (1367.3 to 2342.6)	1868.1 (1278.7 to 2729.3)
Neutralizing antibody titers variant - Day 29	271.3 (157.9 to 466.1)	325.1 (233.2 to 453.3)	9999 (9999 to 9999)	9999 (-9999 to 9999)
Neutralizing antibody titers ref. strain - Day 50	9999 (-9999 to 9999)	9999 (-9999 to 9999)	1386.0 (1054.5 to 1821.6)	1429.2 (864.5 to 2362.8)
Neutralizing antibody titers ref. strain - Day 85	371.2 (202.5 to 680.5)	282.1 (181.0 to 439.8)	1348.3 (992.8 to 1831.1)	1301.3 (795.2 to 2129.5)
Neutralizing antibody titers variant - Day 85	122.9 (65.3 to 231.4)	259.4 (162.6 to 413.7)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Neutralizing antibody titers ref. strain - Day 182	336.2 (159.6 to 708.6)	132.0 (64.6 to 269.7)	659.8 (469.5 to 927.1)	710.1 (439.5 to 1147.3)
Neutralizing antibody titers variant - Day 182	140.2 (60.4 to 325.2)	129.5 (63.8 to 262.6)	9999 (-9999 to 9999)	9999 (-9999 to 9999)

End point values	Group A Total			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: Titer				
geometric mean (confidence interval 95%)				
Neutralizing antibody titers ref. strain - Day 1	21.3 (16.4 to 27.7)			
Neutralizing antibody titers variant - Day 1	99999 (-99999 to 99999)			
Neutralizing antibody titers ref. strain - Day 8	424.5 (322.5 to 558.8)			
Neutralizing antibody titers variant - Day 8	314.9 (235.8 to 420.6)			

Neutralizing antibody titers ref. strain - Day 22	9999 (-9999 to 9999)			
Neutralizing antibody titers ref. strain - Day 29	528.2 (399.1 to 699.2)			
Neutralizing antibody titers variant - Day 29	306.6 (232.4 to 404.6)			
Neutralizing antibody titers ref. strain - Day 50	9999 (-9999 to 9999)			
Neutralizing antibody titers ref. strain - Day 85	313.9 (221.5 to 444.9)			
Neutralizing antibody titers variant - Day 85	194.0 (133.0 to 282.9)			
Neutralizing antibody titers ref. strain - Day 182	218.4 (130.0 to 366.8)			
Neutralizing antibody titers variant - Day 182	135.1 (79.3 to 230.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody Titers (ELISA) to Recombinant S1 and RBD Protein Derived From Reference and SARS-CoV-2 Variant B.1.351

End point title	Antibody Titers (ELISA) to Recombinant S1 and RBD Protein Derived From Reference and SARS-CoV-2 Variant B.1.351[9]

End point description:

For Group A participants and Group B participants (except transplant participants); immunogenicity set, i.e., all participants who received at least one dose of IMP and have at least one post-baseline immunogenicity assessment.
Response antibody Titers (ELISA) to Recombinant S1 and RBD Protein Derived From Reference Ref.) strain and SARS-CoV-2 Variant B.1.351 (variant).
Non-transplant participants in the Group B immunology subset arm are also part of the respective Group B arm and therefore occurring in more than one arm/group. The 'Total' arm for Group A includes all participants from the Group A arms/groups.
9999 indicates data not collected per protocol.
99999 indicates titers were above upper limit of detection and confidence intervals were not computable.

End point type	Secondary

End point timeframe:

Group A: At baseline (Day 1) and Day 8 and at Week 4 Day 29), Week 12 (Day 85), and Week 26 (Day 182). Group B: At baseline (Day 1) and Day 8 and at Week 3 (Day 22), Week 4 (Day 29), Week 7 (Day 50), Week 12 (Day 85), and Week 26 (Day 182).

Notes:

[9] - 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: As per protocol, the results for Group B Non-transplant Participants are presented.

End point values	Group A Comirnaty	Group A BNT162b2s01	Group B Non-transplant Participants	Group B Immunology Subset Non-transplant Participants
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	21	44	61	22
Units: Titers				
geometric mean (confidence interval 95%)				

Antibody titers IgG RBD ref. strain - Day 1	2216.1 (1507.6 to 3257.7)	2161.4 (1634.7 to 2857.8)	2135.4 (1303.7 to 3497.5)	2056.4 (1297.3 to 3259.6)
Antibody titers IgG RBD variant - Day 1	566.5 (370.9 to 865.3)	588.7 (438.4 to 790.6)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG S protein ref. strain - Day 1	3209.0 (2045.6 to 5033.9)	2594.7 (1977.5 to 3404.4)	1634.4 (1025.5 to 2605.0)	1636.2 (885.2 to 3024.5)
Antibody titers IgG S protein variant - Day 1	7164.8 (4231.7 to 12130.9)	9267.9 (6837.3 to 12562.5)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG RBD ref. strain - Day 8	99999 (-99999 to 99999)	48945.7 (35518.9 to 67447.9)	48805.7 (29759.0 to 80043.1)	99999 (-99999 to 99999)
Antibody titers IgG RBD variant - Day 8	22903.0 (11936.4 to 43945.2)	21244.0 (15712.2 to 28723.3)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG S protein ref. strain - Day 8	99999 (-99999 to 99999)	99999 (-99999 to 99999)	45270.4 (27269.8 to 75153.2)	99999 (-99999 to 99999)
Antibody titers IgG S protein variant - Day 8	520744.5 (258322.6 to 1049752.6)	480042.7 (319790.9 to 720599.2)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG RBD ref. strain - Day 22	9999 (-9999 to 9999)	9999 (-9999 to 9999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG S protein ref. strain - Day 22	9999 (-9999 to 9999)	9999 (-9999 to 9999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG RBD ref. strain - Day 29	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG RBD variant - Day 29	18959.7 (11062.8 to 32493.5)	21082.1 (16052.9 to 27686.8)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG S protein ref. strain - Day 29	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG S protein variant - Day 29	394493.5 (198914.7 to 782371.2)	362296.9 (259569.0 to 505680.9)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG RBD ref. strain - Day 50	9999 (-9999 to 9999)	9999 (-9999 to 9999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG S protein ref. strain - Day 50	9999 (-9999 to 9999)	9999 (-9999 to 9999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG RBD ref. strain - Day 85	23883.9 (15193.4 to 37545.2)	28535.3 (20676.5 to 39381.0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG RBD variant - Day 85	11106.8 (6446.7 to 19135.5)	14367.3 (9798.4 to 21066.5)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG S protein ref. strain - Day 85	50709.2 (33710.6 to 76279.3)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Antibody titers IgG S protein variant - Day 85	178167.5 (95710.4 to 331663.8)	305041.0 (196223.1 to 474205.2)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG RBD ref. strain - Day 182	14309.8 (7900.1 to 25920.0)	8670.5 (5238.9 to 14349.9)	34032.7 (25327.8 to 45729.3)	38865.2 (23611.8 to 63972.6)
Antibody titers IgG RBD variant - Day 182	9829.9 (4948.4 to 19526.7)	6967.7 (4124.5 to 11770.9)	9999 (-9999 to 9999)	9999 (-9999 to 9999)
Antibody titers IgG S protein ref. strain - Day182	27732.0 (15894.6 to 48385.3)	17049.8 (10185.6 to 28539.8)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

Antibody titers IgG S protein variant - Day 182	142683.7 (67849.2 to 300057.1)	91825.4 (50843.9 to 165838.9)	9999 (-9999 to 9999)	9999 (-9999 to 9999)

End point values	Group A Total			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: Titers				
geometric mean (confidence interval 95%)				
Antibody titers IgG RBD ref. strain - Day 1	2178.9 (1748.0 to 2716.1)			
Antibody titers IgG RBD variant - Day 1	581.5 (459.5 to 735.8)			
Antibody titers IgG S protein ref. strain - Day 1	2779.1 (2210.9 to 3493.2)			
Antibody titers IgG S protein variant - Day 1	8528.4 (6572.5 to 11066.5)			
Antibody titers IgG RBD ref. strain - Day 8	99999 (-99999 to 99999)			
Antibody titers IgG RBD variant - Day 8	21766.4 (16403.7 to 28882.2)			
Antibody titers IgG S protein ref. strain - Day 8	99999 (-99999 to 99999)			
Antibody titers IgG S protein variant - Day 8	492832.1 (348924.0 to 696092.7)			
Antibody titers IgG RBD ref. strain - Day 22	9999 (-9999 to 9999)			
Antibody titers IgG S protein ref. strain - Day 22	9999 (-9999 to 9999)			
Antibody titers IgG RBD ref. strain - Day 29	99999 (-99999 to 99999)			
Antibody titers IgG RBD variant - Day 29	20371.6 (15940.0 to 26035.3)			
Antibody titers IgG S protein ref. strain - Day 29	99999 (-99999 to 99999)			
Antibody titers IgG S protein variant - Day 29	372400.7 (274455.6 to 505299.6)			
Antibody titers IgG RBD ref. strain - Day 50	9999 (-9999 to 9999)			
Antibody titers IgG S protein ref. strain - Day 50	9999 (-9999 to 9999)			
Antibody titers IgG RBD ref. strain - Day 85	26627.5 (20616.5 to 34391.0)			
Antibody titers IgG RBD variant - Day 85	12998.8 (9570.3 to 17655.4)			
Antibody titers IgG S protein ref. strain - Day 85	99999 (-99999 to 99999)			

Antibody titers IgG S protein variant - Day 85	247480.6 (173229.4 to 353558.0)			
Antibody titers IgG RBD ref. strain - Day 182	11355.5 (7717.3 to 16709.0)			
Antibody titers IgG RBD variant - Day 182	8386.3 (5479.1 to 12835.9)			
Antibody titers IgG S protein ref. strain - Day182	22155.2 (15250.2 to 32186.6)			
Antibody titers IgG S protein variant - Day 182	116420.8 (72901.4 to 185919.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: SARS-CoV-2 Functional Cross-neutralization (GMT Ratios) of Variant B.1.351 to Reference Strain

End point title	SARS-CoV-2 Functional Cross-neutralization (GMT Ratios) of Variant B.1.351 to Reference Strain[10]

End point description:

For Group A only. The geometric mean titer (GMT) ratio is calculated as the GMT of reference divided by the GMT of variant B.1.351.
The 'Total' arm for Group A includes all participants from the two Group A arms/groups.

End point type	Secondary

End point timeframe:

Up to 26 weeks after the first IMP injection (Dose 1)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per protocol, data is presented for Group A only.

End point values	Group A Comirnaty	Group A BNT162b2s01	Group A Total	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	21	44	65	
Units: GMT ratio				
number (not applicable)				
GMT ratio neutralizing antibody titers - Day 1	3.1	3.0	3.0	
GMT ratio antibody titers IgG RBD Domain - Day 1	3.9	3.7	3.7	
GMT ratio antibody titers IgG S Protein - Day 1	0.4	0.3	0.3	
GMT ratio neutralizing antibody titers - Day 8	2.2	1.1	1.3	
GMT ratio antibody titers IgG RBD Domain - Day 8	2.9	2.3	2.5	
GMT ratio antibody titers IgG S Protein - Day 8	0.2	0.2	0.2	

GMT ratio neutralizing antibody titers - Day 29	2.1	1.6	1.7	
GMT ratio antibody titers IgG RBD Domain - Day 29	3.1	2.6	2.8	
GMT ratio antibody titers IgG S Protein - Day 29	0.2	0.2	0.2	
GMT ratio neutralizing antibody titers - Day 85	3.0	1.1	1.6	
GMT ratio antibody titers IgG RBD Domain - Day 85	2.2	2.0	2.0	
GMT ratio antibody titers IgG S Protein - Day 85	0.3	0.2	0.2	
GMT ratio neutralizing antibody titers - Day 182	2.4	1.0	1.6	
MT ratio antibody titers IgG RBD Domain - Day 182	1.5	1.2	1.4	
GMT ratio antibody titers IgG S Protein - Day 182	0.2	0.2	0.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Neutralizing Antibody Titers (Reference Strain) Derived From SARS-CoV-2

End point title	Neutralizing Antibody Titers (Reference Strain) Derived From SARS-CoV-2[11]

End point description:

For Group B transplant participants, assessed at baseline (Day 1 of Dose 1) and then Day 8, Weeks 4, 12, and 26 post Dose 1, and at Dose 2 (Day 1) and the Day 8, Weeks 4, 12, and 26 post Dose 2.
Because the 11 participants of the arm 'Group B Immunology Subset Transplant Participants' are the same 11 participants of the arm 'Group B Immunology Subset Transplant Participants', data is not presented for this arm to avoid duplication of data.
99999 indicates that titers were below lower limit of detection and confidence intervals were not computable.

End point type	Secondary

End point timeframe:

From baseline (Day 1 of Dose 1) up to 26 weeks after Dose 2.

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per protocol, the results for Group B Transplant Participants are presented.

End point values	Group B Transplant Participants			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Titer				
geometric mean (confidence interval 95%)				
Day 1 of Dose 1	99999 (-99999 to 99999)			
Day 8 of Dose 1	48.3 (13.0 to 179.2)			

Day 29 of Dose 1	124.4 (25.4 to 609.6)			
Day 85 of Dose 1	80.0 (17.1 to 374.8)			
Day 182 of Dose 1	108.9 (23.1 to 513.0)			
Day 1 pre Dose 2	47.6 (7.3 to 311.5)			
Day 8 post Dose 2	142.5 (9.4 to 2160.6)			
Day 29 post Dose 2	452.5 (61.7 to 3317.6)			
Day 85 post Dose 2	142.5 (21.5 to 945.6)			
Day 182 post Dose 2	127.0 (19.7 to 819.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody Titers (ELISA) (Reference Strain) to Recombinant S1 and RBD Protein Derived From SARS-CoV-2

End point title	Antibody Titers (ELISA) (Reference Strain) to Recombinant S1 and RBD Protein Derived From SARS-CoV-2[12]

End point description:

For Group B transplant participants, assessed at baseline (Day 1 of Dose 1) and then Day 8, Weeks 4, 12, and 26 post Dose 1, and at Dose 2 (Day 1) and the Day 8, Weeks 4, 12, and 26 post Dose 2.
Response antibody titers for IgG RBD Domain (RBD) and IgG S Protein of the reference strain measured by enzyme-linked immunosorbent assay (ELISA) are presented.
Because the 11 participants of the arm 'Group B Immunology Subset Transplant Participants' are the same 11 participants of the arm 'Group B Immunology Subset Transplant Participants', data is not presented for this arm to avoid duplication of data.

End point type	Secondary

End point timeframe:

From baseline (Day 1 of Dose 1) up to 26 weeks after Dose 2.

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As per protocol, the results for Group B Transplant Participants are presented.

End point values	Group B Transplant Participants			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Titer				
geometric mean (confidence interval 95%)				
Antibody titers RBD Domain - Day 1 of Dose 1	730.5 (157.1 to 3397.0)			
Antibody titers S Protein - Day 1 of Dose 1	599.1 (117.1 to 3064.9)			
Antibody titers RBD Domain - Day 8 of Dose 1	4328.8 (512.9 to 36532.1)			

Antibody titers S Protein - Day 8 of Dose 1	5078.0 (528.0 to 48838.3)			
Antibody titers RBD Domain - Day 29 of Dose 1	6616.9 (987.7 to 44327.3)			
Antibody titers S Protein - Day 29 of Dose 1	7937.6 (1179.2 to 53431.0)			
Antibody titers RBD Domain - Day 85 of Dose 1	5065.9 (791.0 to 32443.1)			
Antibody titers S Protein - Day 85 of Dose 1	11988.6 (1607.4 to 89413.3)			
Antibody titers RBD Domain - Day 182 of Dose 1	10602.6 (2076.7 to 54130.4)			
Antibody titers S Protein - Day 182 of Dose 1	19644.7 (5085.2 to 75890.1)			
Antibody titers RBD Domain - Day 1 pre Dose 2	3633.0 (506.1 to 26078.1)			
Antibody titers S Protein - Day 1 pre Dose 2	5822.9 (894.5 to 37904.8)			
Antibody titers RBD Domain - Day 8 post Dose 2	12441.7 (1398.3 to 110702.9)			
Antibody titers S Protein - Day 8 post Dose 2	22067.6 (2752.2 to 176945.0)			
Antibody titers RBD Domain - Day 29 post Dose 2	13625.0 (2884.8 to 64350.9)			
Antibody titers S Protein - Day 29 post Dose 2	34242.9 (7476.0 to 156845.8)			
Antibody titers RBD Domain - Day 85 post Dose 2	12265.4 (1706.1 to 88179.1)			
Antibody titers S Protein - Day 85 post Dose 2	24015.7 (3852.9 to 149692.4)			
Antibody titers RBD Domain - Day 182 post Dose 2	13468.1 (2320.5 to 78167.7)			
Antibody titers S Protein - Day 182 post Dose 2	10833.5 (1763.7 to 66543.9)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Local reactions/systemic events: within 7 days after each IMP dose; SAEs: from Day 1 (Dose 1) up to Day 182 after Dose 2 (approximately 26 weeks after Dose 2); Time frame of other AEs see in section 'Adverse event reporting additional description'.

Adverse event reporting additional description:

Other AEs in Group B: All AEs from Day 1 up to Day 50 and in addition if assessed as IMP-related from Day 50 up to Day 182 after Dose 2; Other AEs in Group A: All AEs from Day 1 up to Day 29 and in addition if assessed as IMP-related from Day 29 up to Day 182.
Events reported in the Group B immunology subset are also included in Group B.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Group A BNT162b2s01

Reporting group description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2s01 on Day 1.

BNT162b2s01: IM injection

Reporting group title	Group A Comirnaty

Reporting group description:

Study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty) received one booster injection of BNT162b2 (Comirnaty) on Day 1.

BNT162b2: intramuscular (IM) injection

Reporting group title	Group A Total

Reporting group description:

All Group A study participants, i.e., study participants from BNT162-01 (excluding transplant participants from Cohort 13) who received two injections of 30 µg BNT162b2 (Comirnaty), received one booster injection of BNT162b2s01 or BNT162b2 on Day 1.

BNT162b2s01 and BNT162b2: IM injection

Reporting group title	Group B Immunology Subset Non-transplant Participants

Reporting group description:

Study participants in either the study BNT162-01 (excluding transplant study participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.
Participants of the Group B immunology subset are also included in the respective Group B arms and therefore counted in more than one arm/group.

BNT162b2: IM injection

Reporting group title	Group B Immunology Subset Transplant Participants

Reporting group description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).
Participants of the Group B immunology subset are also included in the respective Group B arms and therefore counted in more than one arm/group.

BNT162b2: IM injection

Reporting group title	Group B Total

Reporting group description:

All Group B study participants, i.e., transplant study participants from Cohort 13 of the study BNT162-01 who received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which was followed 3 to 7 months afterward by a second injection of 30 µg BNT162b2, and non-transplant study participants from either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 were offered two injections of 30 µg BNT162b2 as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Reporting group title	Group B Immunology Subset Total

Reporting group description:

All Group B immunology subset study participants, i.e., transplant study participants from Cohort 13 of the study BNT162-01 who received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which was followed 3 to 7 months afterward by a second injection of 30 µg BNT162b2, and non-transplant study participants from either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 were offered two injections of 30 µg BNT162b2 as per the conditional marketing authorization on Day 1 and Day 21.
Participants of the Group B immunology subset are also included in the respective Group B arms and therefore counted in more than one arm/group.

BNT162b2: IM injection

Reporting group title	Group B Non-transplant Participants

Reporting group description:

Study participants in either the study BNT162-01 (excluding transplant participants from Cohort 13) or BNT162-04 who did not receive the full two vaccinations of 30 µg BNT162b2 (Comirnaty) were offered two injections of 30 µg BNT162b2 (Comirnaty) as per the conditional marketing authorization on Day 1 and Day 21.

BNT162b2: IM injection

Reporting group title	Group B Transplant Participants

Reporting group description:

Transplant study participants from Cohort 13 of the study BNT162-01 received one injection of 30 µg BNT162b2 (Comirnaty) on Day 1 which will be followed 3 to 7 months afterward by a second injection of BNT162b2 (Comirnaty).

BNT162b2: IM injection

Serious adverse events	Group A BNT162b2s01	Group A Comirnaty	Group A Total
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 44 (4.55%)	0 / 21 (0.00%)	2 / 65 (3.08%)
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)			
Basal cell carcinoma			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (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			
Shunt blood flow excessive			

subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	1 / 44 (2.27%)	0 / 21 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 21 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Hepatitis E			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (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
Chronic sinusitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (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 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (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	Group B Immunology Subset Non-transplant Participants	Group B Immunology Subset Transplant Participants	Group B Total
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)	4 / 11 (36.36%)	5 / 72 (6.94%)
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)			

Basal cell carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Shunt blood flow excessive			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 72 (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			
Supraventricular tachycardia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 72 (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			
Hepatitis E			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group B Immunology Subset Total	Group B Non-transplant Participants	Group B Transplant Participants

Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 33 (12.12%)	1 / 61 (1.64%)	4 / 11 (36.36%)
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)			
Basal cell carcinoma			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Shunt blood flow excessive			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 61 (0.00%)	0 / 11 (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			
Supraventricular tachycardia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 61 (0.00%)	0 / 11 (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			
Hepatitis E			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 61 (1.64%)	0 / 11 (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
Urinary tract infection			

subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Group A BNT162b2s01	Group A Comirnaty	Group A Total
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 44 (15.91%)	3 / 21 (14.29%)	10 / 65 (15.38%)
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 44 (2.27%)	0 / 21 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 44 (4.55%)	0 / 21 (0.00%)	2 / 65 (3.08%)
occurrences (all)	2	0	2
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	1 / 44 (2.27%)	2 / 21 (9.52%)	3 / 65 (4.62%)
occurrences (all)	1	2	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	3 / 44 (6.82%)	1 / 21 (4.76%)	4 / 65 (6.15%)
occurrences (all)	3	1	4
Urinary tract infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 21 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Group B Immunology Subset Non-transplant Participants	Group B Immunology Subset Transplant Participants	Group B Total
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 22 (18.18%)	7 / 11 (63.64%)	11 / 72 (15.28%)
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 22 (9.09%)	0 / 11 (0.00%)	2 / 72 (2.78%)
occurrences (all)	2	0	2
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Fatigue			
subjects affected / exposed	1 / 22 (4.55%)	1 / 11 (9.09%)	2 / 72 (2.78%)
occurrences (all)	1	1	2
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Muscle tightness			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Musculoskeletal chest pain			

subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 22 (4.55%)	3 / 11 (27.27%)	4 / 72 (5.56%)
occurrences (all)	1	3	4
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	1 / 72 (1.39%)
occurrences (all)	0	1	1

Non-serious adverse events	Group B Immunology Subset Total	Group B Non-transplant Participants	Group B Transplant Participants
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 33 (33.33%)	4 / 61 (6.56%)	7 / 11 (63.64%)
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 33 (6.06%)	2 / 61 (3.28%)	0 / 11 (0.00%)
occurrences (all)	2	2	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	2 / 33 (6.06%)	1 / 61 (1.64%)	1 / 11 (9.09%)
occurrences (all)	2	1	1
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Muscle tightness			

subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Musculoskeletal chest pain			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Arthralgia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 61 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 33 (12.12%)	1 / 61 (1.64%)	3 / 11 (27.27%)
occurrences (all)	4	1	3
Urinary tract infection			
subjects affected / exposed	1 / 33 (3.03%)	0 / 61 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 July 2021	The protocol amendment 01 describes changes made in response to feedback from the German Paul-Ehrlich-Institute (PEI), i.e., update of risk assessment section to include myocarditis and pericarditis, considering any events of myocarditis or pericarditis as AESIs regardless of grade, and add treatment recommendations for participants reporting symptoms that could represent myocarditis or pericarditis. This update was issued before any trial participants were enrolled into the trial and had no impact on the planned trial objectives or trial conduct.
12 August 2021	The protocol amendment 2 includes changes made in response to requests for clarification, i.e., to clarify overall timing of screening and rescreening, update the schedule of activities, update the risk assessment to reflect more recent information, revise the in- and exclusion criteria for clarity and rescreening of participants based on site feedback, include instructions to the site related to safety assessments, modify AESIs definition for clarity and AESIs reporting, and add guidance related to contraception. This amendment had no impact on the planned trial objectives.
20 January 2022	The protocol amendment 3 includes changes made to allow administration of Dose 2 to Group B transplant participants (Cohort 13 of the BNT162-01 trial) based on an Safety Review Committee recommendation and for a reduction of the recruitment period. In addition, details to accommodate participants receiving non-trial SARS-CoV-2 vaccinations and clarifications of AE and TEAEs definitions were added. Further it was clarified that any case of proven COVID-19 disease occurring until the last follow-up visit should be reported as an SAE/AE.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported