Clinical trial results:
A multi-site, Phase I/II, 2-part, dose escalation trial investigating the safety and immunogenicity of a prophylactic SARS-CoV-2 RNA vaccine (BNT162b3) against COVID-19 using different dosing regimens in healthy adults

Summary

EudraCT number	2020-003267-26
Trial protocol	DE
Global end of trial date	07 February 2022

Results information

Result version number	v1 (current)
This version publication date	22 February 2023
First version publication date	22 February 2023

Trial information

Trial identification

Sponsor protocol code	BNT162-04

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04537949
WHO universal trial number (UTN)	U1111-1254-4840

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 6131 90840, patients@biontech.de
Scientific contact	BioNTech clinical trials patient information, BioNTech SE, 0049 6131 90840, 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	22 July 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 February 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety and tolerability profiles of a prophylactic BNT162b3 in healthy adults after prime/boost (P/B) immunization.

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	09 September 2020
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: 96
Worldwide total number of subjects	96
EEA total number of subjects	96

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)	70
From 65 to 84 years	26
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were selected from the volunteer panel at the clinical CRO, who responded to either generic or study-specific advertisements in social media, or who contacted the clinical CRO via a web-based study participant recruitment portal. Participants were selected from this pool of volunteers according to inclusion and exclusion criteria.

Pre-assignment

Screening details:

All enrolled participants were allocated to treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A Participants Aged 18 to 55 Years - 3 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 18 to 55 Years - 10 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 18 to 55 Years - 20 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental

Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 18 to 55 Years - 30 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 3 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 10 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 20 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental

Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 30 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Number of subjects in period 1	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg
Started	12	12	12
Completed	11	12	12
Not completed	1	0	0
Personal reasons not related to the IMP	1	-	-

Number of subjects in period 1	Part A Participants Aged 18 to 55 Years - 30 µg	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg
Started	12	12	12
Completed	12	12	12
Not completed	0	0	0
Personal reasons not related to the IMP	-	-	-

Number of subjects in period 1	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Started	12	12
Completed	12	12
Not completed	0	0
Personal reasons not related to the IMP	-	-

Period 2

Period 2 title	Follow-up Phase
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A Participants Aged 18 to 55 Years - 3 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 18 to 55 Years - 10 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 18 to 55 Years - 20 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 18 to 55 Years - 30 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 3 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 10 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 20 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Arm title	Part A Participants Aged 56 to 85 Years - 30 µg

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Arm type	Experimental
Investigational medicinal product name	BNT162b3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

Number of subjects in period 2	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg
Started	11	12	12
Completed	8	8	12
Not completed	3	4	0
Personal reasons	-	-	-
Consent withdrawn by subject	-	-	-
Roll-over into trial BNT162-14	3	1	-
Lost to follow-up	-	3	-

Number of subjects in period 2	Part A Participants Aged 18 to 55 Years - 30 µg	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg
Started	12	12	12
Completed	9	9	11
Not completed	3	3	1
Personal reasons	1	1	-
Consent withdrawn by subject	-	1	-
Roll-over into trial BNT162-14	2	1	1
Lost to follow-up	-	-	-

Number of subjects in period 2	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Started	12	12
Completed	7	6
Not completed	5	6
Personal reasons	-	-
Consent withdrawn by subject	-	-
Roll-over into trial BNT162-14	5	6
Lost to follow-up	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 10 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 20 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 30 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).	
Reporting group title	Part A Participants Aged 56 to 85 Years - 3 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 10 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 20 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 30 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	

Reporting group values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg
Number of subjects	12	12	12
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	39.32	31.20	31.89
standard deviation	± 9.79	± 9.11	± 13.51
Gender categorical Units: Subjects			
Female	3	4	7
Male	9	8	5

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	12
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	12	12	11
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight Units: kg			
arithmetic mean	72.74	71.68	71.40
standard deviation	± 11.43	± 11.67	± 14.40
Body mass index Units: kg/m^2			
arithmetic mean	23.89	24.23	23.80
standard deviation	± 2.92	± 3.68	± 2.74

Reporting group values	Part A Participants Aged 18 to 55 Years - 30 µg	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg
Number of subjects	12	12	12
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	37.28	66.08	69.32
standard deviation	± 6.40	± 7.16	± 8.74
Gender categorical Units: Subjects			
Female	8	9	8
Male	4	3	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	12
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	12	12	12
More than one race	0	0	0

Unknown or Not Reported	0	0	0

Weight			
Units: kg			
arithmetic mean	71.20	76.05	70.90
standard deviation	± 13.80	± 11.88	± 10.69
Body mass index			
Units: kg/m^2			
arithmetic mean	23.69	25.92	24.69
standard deviation	± 2.03	± 1.66	± 3.09

Reporting group values	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg	Total
Number of subjects	12	12	96
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	64.93	66.42	
standard deviation	± 6.63	± 6.82	-
Gender categorical			
Units: Subjects			
Female	9	6	54
Male	3	6	42
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	96
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	12	12	95
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight			
Units: kg			
arithmetic mean	69.06	84.43	
standard deviation	± 14.25	± 17.53	-
Body mass index			
Units: kg/m^2			
arithmetic mean	24.03	26.73	
standard deviation	± 3.17	± 2.75	-

End points

End points reporting groups

Reporting group title	Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 10 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 20 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 30 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).	
Reporting group title	Part A Participants Aged 56 to 85 Years - 3 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 10 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 20 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 30 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 10 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 20 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 18 to 55 Years - 30 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).	
Reporting group title	Part A Participants Aged 56 to 85 Years - 3 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	

Reporting group title	Part A Participants Aged 56 to 85 Years - 10 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 20 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	
Reporting group title	Part A Participants Aged 56 to 85 Years - 30 µg
Reporting group description:	
BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)	

Primary: Number of Participants With Solicited Local Reactions at the Injection Site (Pain, Tenderness, Erythema/Redness, Induration/Swelling) Recorded up to 7 Days After Each IMP Dose

End point title	Number of Participants With Solicited Local Reactions at the Injection Site (Pain, Tenderness, Erythema/Redness, Induration/Swelling) Recorded up to 7 Days After Each IMP Dose[1]

End point description:

Solicited local reactions at the injection site (pain, tenderness, erythema/redness, and induration/swelling) were monitored and 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 reporting of local reactions was based on the participant's assessments via daily solicited reports in the participant diaries. Safety Set - all participants who received at least one dose of the IMP. 9999 indicates data not available as the boost immunization was withheld for 30 µg younger cohort following Safety Review Committee decision.

End point type	Primary

End point timeframe:

From Day 1 to Day 8 for Prime Immunization and from Day 22 to Day 29 for Boost Immunization

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 end point.

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime up to Day 7: any local reaction	9	9	12	12
Prime up to Day 7: any grade ≥3 local reaction	0	0	2	2
Boost up to Day 7: any local reaction	9	9	12	9999
Boost up to Day 7: any grade ≥3 local reaction	0	0	1	9999

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime up to Day 7: any local reaction	4	10	10	9
Prime up to Day 7: any grade ≥3 local reaction	0	0	0	0
Boost up to Day 7: any local reaction	2	9	8	11
Boost up to Day 7: any grade ≥3 local reaction	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Systemic Reactions (Nausea, Vomiting, Diarrhea, Headache, Fatigue, Myalgia, Arthralgia, Chills, Loss of Appetite, Malaise, and Fever) Recorded up to 7 Days After Each IMP Dose

End point title	Number of Participants With Solicited Systemic Reactions (Nausea, Vomiting, Diarrhea, Headache, Fatigue, Myalgia, Arthralgia, Chills, Loss of Appetite, Malaise, and Fever) Recorded up to 7 Days After Each IMP Dose[2]

End point description:

Solicited systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills, loss of appetite, malaise, and fever) were monitored and 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 reporting of systemic reactions was based on the participant's assessments via daily solicited reports in the participant diaries. Safety Set - all participants who received at least one dose of the IMP. 9999 indicates data not available as the boost immunization was withheld for 30 µg younger cohort following Safety Review Committee decision.

End point type	Primary

End point timeframe:

From Day 1 to Day 8 for Prime Immunization and from Day 22 to Day 29 for Boost Immunization

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 end point.

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime up to Day 7: any systemic reaction	4	10	12	12
Prime up to Day 7: any grade ≥3 systemic reaction	0	0	1	3
Boost up to Day 7: any systemic reaction	10	9	12	9999
Boost up to Day 7: any grade ≥3 systemic reaction	0	2	4	9999

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime up to Day 7: any systemic reaction	3	9	9	10
Prime up to Day 7: any grade ≥3 systemic reaction	0	3	0	2
Boost up to Day 7: any systemic reaction	2	10	9	12
Boost up to Day 7: any grade ≥3 systemic reaction	0	2	2	2

Statistical analyses

No statistical analyses for this end point

Primary: The Percentage of Participants With at Least 1 Unsolicited Treatment Emergent Adverse Event (TEAE) Occurring After Prime Immunization up to Boost Immunization or 28 Days After Prime Immunization

End point title	The Percentage of Participants With at Least 1 Unsolicited Treatment Emergent Adverse Event (TEAE) Occurring After Prime Immunization up to Boost Immunization or 28 Days After Prime Immunization[3]

End point description:

Treatment emergent adverse events (TEAEs) were analyzed by age group, dose level, and for each IMP dose. The number and percentage of participants reporting at least one TEAE was summarized by adverse event types (any TEAE and any grade ≥3 TEAE) using the Safety Set. Safety Set - all participants who received at least one dose of the IMP.

End point type	Primary

End point timeframe:

28 days following first IMP dose or up to second IMP dose (whichever was first)

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 analyses were planned for this primary end point.

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	42	25	25	50
Any grade ≥3 TEAE	0	0	0	0

End point values	Part A	Part A	Part A	Part A

	Participants Aged 56 to 85 Years - 3 µg	Participants Aged 56 to 85 Years - 10 µg	Participants Aged 56 to 85 Years - 20 µg	Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	17	17	25	42
Any grade ≥3 TEAE	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: The Percentage of Participants With at Least 1 Unsolicited TEAE Occurring up to 28 Days After Boost Immunization or After Prime Immunization (if no Boost Immunization)

End point title	The Percentage of Participants With at Least 1 Unsolicited TEAE Occurring up to 28 Days After Boost Immunization or After Prime Immunization (if no Boost Immunization)[4]

End point description:

Treatment emergent adverse events (TEAEs) were analyzed by age group, dose level, and for each IMP dose. The percentage of participants reporting at least one TEAE was summarized by adverse event types (any TEAE and any grade ≥3 TEAE) using the Safety Set. Safety Set - all participants who received at least one dose of the IMP.

End point type	Primary

End point timeframe:

28 days following second IMP dose or first IMP dose (if no second IMP dose as given)

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 end point.

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	50	33	42	50
Any grade ≥3 TEAE	0	0	0	0

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				

number (not applicable)				
Any TEAE	58	25	42	50
Any grade ≥3 TEAE	0	0	0	8

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Antibody Responses

End point title	Functional Antibody Responses

End point description:

At 7 and 21 days after primary immunization and at 7, 14, 21, 28 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates missing Day 36 data of 10 µg and 20 µg younger cohort as they have only re-consented to Clinical Trial Protocol 7.0 (introducing visit 5a/Day 36) on/after their Day 43.

End point type	Secondary

End point timeframe:

Up to 50 days following first IMP dose

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.1 (4.8 to 5.5)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	6.1 (4.5 to 8.4)	25.9 (13.8 to 48.7)	8.9 (6.0 to 13.3)	12.2 (7.5 to 20.0)
7 days after Boost Immunization (Day 29)	51.5 (26.4 to 100.3)	479.5 (300.3 to 765.5)	106.8 (58.2 to 196.0)	10.0 (6.5 to 15.4)
14 days after Boost Immunization (Day 36)	60.6 (33.5 to 109.8)	9999 (9999 to 9999)	9999 (9999 to 9999)	10.3 (6.9 to 15.4)
21 days after Boost Immunization (Day 43)	36.4 (20.0 to 66.2)	116.5 (79.6 to 170.4)	201.6 (104.9 to 387.2)	9.7 (5.7 to 16.5)
28 days after Boost Immunization (Day 50)	31.7 (18.5 to 54.6)	80.0 (49.1 to 130.4)	219.8 (117.5 to 411.1)	7.9 (5.0 to 12.5)

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12

Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	7.3 (3.2 to 16.6)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	6.3 (4.8 to 8.3)	5.3 (4.9 to 5.8)	15.0 (5.9 to 37.9)	9.4 (5.4 to 16.4)
7 days after Boost Immunization (Day 29)	53.4 (25.1 to 113.7)	51.9 (25.0 to 107.4)	320.0 (189.7 to 539.7)	207.5 (118.0 to 364.8)
14 days after Boost Immunization (Day 36)	77.7 (40.4 to 149.4)	219.8 (148.5 to 325.4)	320.0 (169.3 to 604.9)	359.2 (204.0 to 632.6)
21 days after Boost Immunization (Day 43)	53.4 (27.5 to 103.6)	155.4 (105.0 to 230.1)	285.1 (152.6 to 532.7)	261.4 (136.0 to 502.6)
28 days after Boost Immunization (Day 50)	41.2 (20.5 to 82.8)	138.5 (87.9 to 218.2)	232.9 (131.1 to 413.8)	195.8 (109.4 to 350.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Increase in Functional Antibody Titers

End point title	Fold Increase in Functional Antibody Titers

End point description:

At 7 and 21 days after primary immunization and at 7, 14, 21, and 28 days after the boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision.

End point type	Secondary

End point timeframe:

Up to 50 days following first IMP dose

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Fold rise				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	1.2 (0.9 to 1.7)	5.2 (2.8 to 9.7)	1.8 (1.2 to 2.7)	2.4 (1.5 to 4.0)
7 days after Boost Immunization (Day 29)	10.3 (5.3 to 20.1)	95.6 (60.1 to 153.1)	21.4 (11.6 to 39.2)	2.0 (1.3 to 3.1)
14 days after Boost Immunization (Day 36)	12.1 (6.7 to 22.0)	9999 (9999 to 9999)	9999 (9999 to 9999)	2.1 (1.4 to 3.1)
21 days after Boost Immunization (Day 43)	7.3 (4.0 to 13.2)	23.3 (15.9 to 34.1)	40.3 (21.0 to 77.4)	1.9 (1.1 to 3.3)
28 days after Boost Immunization (Day 50)	6.3 (3.7 to 10.9)	16.0 (9.8 to 26.1)	44.0 (23.5 to 82.2)	1.6 (1.0 to 2.5)

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Fold rise				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.3 (0.8 to 2.1)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	1.3 (1.0 to 1.7)	1.1 (1.0 to 1.2)	2.6 (1.3 to 5.0)	1.9 (1.1 to 3.3)
7 days after Boost Immunization (Day 29)	10.7 (5.0 to 22.7)	10.4 (5.0 to 21.5)	55.4 (35.5 to 86.4)	41.5 (23.6 to 73.0)
14 days after Boost Immunization (Day 36)	15.5 (8.1 to 29.9)	44.0 (29.7 to 65.1)	55.4 (31.2 to 98.4)	71.8 (40.8 to 126.5)
21 days after Boost Immunization (Day 43)	10.7 (5.5 to 20.7)	31.1 (21.0 to 46.0)	49.4 (29.7 to 81.9)	52.3 (27.2 to 100.5)
28 days after Boost Immunization (Day 50)	8.2 (4.1 to 16.6)	27.7 (17.6 to 43.6)	40.3 (26.7 to 60.9)	39.2 (21.9 to 70.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline

End point title	Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline

End point description:

At 7 and 21 days after primary immunization and at 7, 14, 21, and 28 days after the boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates missing Day 36 data of 10 µg and 20 µg younger cohort as they have only re-consented to Clinical Trial Protocol 7.0 (introducing visit 5a/Day 36) on/after their Day 43.

End point type	Secondary

End point timeframe:

Up to 50 days following first IMP dose

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	0	0
21 days after Prime Immunization (Day 22)	1	9	2	5
7 days after Boost Immunization (Day 29)	9	12	12	3
14 days after Boost Immunization (Day 36)	9	9999	9999	4
21 days after Boost Immunization (Day 43)	8	12	12	3
28 days after Boost Immunization (Day 50)	8	11	12	1

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	1	0
21 days after Prime Immunization (Day 22)	1	0	4	2
7 days after Boost Immunization (Day 29)	10	10	12	12
14 days after Boost Immunization (Day 36)	11	12	12	12
21 days after Boost Immunization (Day 43)	9	12	12	12
28 days after Boost Immunization (Day 50)	9	12	12	12

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Antibody Responses

End point title	Functional Antibody Responses

End point description:

At 63, 162, 365 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates Day 387 data is either missing due to exclusion because of non-study vaccination or due to premature discontinuation. 99999 indicates value not evaluable, confidence intervals were only calculated if values of at least 3 participants were available.

End point type	Secondary

End point timeframe:

From 51 to up to 387 days following first IMP dose

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
63 days after Boost Immunization (Day 85)	40.0 (22.4 to 71.4)	51.9 (39.1 to 68.9)	116.5 (51.0 to 266.1)	13.0 (7.8 to 21.5)
162 days after Boost Immunization (Day 184)	11.7 (5.8 to 23.8)	51.5 (33.9 to 78.1)	119.9 (62.6 to 229.5)	11.0 (4.7 to 25.8)
365 days after Boost Immunization (Day 387)	197.0 (14.2 to 2727.9)	452.5 (47.4 to 4322.3)	513.3 (215.8 to 1221.2)	5.0 (-99999 to 99999)

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
63 days after Boost Immunization (Day 85)	34.6 (18.1 to 66.1)	85.2 (48.7 to 149.0)	142.5 (77.9 to 260.7)	75.5 (45.6 to 125.0)
162 days after Boost Immunization (Day 184)	9.6 (6.1 to 15.0)	28.3 (11.2 to 71.6)	44.9 (22.0 to 91.8)	107.7 (42.3 to 273.8)
365 days after Boost Immunization (Day 387)	1280.0 (-99999 to 99999)	9999 (-9999 to 9999)	9999 (-9999 to 9999)	9999 (-9999 to 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Increase in Functional Antibody Titers

End point title	Fold Increase in Functional Antibody Titers

End point description:

At 63, 162, 365 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates Day 387 data is either missing due to exclusion because of non-study vaccination or due to premature discontinuation. 99999 indicates value not evaluable, confidence intervals were only calculated if values of at least 3 participants were available.

End point type	Secondary

End point timeframe:

From 51 to up to 387 days following first IMP dose

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Fold rise				
geometric mean (confidence interval 95%)				
63 days after Boost Immunization (Day 85)	8.0 (4.5 to 14.3)	10.4 (7.8 to 13.8)	23.3 (10.2 to 53.2)	2.6 (1.6 to 4.3)
162 days after Boost Immunization (Day 184)	2.3 (1.2 to 4.8)	10.3 (6.8 to 15.6)	24.0 (12.5 to 45.9)	2.2 (0.9 to 5.2)
365 days after Boost Immunization (Day 387)	39.4 (2.8 to 545.6)	90.5 (9.5 to 864.5)	102.7 (43.2 to 244.2)	1.0 (-99999 to 99999)

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Fold rise				
geometric mean (confidence interval 95%)				
63 days after Boost Immunization (Day 85)	6.9 (3.6 to 13.2)	17.0 (9.7 to 29.8)	24.7 (15.3 to 39.9)	15.1 (9.1 to 25.0)
162 days after Boost Immunization (Day 184)	1.9 (1.2 to 3.0)	5.7 (2.2 to 14.3)	9.0 (4.4 to 18.4)	21.5 (8.5 to 54.8)
365 days after Boost Immunization (Day 387)	256.0 (-99999 to 99999)	9999 (-9999 to 9999)	9999 (-9999 to 9999)	9999 (-9999 to 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline

End point title	Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline

End point description:

At 63, 162, 365 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates Day 387 data is either missing due to exclusion because of non-study

vaccination or due to premature discontinuation.

End point type	Secondary

End point timeframe:

From 51 to up to 387 days following first IMP dose

End point values	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg	Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
63 days after Boost Immunization (Day 85)	9	12	11	3
162 days after Boost Immunization (Day 184)	4	11	12	2
365 days after Boost Immunization (Day 387)	4	5	11	0

End point values	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
63 days after Boost Immunization (Day 85)	8	11	12	12
162 days after Boost Immunization (Day 184)	2	6	6	6
365 days after Boost Immunization (Day 387)	1	9999	9999	9999

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Day 1 (Prime Immunization) up to Day 50 (with or without Boost Immunization). Adverse events with an onset date more than 28 days after the last administration of IMP are reported only if assessed as related to IMP by the investigator.

Adverse event reporting additional description:

Treatment emergent adverse events (TEAEs) are reported, i.e., adverse events (AEs) with an onset date on or after the first administration of IMP (if the AE was absent before the first administration of IMP) or worsened after the first administration of IMP (if the AE was present before the first administration of IMP).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Reporting group title	Part A Participants Aged 18 to 55 Years - 10 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Reporting group title	Part A Participants Aged 18 to 55 Years - 20 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Reporting group title	Part A Participants Aged 18 to 55 Years - 30 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).

Reporting group title	Part A Participants Aged 56 to 85 Years - 3 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Reporting group title	Part A Participants Aged 56 to 85 Years - 10 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Reporting group title	Part A Participants Aged 56 to 85 Years - 20 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Reporting group title	Part A Participants Aged 56 to 85 Years - 30 µg

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

Serious adverse events	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Part A Participants Aged 18 to 55 Years - 30 µg	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Part A Participants Aged 18 to 55 Years - 3 µg	Part A Participants Aged 18 to 55 Years - 10 µg	Part A Participants Aged 18 to 55 Years - 20 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 12 (58.33%)	4 / 12 (33.33%)	5 / 12 (41.67%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			

Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	1	2	2
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Meibomian gland dysfunction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Myalgia			

subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Myofascial pain syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pulpitis dental			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A Participants Aged 18 to 55 Years - 30 µg	Part A Participants Aged 56 to 85 Years - 3 µg	Part A Participants Aged 56 to 85 Years - 10 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 12 (50.00%)	7 / 12 (58.33%)	5 / 12 (41.67%)
Vascular disorders			

Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tenderness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Nasal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	3 / 12 (25.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Meibomian gland dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myofascial pain syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pulpitis dental			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part A Participants Aged 56 to 85 Years - 20 µg	Part A Participants Aged 56 to 85 Years - 30 µg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 12 (41.67%)	6 / 12 (50.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Tenderness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Seasonal allergy			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	4	
Nasal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Lipase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			

Skin laceration subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	
Cardiac disorders Palpitations subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	
Headache subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	
Hyperaesthesia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	
Sciatica subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	
Vertigo subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	
Eye disorders Meibomian gland dysfunction subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	
Gastrointestinal disorders Dyspepsia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 12 (0.00%) 0	
Flatulence			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Myofascial pain syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pulpitis dental			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 September 2020	This amendment described changes made to clarify potential inconsistencies, to align trial reporting with other ongoing BNT162 trials, and to enhance assessments for immunogenicity.
02 December 2020	This update implemented: a change in sponsor name; the addition of two additional dosing cohorts in older adults; measures to avoid under reporting of mild COVID-19 related events revealed within the trial; terminology alignment with other ongoing trials; correction to some errors. The rational for the addition of two older adult cohorts was based on the available immunogenicity and cell-mediated immune response data after dosing with BNT162b1 and BNT162b2 in younger and elderly adults in the BNT162-01 (2020-001038-36) and BNT162-02 (2020-002641-42) trials elicited measurable but lower responses in elderly adults than in younger adults. Therefore, the additional older adult cohorts were to be used to investigate BNT162b3 doses above the already tested 20 µg BNT162b3 dose, to support any future Phase III program planned to support marketing approval.
25 March 2021	This update implemented the removal of Part B, changes to the primary objective endpoints, and a change to concomitant medication reporting during study follow-up to allow capture of vaccinations, e.g., SARS-CoV-2 vaccinations.
12 May 2021	This update implemented corrections to time points in the exploratory objectives and a deletion within Section 4.4 (End of Treatment and end of trial definition) in order to allow subjects to participate in other clinical trials investigating COVID-19 vaccines and treatments.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported