Clinical trial results:
A Phase 2/3 Protocol to Investigate the Safety, Tolerability, and Immunogenicity of BNT162b2 RNA - Based Vaccine Candidates for SARS-Cov-2 New Variants in Healthy Individuals

Summary

EudraCT number	2024-000361-24
Trial protocol	Outside EU/EEA
Global end of trial date	11 March 2025

Results information

Result version number	v2 (current)
This version publication date	23 October 2025
First version publication date	20 December 2024
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	C4591054

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05997290
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de
Scientific contact	BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 May 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 March 2025
Global end of trial reached?	Yes
Global end of trial date	11 March 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability and immunogenicity of one or more SARS-CoV-2 variant-adapted BNT162b2 vaccine candidates in the following substudies:SSA - BNT162b2 (Omi XBB.1.5) in COVID-19 vaccine–experienced participants ≥12 years of age.SSB - BNT162b2 (Omi XBB.1.5) as a single dose in participants ≥12 years of age who were previously exposed to SARS-CoV-2 and are COVID-19 vaccine naïve.SSC - BNT162b2 (Omi JN.1) as a single dose in participants ≥18 years of age (Cohort 1) and ≥12 years of age (Cohort 2) and BNT162b2 (Omi KP.2) as a single dose in participants ≥18 years of age (Cohort 3).

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 trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 August 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1041
Worldwide total number of subjects	1041
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	57
Adults (18-64 years)	723

From 65 to 84 years	259
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

In this study there were 3 sub-studies: sub-study A (SSA), sub-study B (SSB), and sub-study C (SSC).

Pre-assignment

Screening details:

SSA: A total of 417 participants were screened, out of which, 412 were vaccinated. SSB: A total of 311 participants were screened and vaccinated. SSC: A total of 321 participants were screened, out of which 318 were vaccinated.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	SSA: Group 1: 12-17 years

Arm description:

Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via intramuscular (IM) route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi XBB.1.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

Arm title	SSA: Group 2: 18-55 years

Arm description:

Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi XBB.1.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

Arm title	SSA: Group 3: >55 years

Arm description:

Participants aged greater than (>) 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150

days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi XBB.1.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

Arm title	SSB: Group 1: 12-17 years

Arm description:

Participants aged 12-17 years who were previously exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi XBB.1.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

Arm title	SSB: Group 2: 18-55 years

Arm description:

Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi XBB.1.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

Arm title	SSB: Group 3: >55 years

Arm description:

Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi XBB.1.5)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

Arm title	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years

Arm description:

Participants aged 12-17 years received a single dose of BNT162b2 (Omi JN.1)30 mcg via IM route on Day 1 of this study.

Arm type	Experimental

Investigational medicinal product name	BNT162b2 (Omi JN.1)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (OmiJN.1) administered intramuscularly.

Arm title	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years

Arm description:

Participants aged 18-55 years received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi JN.1)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (OmiJN.1) administered intramuscularly.

Arm title	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years

Arm description:

Participants aged >55 years received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi JN.1)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (OmiJN.1) administered intramuscularly.

Arm title	SSC: Cohort 3: 18-55 Years

Arm description:

Participants aged 18-55 years received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental
Investigational medicinal product name	BNT162b2 (Omi KP.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (OmiKP.2) administered intramuscularly.

Arm title	SSC: Cohort 3: > 55 Years

Arm description:

Participants aged >55 years received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.

Arm type	Experimental

Investigational medicinal product name	BNT162b2 (Omi KP.2)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (OmiKP.2) administered intramuscularly.

Number of subjects in period 1	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years
Started	30	174	208
Safety Population	30	174	208
Evaluable Immunogenicity Population	27 [1]	167 [2]	188 [3]
Completed	29	172	203
Not completed	1	2	5
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	1	-	2
Unspecified	-	-	-
Lost to follow-up	-	2	-
Protocol deviation	-	-	2

Number of subjects in period 1	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSB: Group 3: >55 years
Started	9	253	49
Safety Population	9	253	49
Evaluable Immunogenicity Population	9	243	47
Completed	9	225	44
Not completed	0	28	5
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	6	1
Unspecified	-	-	-
Lost to follow-up	-	22	4
Protocol deviation	-	-	-

Number of subjects in period 1	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years
Started	18	92	106
Safety Population	18	92	106
Evaluable Immunogenicity Population	18	91	103
Completed	18	87	100
Not completed	0	5	6
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	-	2	1

Unspecified	-	-	-
Lost to follow-up	-	3	2
Protocol deviation	-	-	2

Number of subjects in period 1	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years
Started	51	51
Safety Population	51	51
Evaluable Immunogenicity Population	50	50
Completed	48	49
Not completed	3	2
Adverse event, serious fatal	-	-
Consent withdrawn by subject	1	-
Unspecified	1	-
Lost to follow-up	-	1
Protocol deviation	1	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.

Baseline characteristics

Reporting groups

Reporting group title	SSA: Group 1: 12-17 years

Reporting group description:

Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via intramuscular (IM) route on Day 1 of this study.

Reporting group title	SSA: Group 2: 18-55 years

Reporting group description:

Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSA: Group 3: >55 years

Reporting group description:

Participants aged greater than (>) 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 1: 12-17 years

Reporting group description:

Participants aged 12-17 years who were previously exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 2: 18-55 years

Reporting group description:

Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 3: >55 years

Reporting group description:

Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years

Reporting group description:

Participants aged 12-17 years received a single dose of BNT162b2 (Omi JN.1)30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years

Reporting group description:

Participants aged 18-55 years received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years

Reporting group description:

Participants aged >55 years received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 3: 18-55 Years

Reporting group description:

Participants aged 18-55 years received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 3: > 55 Years

Reporting group description:

Participants aged >55 years received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.

Reporting group values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years
Number of subjects	30	174	208
Age categorical Units: Participants			
Adolescents (12-17 years)	30	0	0
Adults (18-64 years)	0	174	63
From 65-84 years	0	0	143
85 years and over	0	0	2
Age Continuous Units: years			
arithmetic mean	14.0	40.4	68.6
standard deviation	± 1.74	± 9.82	± 6.74
Gender Categorical Units: Participants			
Female	19	100	123
Male	11	74	85
Race Units: Subjects			
White	26	135	164
Black or African American	3	23	27
American Indian or Alaska Native	0	0	1
Asian	1	11	10
Native Hawaiian or other Pacific Islander	0	0	2
Multiracial	0	5	3
Unknown	0	0	1
Ethnicity Units: Subjects			
Hispanic/Latino	6	35	34
Non-Hispanic/non-Latino	24	138	173
Not reported	0	1	1

Reporting group values	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSB: Group 3: >55 years
Number of subjects	9	253	49
Age categorical Units: Participants			
Adolescents (12-17 years)	9	0	0
Adults (18-64 years)	0	253	27
From 65-84 years	0	0	22
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	14.6	34.5	64.0
standard deviation	± 1.67	± 10.43	± 6.35
Gender Categorical Units: Participants			
Female	5	138	23
Male	4	115	26

Race Units: Subjects			
White	2	162	30
Black or African American	7	87	16
American Indian or Alaska Native	0	0	1
Asian	0	4	2
Native Hawaiian or other Pacific Islander	0	0	0
Multiracial	0	0	0
Unknown	0	0	0
Ethnicity Units: Subjects			
Hispanic/Latino	3	136	19
Non-Hispanic/non-Latino	6	117	30
Not reported	0	0	0

Reporting group values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years
Number of subjects	18	92	106
Age categorical Units: Participants			
Adolescents (12-17 years)	18	0	0
Adults (18-64 years)	0	92	45
From 65-84 years	0	0	61
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	15.1	38.3	66.3
standard deviation	± 1.49	± 10.93	± 6.57
Gender Categorical Units: Participants			
Female	8	60	58
Male	10	32	48
Race Units: Subjects			
White	15	60	76
Black or African American	2	20	16
American Indian or Alaska Native	0	1	1
Asian	0	6	6
Native Hawaiian or other Pacific Islander	0	0	1
Multiracial	1	4	6
Unknown	0	1	0
Ethnicity Units: Subjects			
Hispanic/Latino	1	20	29
Non-Hispanic/non-Latino	17	72	76
Not reported	0	0	1

Reporting group values	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years	Total
Number of subjects	51	51	1041

Age categorical Units: Participants			
Adolescents (12-17 years)	0	0	57
Adults (18-64 years)	51	18	723
From 65-84 years	0	33	259
85 years and over	0	0	2
Age Continuous Units: years			
arithmetic mean	41.2	67.1	
standard deviation	± 8.55	± 6.59	-
Gender Categorical Units: Participants			
Female	35	27	596
Male	16	24	445
Race Units: Subjects			
White	39	37	746
Black or African American	6	7	214
American Indian or Alaska Native	0	0	4
Asian	4	6	50
Native Hawaiian or other Pacific Islander	0	0	3
Multiracial	2	1	22
Unknown	0	0	2
Ethnicity Units: Subjects			
Hispanic/Latino	6	9	298
Non-Hispanic/non-Latino	44	42	739
Not reported	1	0	4

Subject analysis sets

Subject analysis set title	SSA Total Study Participants: C4591054
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study. This analysis set is created for safety analysis.

Subject analysis set title	SSA Historical Control: 12-17 years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) who aged 12 to 17 years who received BNT162b2 (Omi XBB.1.5) 30 mcg as historical control for immunogenicity analysis. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Historical Control: 18-55 years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) who aged 18 to 55 years who received BNT162b2 (Omi XBB.1.5) 30 mcg as historical control for immunogenicity analysis. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Historical Control: >55 years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) who aged > 55 years who received BNT162b2 (Omi XBB.1.5) 30 mcg as historical control for immunogenicity analysis. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Historical Control: All Age Groups
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) of any age group who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Total Historical Control: C4591044 BNT162b2
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from study C4591044 (NCT05472038) Cohort 2/Cohort 3 who received bivalent BNT162b2 (WT/Omi BA.4/BA.5) 30 mcg as a fourth dose were used as historical control for immunogenicity. This analysis set is created for immunogenicity analysis.

Subject analysis set title	SSB Total Study Participants
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants aged >=12 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSB. This analysis set is created for safety analysis.

Subject analysis set title	SSB: Vaccine-Naïve Substudy B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged >=12 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSB. This analysis set is created for immunogenicity analysis.

Subject analysis set title	SSB Control: Vaccine-Experienced Substudy A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants who received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSA were included. This analysis set is created for immunogenicity analysis.

Subject analysis set title	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject analysis set type	Per protocol

Subject analysis set description:

Participants of any age group who received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSC: Cohort 3 Combined: All Age Groups
Subject analysis set type	Full analysis

Subject analysis set description:

Participants of any age group who received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study. This analysis set is created for safety analysis.

Subject analysis set title	SSC Cohort 1 and Cohort 2 Combined BNT162b2
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study. This analysis set is created for evaluable immunogenicity population.

Reporting group values	SSA Total Study Participants: C4591054	SSA Historical Control: 12-17 years	SSA Historical Control: 18-55 years
Number of subjects	412	15	85

Age categorical Units: Participants			
Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years arithmetic mean standard deviation	±	±	±
Gender Categorical Units: Participants			
Female Male			
Race Units: Subjects			
White Black or African American American Indian or Alaska Native Asian Native Hawaiian or other Pacific Islander Multiracial Unknown			
Ethnicity Units: Subjects			
Hispanic/Latino Non-Hispanic/non-Latino Not reported			

Reporting group values	SSA Historical Control: >55 years	SSA Historical Control: All Age Groups	SSA Total Historical Control: C4591044 BNT162b2
Number of subjects	100	382	200
Age categorical Units: Participants			
Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years arithmetic mean standard deviation	±	±	±
Gender Categorical Units: Participants			
Female Male			
Race Units: Subjects			
White Black or African American			

American Indian or Alaska Native Asian Native Hawaiian or other Pacific Islander Multiracial Unknown			
Ethnicity Units: Subjects			
Hispanic/Latino Non-Hispanic/non-Latino Not reported			

Reporting group values	SSB Total Study Participants	SSB: Vaccine-Naïve Substudy B	SSB Control: Vaccine-Experienced Substudy A
Number of subjects	311	299	296
Age categorical Units: Participants			
Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years arithmetic mean standard deviation	±	±	±
Gender Categorical Units: Participants			
Female Male			
Race Units: Subjects			
White Black or African American American Indian or Alaska Native Asian Native Hawaiian or other Pacific Islander Multiracial Unknown			
Ethnicity Units: Subjects			
Hispanic/Latino Non-Hispanic/non-Latino Not reported			

Reporting group values	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups	SSC: Cohort 3 Combined: All Age Groups	SSC Cohort 1 and Cohort 2 Combined BNT162b2
Number of subjects	1	1	1
Age categorical Units: Participants			
Adolescents (12-17 years)		0	0
Adults (18-64 years)		0	0

From 65-84 years		0	0
85 years and over		0	0

Age Continuous			
Units: years			
arithmetic mean		0	0
standard deviation	±	±	±
Gender Categorical			
Units: Participants			
Female		0	0
Male		0	0
Race			
Units: Subjects			
White		0	0
Black or African American		0	0
American Indian or Alaska Native		0	0
Asian		0	0
Native Hawaiian or other Pacific Islander		0	0
Multiracial		0	0
Unknown		0	0
Ethnicity			
Units: Subjects			
Hispanic/Latino		0	0
Non-Hispanic/non-Latino		0	0
Not reported		0	0

End points

End points reporting groups

Reporting group title	SSA: Group 1: 12-17 years

Reporting group description:

Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via intramuscular (IM) route on Day 1 of this study.

Reporting group title	SSA: Group 2: 18-55 years

Reporting group description:

Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSA: Group 3: >55 years

Reporting group description:

Participants aged greater than (>) 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 1: 12-17 years

Reporting group description:

Participants aged 12-17 years who were previously exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 2: 18-55 years

Reporting group description:

Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 3: >55 years

Reporting group description:

Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years

Reporting group description:

Participants aged 12-17 years received a single dose of BNT162b2 (Omi JN.1)30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years

Reporting group description:

Participants aged 18-55 years received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years

Reporting group description:

Participants aged >55 years received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 3: 18-55 Years

Reporting group description:

Participants aged 18-55 years received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 3: > 55 Years

Reporting group description:

Participants aged >55 years received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.

Subject analysis set title	SSA Total Study Participants: C4591054
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study. This analysis set is created for safety analysis.

Subject analysis set title	SSA Historical Control: 12-17 years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) who aged 12 to 17 years who received BNT162b2 (Omi XBB.1.5) 30 mcg as historical control for immunogenicity analysis. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Historical Control: 18-55 years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) who aged 18 to 55 years who received BNT162b2 (Omi XBB.1.5) 30 mcg as historical control for immunogenicity analysis. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Historical Control: >55 years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) who aged > 55 years who received BNT162b2 (Omi XBB.1.5) 30 mcg as historical control for immunogenicity analysis. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Historical Control: All Age Groups
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from sub-study A of the current study C4591054 (NCT05997290) of any age group who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSA Total Historical Control: C4591044 BNT162b2
Subject analysis set type	Per protocol

Subject analysis set description:

Participants from study C4591044 (NCT05472038) Cohort 2/Cohort 3 who received bivalent BNT162b2 (WT/Omi BA.4/BA.5) 30 mcg as a fourth dose were used as historical control for immunogenicity. This analysis set is created for immunogenicity analysis.

Subject analysis set title	SSB Total Study Participants
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants aged >=12 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSB. This analysis set is created for safety analysis.

Subject analysis set title	SSB: Vaccine-Naïve Substudy B
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged >=12 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSB. This analysis set is created for immunogenicity analysis.

Subject analysis set title	SSB Control: Vaccine-Experienced Substudy A
Subject analysis set type	Per protocol

Subject analysis set description:

Participants who received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSA were included. This analysis set is created for immunogenicity analysis.

Subject analysis set title	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject analysis set type	Per protocol

Subject analysis set description:

Participants of any age group who received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study. This analysis set is created for analysis of this outcome measure.

Subject analysis set title	SSC: Cohort 3 Combined: All Age Groups
Subject analysis set type	Full analysis

Subject analysis set description:

Participants of any age group who received a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study. This analysis set is created for safety analysis.

Subject analysis set title	SSC Cohort 1 and Cohort 2 Combined BNT162b2
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received a single dose of BNT162b2 (Omi JN.1) 30 mcg via IM route on Day 1 of this study. This analysis set is created for evaluable immunogenicity population.

Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSA

End point title	Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSA[1][2]

End point description:

Local reactions: pain at injection site, redness and swelling recorded by participants in an electronic diary (e-diary) or as adverse events (AEs) in the case report form (CRF). Redness & swelling measured & recorded in measuring device units (mdu)(range:1 to 21),1mdu=0.5 cm &were graded as mild (greater than[>] 2.0 to 5.0 cm),moderate(>5.0 to 10.0 cm),severe(>10.0 cm)&Grade 4(necrosis [swelling]&necrosis or exfoliative dermatitis[redness]).Pain at injection site graded as mild(did not interfere with activity),moderate(interfered with activity),severe(prevented daily activity)&Grade(G)4(emergency room [ER]visit or hospitalisation for severe pain at injection site).G4 LR classified by investigator or medically qualified person.Exact 2-sided confidence interval(CI)based on Clopper and Pearson method. Safety population: all participants who received study intervention.Number of Participants Analysed=Participants evaluable.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Total Study Participants: C4591054
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	30	174	206	410
Units: Percentage of Participants				
number (confidence interval 95%)				
Redness: Any	10.0 (2.1 to 26.5)	4.0 (1.6 to 8.1)	5.8 (3.0 to 10.0)	5.4 (3.4 to 8.0)
Redness: Mild	6.7 (0.8 to 22.1)	3.4 (1.3 to 7.4)	3.9 (1.7 to 7.5)	3.9 (2.2 to 6.3)
Redness: Moderate	3.3 (0.1 to 17.2)	0.6 (0.0 to 3.2)	1.9 (0.5 to 4.9)	1.5 (0.5 to 3.2)
Redness: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Redness: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Swelling: Any	16.7 (5.6 to 34.7)	7.5 (4.0 to 12.4)	5.8 (3.0 to 10.0)	7.3 (5.0 to 10.3)

Swelling: Mild	13.3 (3.8 to 30.7)	5.7 (2.8 to 10.3)	3.9 (1.7 to 7.5)	5.4 (3.4 to 8.0)
Swelling: Moderate	3.3 (0.1 to 17.2)	1.7 (0.4 to 5.0)	1.9 (0.5 to 4.9)	2.0 (0.8 to 3.8)
Swelling: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Swelling: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Pain at the injection site: Any	80.0 (61.4 to 92.3)	75.9 (68.8 to 82.0)	52.4 (45.4 to 59.4)	64.4 (59.5 to 69.0)
Pain at the injection site: Mild	50.0 (31.3 to 68.7)	59.8 (52.1 to 67.1)	46.6 (39.6 to 53.7)	52.4 (47.5 to 57.4)
Pain at the injection site: Moderate	30.0 (14.7 to 49.4)	16.1 (11.0 to 22.4)	5.8 (3.0 to 10.0)	12.0 (9.0 to 15.5)
Pain at the injection site: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Pain at the injection site: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSA

End point title	Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSA[3][4]

End point description:

Systemic events were recorded by participants in an e-diary or as AEs in the CRF. Fever: defined as oral temperature >=38 degree Celsius (deg C) and categorised as >= 38.0-38.4 deg C, >38.4-38.9 deg C, >38.9-40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and joint pain: mild (didn't interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours (h), moderate: >2 times in 24h, severe: required intravenous (IV) hydration. Diarrhoea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6 or more loose stools in 24h. Grade 4 for all events except fever: ER visit/hospitalization. Grade 4 events were classified by investigator or medically qualified person. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: All participants who received the study intervention. Number of Participants Analysed= Participants evaluable.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Total Study Participants: C4591054
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	30	174	206	410
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	16.7 (5.6 to 34.7)	4.0 (1.6 to 8.1)	3.9 (1.7 to 7.5)	4.9 (3.0 to 7.4)

Fever: >=38.0 degree C to 38.4 degree C	10.0 (2.1 to 26.5)	3.4 (1.3 to 7.4)	2.4 (0.8 to 5.6)	3.4 (1.9 to 5.7)
Fever: >38.4 degree C to 38.9 degree C	3.3 (0.1 to 17.2)	0.6 (0.0 to 3.2)	1.0 (0.1 to 3.5)	1.0 (0.3 to 2.5)
Fever: >38.9 degree C to 40.0 degree C	3.3 (0.1 to 17.2)	0 (0.0 to 2.1)	0.5 (0.0 to 2.7)	0.5 (0.1 to 1.8)
Fever: >40.0 degree C	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Fatigue: Any	56.7 (37.4 to 74.5)	56.9 (49.2 to 64.4)	35.4 (28.9 to 42.4)	46.1 (41.2 to 51.1)
Fatigue: Mild	30.0 (14.7 to 49.4)	31.6 (24.8 to 39.1)	18.4 (13.4 to 24.4)	24.9 (20.8 to 29.4)
Fatigue: Moderate	26.7 (12.3 to 45.9)	24.1 (18.0 to 31.2)	17.0 (12.1 to 22.8)	20.7 (16.9 to 25.0)
Fatigue: Severe	0 (0.0 to 11.6)	1.1 (0.1 to 4.1)	0 (0.0 to 1.8)	0.5 (0.1 to 1.8)
Fatigue: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Headache: Any	36.7 (19.9 to 56.1)	43.7 (36.2 to 51.4)	26.2 (20.3 to 32.8)	34.4 (29.8 to 39.2)
Headache: Mild	30.0 (14.7 to 49.4)	31.0 (24.3 to 38.5)	20.4 (15.1 to 26.5)	25.6 (21.5 to 30.1)
Headache: Moderate	6.7 (0.8 to 22.1)	12.6 (8.1 to 18.5)	5.8 (3.0 to 10.0)	8.8 (6.2 to 11.9)
Headache: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Headache: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Chills: Any	20.0 (7.7 to 38.6)	9.2 (5.3 to 14.5)	9.2 (5.6 to 14.0)	10.0 (7.3 to 13.3)
Chills: Mild	10.0 (2.1 to 26.5)	6.9 (3.6 to 11.7)	6.3 (3.4 to 10.5)	6.8 (4.6 to 9.7)
Chills: Moderate	10.0 (2.1 to 26.5)	2.3 (0.6 to 5.8)	2.9 (1.1 to 6.2)	3.2 (1.7 to 5.4)
Chills: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Chills: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Vomiting: Any	0 (0.0 to 11.6)	2.3 (0.6 to 5.8)	0 (0.0 to 1.8)	1.0 (0.3 to 2.5)
Vomiting: Mild	0 (0.0 to 11.6)	2.3 (0.6 to 5.8)	0 (0.0 to 1.8)	1.0 (0.3 to 2.5)
Vomiting: Moderate	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Vomiting: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Vomiting: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
Diarrhoea: Any	0 (0.0 to 11.6)	13.2 (8.6 to 19.2)	8.7 (5.3 to 13.5)	10.0 (7.3 to 13.3)
Diarrhoea: Mild	0 (0.0 to 11.6)	11.5 (7.2 to 17.2)	7.3 (4.1 to 11.7)	8.5 (6.0 to 11.7)
Diarrhoea: Moderate	0 (0.0 to 11.6)	1.1 (0.1 to 4.1)	1.5 (0.3 to 4.2)	1.2 (0.4 to 2.8)
Diarrhoea: Severe	0 (0.0 to 11.6)	0.6 (0.0 to 3.2)	0 (0.0 to 1.8)	0.2 (0.0 to 1.4)
Diarrhoea: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
New or worsened muscle pain: Any	23.3 (9.9 to 42.3)	21.8 (15.9 to 28.7)	12.1 (8.0 to 17.4)	17.1 (13.6 to 21.1)
New or worsened muscle pain: Mild	3.3 (0.1 to 17.2)	12.1 (7.6 to 17.9)	5.3 (2.7 to 9.4)	8.0 (5.6 to 11.1)
New or worsened muscle pain: Moderate	20.0 (7.7 to 38.6)	9.8 (5.8 to 15.2)	6.8 (3.8 to 11.1)	9.0 (6.4 to 12.2)
New or worsened muscle pain: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
New or worsened muscle pain: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)
New or worsened joint pain: Any	16.7 (5.6 to 34.7)	14.4 (9.5 to 20.5)	7.8 (4.5 to 12.3)	11.2 (8.3 to 14.7)
New or worsened joint pain: Mild	6.7 (0.8 to 22.1)	8.6 (4.9 to 13.8)	5.3 (2.7 to 9.4)	6.8 (4.6 to 9.7)
New or worsened joint pain: Moderate	10.0 (2.1 to 26.5)	5.7 (2.8 to 10.3)	2.4 (0.8 to 5.6)	4.4 (2.6 to 6.8)
New or worsened joint pain: Severe	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)

New or worsened joint pain: Grade 4	0 (0.0 to 11.6)	0 (0.0 to 2.1)	0 (0.0 to 1.8)	0 (0.0 to 0.9)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants With Adverse Events (AEs) From Vaccination Through 1 Month After Vaccination: SSA[5][6]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs from study vaccination on Day 1 up to 1 month after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received the study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Total Study Participants: C4591054
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	30	174	208	412
Units: Percentage of participants				
number (confidence interval 95%)	16.7 (5.6 to 34.7)	7.5 (4.0 to 12.4)	8.2 (4.8 to 12.8)	8.5 (6.0 to 11.6)

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants With Serious Adverse Events (SAEs) From Vaccination Through 6 Months After the Study Vaccination: SSA[7][8]

End point description:

An SAE was defined as any untoward medical occurrence at any dose that resulted in any of the following outcomes: death; life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; or considered as an important medical event. Percentage of participants reporting SAEs from study vaccination on Day 1 up to 6 months after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Safety population included all participants who received the study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 6 months after vaccination

Notes:

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

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Total Study Participants: C4591054
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	30	174	208	412
Units: Percentage of Participants				
number (confidence interval 95%)	3.3 (0.1 to 17.2)	0 (0.0 to 2.1)	1.9 (0.5 to 4.9)	1.2 (0.4 to 2.8)

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMT) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

End point title	Geometric Mean Titers (GMT) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044[9][10]

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the lower limit of quantitation (LLOQ) were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Historical Control: 12-17 years
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	27	166	185	15
Units: Titer				
geometric mean (confidence interval 95%)	3632.1 (2043.8 to 6454.7)	2503.6 (2003.0 to 3129.3)	2606.8 (2065.5 to 3289.9)	837.1 (459.5 to 1524.9)

End point values	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSA Historical Control: All Age Groups	SSA Total Historical Control: C4591044 BNT162b2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	85	100	378	200
Units: Titer				
geometric mean (confidence interval 95%)	615.5 (459.0 to 825.2)	560.4 (430.0 to 730.2)	2622.3 (2246.6 to 3060.9)	601.0 (499.5 to 723.1)

Statistical analyses

No statistical analyses for this end point

Primary: GMT of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

End point title	GMT of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044[11][12]

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Historical Control: 12-17 years
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	26	167	187	15
Units: Titer				
geometric mean (confidence interval 95%)	7903.6 (4961.5 to 12590.4)	4831.8 (4044.5 to 5772.3)	5046.1 (4123.3 to 6175.3)	6376.3 (3568.4 to 11393.8)

End point values	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSA Historical Control: All Age Groups	SSA Total Historical Control: C4591044 BNT162b2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	85	100	380	200
Units: Titer				
geometric mean (confidence interval 95%)	3868.2 (2974.8 to 5029.9)	4122.7 (3261.2 to 5211.6)	5105.1 (4483.4 to 5813.0)	4146.0 (3512.6 to 4893.5)

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

End point title	Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044[13][14]

End point description:

GMFR and 2-sided 95% CI were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From before vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Historical Control: 12-17 years
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	27	165	184	15
Units: Fold rise				
geometric mean (confidence interval 95%)	11.8 (6.3 to 22.2)	10.7 (8.7 to 13.1)	13.5 (10.7 to 17.1)	7.1 (3.9 to 12.8)

End point values	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSA Historical Control: All Age Groups	SSA Total Historical Control: C4591044 BNT162b2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	82	100	376	197
Units: Fold rise				
geometric mean (confidence interval 95%)	6.1 (4.5 to 8.3)	5.2 (4.1 to 6.5)	12.1 (10.4 to 14.0)	5.7 (4.8 to 6.8)

Statistical analyses

No statistical analyses for this end point

Primary: GMFR of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

End point title	GMFR of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044[15][16]

End point description:

GMFR and 2-sided 95% CI were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From before vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Historical Control: 12-17 years
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	26	167	186	15
Units: Fold rise				
geometric mean (confidence interval 95%)	3.5 (2.2 to 5.8)	4.3 (3.7 to 5.0)	5.1 (4.3 to 6.2)	5.7 (3.4 to 9.4)

End point values	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSA Historical Control: All Age Groups	SSA Total Historical Control: C4591044 BNT162b2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	85	100	379	200
Units: Fold rise				
geometric mean (confidence interval 95%)	6.2 (4.6 to 8.4)	7.4 (5.7 to 9.6)	4.6 (4.1 to 5.2)	6.8 (5.6 to 8.1)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Seroresponse to SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

End point title	Percentage of Participants With Seroresponse to SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044[17][18]

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination assay result of >= 4* LLOQ was considered a seroresponse. Exact 2-sided CI was based on the Clopper and Pearson method. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Historical Control: 12-17 years
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	27	165	184	15
Units: Percentage of Participants				
number (confidence interval 95%)	74.1 (53.7 to 88.9)	76.4 (69.1 to 82.6)	71.7 (64.6 to 78.1)	66.7 (38.4 to 88.2)

End point values	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSA Historical Control: All Age Groups	SSA Total Historical Control: C4591044 BNT162b2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	82	100	376	197
Units: Percentage of Participants				
number (confidence interval 95%)	52.4 (41.1 to 63.6)	51.0 (40.8 to 61.1)	73.9 (69.2 to 78.3)	52.8 (45.6 to 59.9)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Seroresponse to SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

End point title	Percentage of Participants With Seroresponse to SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044[19][20]

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination assay result of >= 4* LLOQ was considered a seroresponse. Exact 2-sided CI was based on the Clopper and Pearson method. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years	SSA Historical Control: 12-17 years
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	26	167	186	15
Units: Percentage of participants				
number (confidence interval 95%)	46.2 (26.6 to 66.6)	43.7 (36.1 to 51.6)	52.7 (45.3 to 60.0)	73.3 (44.9 to 92.2)

End point values	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSA Historical Control: All Age Groups	SSA Total Historical Control: C4591044 BNT162b2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	85	100	379	200
Units: Percentage of participants				
number (confidence interval 95%)	58.8 (47.6 to 69.4)	65.0 (54.8 to 74.3)	48.3 (43.2 to 53.4)	63.0 (55.9 to 69.7)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSB

End point title	Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSB[21][22]

End point description:

Local reactions: pain at injection site, redness and swelling recorded by participants in an e-diary or as AEs in the CRF. Redness & swelling measured & recorded in mdu (range:1 to 21), 1 mdu= 0.5 cm & were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) & Grade 4 (necrosis [swelling] & necrosis or exfoliative dermatitis [redness]). Pain at injection site graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) & G4 (ER visit or hospitalisation for severe pain at injection site). G4 LR classified by investigator or medically qualified person. Exact 2-sided CI based on Clopper and Pearson method. Safety population: all participants who received study intervention. Number of Participants Analysed= Participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSB: Group 3: >55 years	SSB Total Study Participants
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	9	250	49	308
Units: Percentage of Participants				
number (confidence interval 95%)				
Redness: Any	0 (0.0 to 33.6)	8.8 (5.6 to 13.0)	2.0 (0.1 to 10.9)	7.5 (4.8 to 11.0)
Redness: Mild	0 (0.0 to 33.6)	5.6 (3.1 to 9.2)	2.0 (0.1 to 10.9)	4.9 (2.8 to 7.9)
Redness: Moderate	0 (0.0 to 33.6)	2.8 (1.1 to 5.7)	0 (0.0 to 7.3)	2.3 (0.9 to 4.6)
Redness: Severe	0 (0.0 to 33.6)	0.4 (0.0 to 2.2)	0 (0.0 to 7.3)	0.3 (0.0 to 1.8)
Redness: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Swelling: Any	11.1 (0.3 to 48.2)	12.0 (8.2 to 16.7)	10.2 (3.4 to 22.2)	11.7 (8.3 to 15.8)
Swelling: Mild	11.1 (0.3 to 48.2)	6.8 (4.0 to 10.7)	8.2 (2.3 to 19.6)	7.1 (4.5 to 10.6)
Swelling: Moderate	0 (0.0 to 33.6)	5.2 (2.8 to 8.7)	2.0 (0.1 to 10.9)	4.5 (2.5 to 7.5)
Swelling: Severe	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Swelling: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Pain at the injection site: Any	44.4 (13.7 to 78.8)	58.0 (51.6 to 64.2)	36.7 (23.4 to 51.7)	54.2 (48.5 to 59.9)
Pain at the injection site: Mild	44.4 (13.7 to 78.8)	36.4 (30.4 to 42.7)	32.7 (19.9 to 47.5)	36.0 (30.7 to 41.7)
Pain at the injection site: Moderate	0 (0.0 to 33.6)	21.2 (16.3 to 26.8)	4.1 (0.5 to 14.0)	17.9 (13.7 to 22.6)
Pain at the injection site: Severe	0 (0.0 to 33.6)	0.4 (0.0 to 2.2)	0 (0.0 to 7.3)	0.3 (0.0 to 1.8)
Pain at the injection site: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSB

End point title	Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSB[23][24]

End point description:

Systemic events were recorded by participants in an e-diary or as AEs in the CRF. Fever: defined as oral temperature >=38 deg C and categorised as >= 38.0-38.4 deg C, >38.4-38.9 deg C, >38.9-40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and joint pain: mild (didn't interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24h, moderate: >2 times in 24h, severe: required IV hydration. Diarrhoea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6 or more loose stools in 24h. Grade 4 for all events except fever: ER visit/hospitalization. Grade 4 events were

classified by investigator or medically qualified person. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: All participants who received the study intervention. Number of Participants Analysed= Participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSB: Group 3: >55 years	SSB Total Study Participants
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	9	250	49	308
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any	11.1 (0.3 to 48.2)	2.4 (0.9 to 5.2)	6.1 (1.3 to 16.9)	3.2 (1.6 to 5.9)
Fever: >=38.0 degree C to 38.4 degree C	0 (0.0 to 33.6)	0.8 (0.1 to 2.9)	4.1 (0.5 to 14.0)	1.3 (0.4 to 3.3)
Fever: >38.4 degree C to 38.9 degree C	11.1 (0.3 to 48.2)	1.2 (0.2 to 3.5)	0 (0.0 to 7.3)	1.3 (0.4 to 3.3)
Fever: >38.9 degree C to 40.0 degree C	0 (0.0 to 33.6)	0.4 (0.0 to 2.2)	2.0 (0.1 to 10.9)	0.6 (0.1 to 2.3)
Fever: >40.0 degree C	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Fatigue: Any	11.1 (0.3 to 48.2)	34.8 (28.9 to 41.1)	24.5 (13.3 to 38.9)	32.5 (27.3 to 38.0)
Fatigue: Mild	0 (0.0 to 33.6)	13.6 (9.6 to 18.5)	8.2 (2.3 to 19.6)	12.3 (8.9 to 16.5)
Fatigue: Moderate	11.1 (0.3 to 48.2)	21.2 (16.3 to 26.8)	16.3 (7.3 to 29.7)	20.1 (15.8 to 25.0)
Fatigue: Severe	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Fatigue: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Headache: Any	11.1 (0.3 to 48.2)	30.8 (25.1 to 36.9)	16.3 (7.3 to 29.7)	27.9 (23.0 to 33.3)
Headache: Mild	11.1 (0.3 to 48.2)	12.0 (8.2 to 16.7)	12.2 (4.6 to 24.8)	12.0 (8.6 to 16.2)
Headache: Moderate	0 (0.0 to 33.6)	18.0 (13.4 to 23.3)	4.1 (0.5 to 14.0)	15.3 (11.4 to 19.8)
Headache: Severe	0 (0.0 to 33.6)	0.8 (0.1 to 2.9)	0 (0.0 to 7.3)	0.6 (0.1 to 2.3)
Headache: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Chills: Any	11.1 (0.3 to 48.2)	12.0 (8.2 to 16.7)	10.2 (3.4 to 22.2)	11.7 (8.3 to 15.8)
Chills: Mild	11.1 (0.3 to 48.2)	7.2 (4.3 to 11.1)	4.1 (0.5 to 14.0)	6.8 (4.3 to 10.2)
Chills: Moderate	0 (0.0 to 33.6)	4.8 (2.5 to 8.2)	6.1 (1.3 to 16.9)	4.9 (2.8 to 7.9)
Chills: Severe	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Chills: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Vomiting: Any	0 (0.0 to 33.6)	4.8 (2.5 to 8.2)	2.0 (0.1 to 10.9)	4.2 (2.3 to 7.1)
Vomiting: Mild	0 (0.0 to 33.6)	2.4 (0.9 to 5.2)	2.0 (0.1 to 10.9)	2.3 (0.9 to 4.6)

Vomiting: Moderate	0 (0.0 to 33.6)	2.4 (0.9 to 5.2)	0 (0.0 to 7.3)	1.9 (0.7 to 4.2)
Vomiting: Severe	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Vomiting: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
Diarrhoea: Any	11.1 (0.3 to 48.2)	16.8 (12.4 to 22.0)	8.2 (2.3 to 19.6)	15.3 (11.4 to 19.8)
Diarrhoea: Mild	11.1 (0.3 to 48.2)	10.0 (6.6 to 14.4)	6.1 (1.3 to 16.9)	9.4 (6.4 to 13.2)
Diarrhoea: Moderate	0 (0.0 to 33.6)	6.4 (3.7 to 10.2)	2.0 (0.1 to 10.9)	5.5 (3.2 to 8.7)
Diarrhoea: Severe	0 (0.0 to 33.6)	0.4 (0.0 to 2.2)	0 (0.0 to 7.3)	0.3 (0.0 to 1.8)
Diarrhoea: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
New or worsened muscle pain: Any	11.1 (0.3 to 48.2)	18.0 (13.4 to 23.3)	18.4 (8.8 to 32.0)	17.9 (13.7 to 22.6)
New or worsened muscle pain: Mild	11.1 (0.3 to 48.2)	8.0 (5.0 to 12.1)	10.2 (3.4 to 22.2)	8.4 (5.6 to 12.1)
New or worsened muscle pain: Moderate	0 (0.0 to 33.6)	10.0 (6.6 to 14.4)	8.2 (2.3 to 19.6)	9.4 (6.4 to 13.2)
New or worsened muscle pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
New or worsened muscle pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
New or worsened joint pain: Any	11.1 (0.3 to 48.2)	12.8 (8.9 to 17.6)	12.2 (4.6 to 24.8)	12.7 (9.2 to 16.9)
New or worsened joint pain: Mild	11.1 (0.3 to 48.2)	6.4 (3.7 to 10.2)	6.1 (1.3 to 16.9)	6.5 (4.0 to 9.9)
New or worsened joint pain: Moderate	0 (0.0 to 33.6)	6.4 (3.7 to 10.2)	6.1 (1.3 to 16.9)	6.2 (3.8 to 9.5)
New or worsened joint pain: Severe	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)
New or worsened joint pain: Grade 4	0 (0.0 to 33.6)	0 (0.0 to 1.5)	0 (0.0 to 7.3)	0 (0.0 to 1.2)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSB

End point title	Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSB[25][26]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs from study vaccination on Day 1 up to 1 month after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received the study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSB: Group 3: >55 years	SSB Total Study Participants
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	9	253	49	311
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 33.6)	2.4 (0.9 to 5.1)	2.0 (0.1 to 10.9)	2.3 (0.9 to 4.6)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSB

End point title	Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSB[27][28]

End point description:

An SAE was defined as any untoward medical occurrence at any dose that resulted in any of the following outcomes: death; life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; or considered as an important medical event. Percentage of participants reporting SAEs from study vaccination on Day 1 up to 6 months after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Safety population included all participants who received the study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 6 months after vaccination

Notes:

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

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSB: Group 3: >55 years	SSB Total Study Participants
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	9	253	49	311
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 33.6)	0.8 (0.1 to 2.8)	2.0 (0.1 to 10.9)	1.0 (0.2 to 2.8)

Statistical analyses

No statistical analyses for this end point

Primary: Difference in Percentages of Participants With Seroresponse to the XBB.1.5

Strain 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA

End point title	Difference in Percentages of Participants With Seroresponse to the XBB.1.5 Strain 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA

End point description:

Seroresponse was defined as achieving >= 4-fold rise from baseline. If the baseline measurement was below the LLOQ, the postvaccination assay result of >= 4* LLOQ was considered a seroresponse. Percentage of participants with seroresponse is reported in descriptive section and percentage difference in statistical analysis section. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

At 1 month after vaccination

End point values	SSB: Vaccine-Naïve Substudy B	SSB Control: Vaccine-Experienced Substudy A		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	298	295		
Units: Percentage of participants				
number (confidence interval 95%)	84.9 (80.3 to 88.8)	73.9 (68.5 to 78.8)		

Statistical analyses

Statistical analysis title	Vaccine-Naïve SSB vs Vaccine-Experienced SSA

Statistical analysis description:

2-Sided CI, based on the Miettinen and Nurminen method stratified by baseline neutralizing titer category (< median, >= median) and age group (< median, >= median). Noninferiority based on seroresponse was declared if the lower limit of the 2-sided 95% CI for the difference in percentages was greater than -10%.

Comparison groups	SSB: Vaccine-Naïve Substudy B v SSB Control: Vaccine-Experienced Substudy A
Number of subjects included in analysis	593
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Percentage Difference
Point estimate	7.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.34
upper limit	13.28

Primary: Geometric Mean Ratio (GMR) of the SARS-CoV-2 XBB.1.5-Neutralizing Titers 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA

End point title	Geometric Mean Ratio (GMR) of the SARS-CoV-2 XBB.1.5-Neutralizing Titers 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the least square (LS) means and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline assay results (log scale), age and vaccine group as covariates. Assay results below the LLOQ were set to 0.5*LLOQ. GMT is reported in descriptive section and GMR in statistical analysis section. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

At 1 month after vaccination

End point values	SSB: Vaccine-Naïve Substudy B	SSB Control: Vaccine-Experienced Substudy A		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	298	295		
Units: Titer				
geometric mean (confidence interval 95%)	4951.6 (4222.8 to 5806.2)	2566.5 (2186.8 to 3012.1)		

Statistical analyses

Statistical analysis title	Vaccine-Naïve SSB vs Vaccine-Experienced SSA

Statistical analysis description:

GMRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the difference in LS means (Substudy B - Substudy A) and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline assay results (log scale), age and vaccine group as covariates. Noninferiority of GMR was met if the lower limit of the 95% CI was greater than 0.67.

Comparison groups	SSB: Vaccine-Naïve Substudy B v SSB Control: Vaccine-Experienced Substudy A

Number of subjects included in analysis	593
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Geometric mean ratio
Point estimate	1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.52
upper limit	2.44

Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSC Cohort 1 and Cohort 2 Combined

End point title	Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSC Cohort 1 and Cohort 2 Combined[29][30]

End point description:

Local reactions: pain at injection site, redness and swelling recorded by participants in an e-diary or as AEs in the CRF. Redness & swelling measured & recorded in mdu (range:1 to 21), 1 mdu= 0.5 cm & were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) & Grade 4 (necrosis [swelling] & necrosis or exfoliative dermatitis [redness]). Pain at injection site graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) & G4 (ER visit or hospitalisation for severe pain at injection site). G4 LR classified by investigator or medically qualified person. Exact 2-sided CI based on Clopper and Pearson method. Safety population: all participants who received study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	92	106	216
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: any	11.1 (1.4 to 34.7)	8.7 (3.8 to 16.4)	9.4 (4.6 to 16.7)	9.3 (5.7 to 13.9)
Redness: mild	5.6 (0.1 to 27.3)	1.1 (0.0 to 5.9)	6.6 (2.7 to 13.1)	4.2 (1.9 to 7.8)
Redness: moderate	5.6 (0.1 to 27.3)	6.5 (2.4 to 13.7)	2.8 (0.6 to 8.0)	4.6 (2.2 to 8.3)
Redness: severe	0 (0.0 to 18.5)	1.1 (0.0 to 5.9)	0 (0.0 to 3.4)	0.5 (0.0 to 2.6)
Redness: grade 4	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)
Swelling: any	0 (0.0 to 18.5)	13.0 (6.9 to 21.7)	11.3 (6.0 to 18.9)	11.1 (7.3 to 16.1)

Swelling: mild	0 (0.0 to 18.5)	8.7 (3.8 to 16.4)	4.7 (1.5 to 10.7)	6.0 (3.2 to 10.1)
Swelling: moderate	0 (0.0 to 18.5)	4.3 (1.2 to 10.8)	6.6 (2.7 to 13.1)	5.1 (2.6 to 8.9)
Swelling: severe	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)
Swelling: grade 4	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)
Pain at the injection site: any	88.9 (65.3 to 98.6)	72.8 (62.6 to 81.6)	49.1 (39.2 to 59.0)	62.5 (55.7 to 69.0)
Pain at the injection site: mild	55.6 (30.8 to 78.5)	58.7 (47.9 to 68.9)	42.5 (32.9 to 52.4)	50.5 (43.6 to 57.3)
Pain at the injection site: moderate	27.8 (9.7 to 53.5)	12.0 (6.1 to 20.4)	5.7 (2.1 to 11.9)	10.2 (6.5 to 15.0)
Pain at the injection site: severe	5.6 (0.1 to 27.3)	2.2 (0.3 to 7.6)	0.9 (0.0 to 5.1)	1.9 (0.5 to 4.7)
Pain at the injection site: grade 4	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSC Cohort 1 and Cohort 2 Combined

End point title	Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSC Cohort 1 and Cohort 2 Combined[31][32]

End point description:

Systemic events were recorded by participants in an e-diary or as AEs in the CRF. Fever: defined as oral temperature >=38 deg C and categorised as >= 38.0-38.4 deg C, >38.4-38.9 deg C, >38.9-40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and joint pain: mild (didn't interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24h, moderate: >2 times in 24h, severe: required IV hydration. Diarrhoea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6 or more loose stools in 24h. Grade 4 for all events except fever: ER visit/hospitalization. Grade 4 events were classified by investigator or medically qualified person. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: All participants who received the study intervention. Here "n" signifies participants evaluable at specific event.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	92	106	216
Units: Percentage of participants				
number (confidence interval 95%)				

Fever: any(n=18, 92, 104, 214)	11.1 (1.4 to 34.7)	4.3 (1.2 to 10.8)	1.9 (0.2 to 6.8)	3.7 (1.6 to 7.2)
Fever:>=38.0deg C to38.4deg C(n=18, 92, 104, 214)	5.6 (0.1 to 27.3)	2.2 (0.3 to 7.6)	1.0 (0.0 to 5.2)	1.9 (0.5 to 4.7)
Fever:>38.4 degC to 38.9 deg C(n=18, 92, 104,214)	5.6 (0.1 to 27.3)	2.2 (0.3 to 7.6)	0 (0.0 to 3.5)	1.4 (0.3 to 4.0)
Fever: >38.9 degC to40.0 degC(n=18, 92, 104, 214)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	1.0 (0.0 to 5.2)	0.5 (0.0 to 2.6)
Fever: >40.0 degree C(n=18, 92, 104, 214)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.5)	0 (0.0 to 1.7)
Fatigue: any (n=18,92,106,216)	55.6 (30.8 to 78.5)	47.8 (37.3 to 58.5)	29.2 (20.8 to 38.9)	39.4 (32.8 to 46.2)
Fatigue: mild(n=18,92,106,216)	11.1 (1.4 to 34.7)	22.8 (14.7 to 32.8)	17.0 (10.4 to 25.5)	19.0 (14.0 to 24.9)
Fatigue: moderate (n=18,92,106,216)	38.9 (17.3 to 64.3)	25.0 (16.6 to 35.1)	11.3 (6.0 to 18.9)	19.4 (14.4 to 25.4)
Fatigue: severe (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0.9 (0.0 to 5.1)	0.5 (0.0 to 2.6)
Fatigue: grade 4 (n=18,92,106,216)	5.6 (0.1 to 27.3)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0.5 (0.0 to 2.6)
Headache: any (n=18,92,106,216)	61.1 (35.7 to 82.7)	35.9 (26.1 to 46.5)	17.9 (11.2 to 26.6)	29.2 (23.2 to 35.7)
Headache: mild (n=18,92,106,216)	44.4 (21.5 to 69.2)	21.7 (13.8 to 31.6)	13.2 (7.4 to 21.2)	19.4 (14.4 to 25.4)
Headache: moderate (n=18,92,106,216)	11.1 (1.4 to 34.7)	13.0 (6.9 to 21.7)	3.8 (1.0 to 9.4)	8.3 (5.0 to 12.9)
Headache: severe (n=18,92,106,216)	0 (0.0 to 18.5)	1.1 (0.0 to 5.9)	0.9 (0.0 to 5.1)	0.9 (0.1 to 3.3)
Headache: grade 4 (n=18,92,106,216)	5.6 (0.1 to 27.3)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0.5 (0.0 to 2.6)
Chills: any (n=18,92,106,216)	44.4 (21.5 to 69.2)	17.4 (10.3 to 26.7)	8.5 (4.0 to 15.5)	15.3 (10.8 to 20.8)
Chills: mild (n=18,92,106,216)	27.8 (9.7 to 53.5)	10.9 (5.3 to 19.1)	4.7 (1.5 to 10.7)	9.3 (5.7 to 13.9)
Chills: moderate (n=18,92,106,216)	11.1 (1.4 to 34.7)	6.5 (2.4 to 13.7)	2.8 (0.6 to 8.0)	5.1 (2.6 to 8.9)
Chills: severe (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0.9 (0.0 to 5.1)	0.5 (0.0 to 2.6)
Chills: grade 4 (n=18,92,106,216)	5.6 (0.1 to 27.3)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0.5 (0.0 to 2.6)
Vomiting: any (n=18,92,106,216)	11.1 (1.4 to 34.7)	2.2 (0.3 to 7.6)	0.9 (0.0 to 5.1)	2.3 (0.3 to 5.3)
Vomiting: mild (n=18,92,106,216)	5.6 (0.1 to 27.3)	2.2 (0.3 to 7.6)	0 (0.0 to 3.4)	1.4 (0.3 to 4.0)
Vomiting: moderate (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0.9 (0.0 to 5.1)	0.5 (0.0 to 2.6)
Vomiting: severe (n=18,92,106,216)	5.6 (0.1 to 27.3)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0.5 (0.0 to 2.6)
Vomiting: grade 4 (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)
Diarrhoea: any (n=18,92,106,216)	0 (0.0 to 18.5)	9.8 (4.6 to 17.8)	7.5 (3.3 to 14.3)	7.9 (4.7 to 12.3)
Diarrhoea: mild (n=18,92,106,216)	0 (0.0 to 18.5)	6.5 (2.4 to 13.7)	6.6 (2.7 to 13.1)	6.0 (3.2 to 10.1)
Diarrhoea: moderate (n=18,92,106,216)	0 (0.0 to 18.5)	3.3 (0.7 to 9.2)	0.9 (0.0 to 5.1)	1.9 (0.5 to 4.7)
Diarrhoea: severe (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)
Diarrhoea: grade 4 (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)
New/worsened muscle pain: any (n=18,92,106,216)	33.3 (13.3 to 59.0)	17.4 (10.3 to 26.7)	10.4 (5.3 to 17.8)	15.3 (10.8 to 20.8)
New/worsened muscle pain:mild (n=18,92,106,216)	16.7 (3.6 to 41.4)	8.7 (3.8 to 16.4)	5.7 (2.1 to 11.9)	7.9 (4.7 to 12.3)
New/worsened muscle pain:moderate(n=18,92,106,216	11.1 (1.4 to 34.7)	8.7 (3.8 to 16.4)	4.7 (1.5 to 10.7)	6.9 (3.9 to 11.2)
New/worsened muscle pain:severe(n=18,92,106,216	5.6 (0.1 to 27.3)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0.5 (0.0 to 2.6)

New or worsened muscle pain: g4 (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)
New or worsened joint pain: any (n=18,92,106,216)	11.1 (1.4 to 34.7)	8.7 (3.8 to 16.4)	7.5 (3.3 to 14.3)	8.3 (5.0 to 12.9)
New or worsened joint pain:mild (n=18,92,106,216)	5.6 (0.1 to 27.3)	6.5 (2.4 to 13.7)	3.8 (1.0 to 9.4)	5.1 (2.6 to 8.9)
New/worsened joint pain:moderate(n=18,92,106,216)	0 (0.0 to 18.5)	2.2 (0.3 to 7.6)	3.8 (1.0 to 9.4)	2.8 (1.0 to 5.9)
New/worsened joint pain: severe (n=18,92,106,216)	5.6 (0.1 to 27.3)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0.5 (0.0 to 2.6)
New or worsened joint pain: g4 (n=18,92,106,216)	0 (0.0 to 18.5)	0 (0.0 to 3.9)	0 (0.0 to 3.4)	0 (0.0 to 1.7)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSC Cohort 1 and Cohort 2 Combined

End point title	Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSC Cohort 1 and Cohort 2 Combined[33][34]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with use of study intervention, whether or not considered related to study intervention. Percentage of participants reporting AEs from study vaccination on Day 1 up to 1 month after the study vaccination were reported in this outcome measure. Exact 2-sided CI was based on Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this outcome measure. Safety population: All participants who received the study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	92	106	216
Units: Percentage of participants				
number (confidence interval 95%)	5.6 (0.1 to 27.3)	3.3 (0.7 to 9.2)	8.5 (4.0 to 15.5)	6.0 (3.2 to 10.1)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSC Cohort 3

End point title	Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSC Cohort 3[35][36]

End point description:

Local reactions: pain at injection site, redness and swelling recorded by participants in an e-diary or as AEs in the CRF. Redness & swelling measured & recorded in mdu (range:1 to 21), 1 mdu= 0.5 cm & were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) & Grade 4 (necrosis [swelling] & necrosis or exfoliative dermatitis [redness]). Pain at injection site graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) & G4 (ER visit or hospitalisation for severe pain at injection site). G4 LR classified by investigator or medically qualified person. Exact 2-sided CI based on Clopper and Pearson method. Safety population: all participants who received study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years	SSC: Cohort 3 Combined: All Age Groups	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	51	51	102	
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: any	5.9 (1.2 to 16.2)	2.0 (0.0 to 10.4)	3.9 (1.1 to 9.7)	
Redness: mild	2.0 (0.0 to 10.4)	2.0 (0.0 to 10.4)	2.0 (0.2 to 6.9)	
Redness: moderate	3.9 (0.5 to 13.5)	0 (0.0 to 7.0)	2.0 (0.2 to 6.9)	
Redness: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Redness: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Swelling: any	9.8 (3.3 to 21.4)	3.9 (0.5 to 13.5)	6.9 (2.8 to 13.6)	
Swelling: mild	3.9 (0.5 to 13.5)	3.9 (0.5 to 13.5)	3.9 (1.1 to 9.7)	
Swelling: moderate	5.9 (1.2 to 16.2)	0 (0.0 to 7.0)	2.9 (0.6 to 8.4)	
Swelling: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Swelling: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Pain at the injection site: any	72.5 (58.3 to 84.1)	45.1 (31.1 to 59.7)	58.8 (48.6 to 68.5)	
Pain at the injection site: mild	60.8 (46.1 to 74.2)	39.2 (25.8 to 53.9)	50.0 (39.9 to 60.1)	
Pain at the injection site: moderate	11.8 (4.4 to 23.9)	5.9 (1.2 to 16.2)	8.8 (4.1 to 16.1)	
Pain at the injection site: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Pain at the injection site: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSC Cohort 1 and Cohort 2 Combined

End point title	Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSC Cohort 1 and Cohort 2 Combined[37][38]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An SAE was defined as any untoward medical occurrence at any dose that resulted in any of the following outcomes: death; life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; or considered as an important medical event. Percentage of participants reporting SAEs from study vaccination on Day 1 up to 6 months after the study vaccination were reported in this outcome measure. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: all participants who received study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 6 months after vaccination

Notes:

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

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	92	106	216
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 18.5)	1.1 (0.0 to 5.9)	2.8 (0.6 to 8.0)	1.9 (0.5 to 4.7)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSC Cohort 3

End point title	Percentage of Participants With Systemic Events Within 7 Days

	After Vaccination: SSC Cohort 3[39][40]

End point description:

Systemic events were recorded by participants in an e-diary or as AEs in the CRF. Fever: defined as oral temperature >=38 deg C and categorised as >= 38.0-38.4 deg C, >38.4-38.9 deg C, >38.9-40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and joint pain: mild (didn't interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24h, moderate: >2 times in 24h, severe: required IV hydration. Diarrhoea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6 or more loose stools in 24h. Grade 4 for all events except fever: ER visit/hospitalization. Grade 4 events were classified by investigator or medically qualified person. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: All participants who received the study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

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

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years	SSC: Cohort 3 Combined: All Age Groups	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	51	51	102	
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: any	3.9 (0.5 to 13.5)	3.9 (0.5 to 13.5)	3.9 (1.1 to 9.7)	
Fever: >=38.0 degree C to 38.4 degree C	3.9 (0.5 to 13.5)	2.0 (0.0 to 10.4)	2.9 (0.6 to 8.4)	
Fever: >38.4 degree C to 38.9 degree C	0 (0.0 to 7.0)	2.0 (0.0 to 10.4)	1.0 (0.0 to 5.3)	
Fever: >38.9 degree C to 40.0 degree C	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Fever: >40.0 degree C	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Fatigue: any	58.8 (44.2 to 72.4)	33.3 (20.8 to 47.9)	46.1 (36.2 to 56.2)	
Fatigue: mild	33.3 (20.8 to 47.9)	19.6 (9.8 to 33.1)	26.5 (18.2 to 36.1)	
Fatigue: moderate	25.5 (14.3 to 39.6)	13.7 (5.7 to 26.3)	19.6 (12.4 to 28.6)	
Fatigue: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Fatigue: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Headache: any	39.2 (25.8 to 53.9)	17.6 (8.4 to 30.9)	28.4 (19.9 to 38.2)	
Headache: mild	27.5 (15.9 to 41.7)	11.8 (4.4 to 23.9)	19.6 (12.4 to 28.6)	
Headache: moderate	11.8 (4.4 to 23.9)	5.9 (1.2 to 16.2)	8.8 (4.1 to 16.1)	
Headache: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Headache: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Chills: any	7.8 (2.2 to 18.9)	9.8 (3.3 to 21.4)	8.8 (4.1 to 16.1)	
Chills: mild	3.9 (0.5 to 13.5)	9.8 (3.3 to 21.4)	6.9 (2.8 to 13.6)	

Chills: moderate	3.9 (0.5 to 13.5)	0 (0.0 to 7.0)	2.0 (0.2 to 6.9)	
Chills: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Chills: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Vomiting: any	2.0 (0.0 to 10.4)	3.9 (0.5 to 13.5)	2.9 (0.6 to 8.4)	
Vomiting: mild	2.0 (0.0 to 10.4)	2.0 (0.0 to 10.4)	2.0 (0.2 to 6.9)	
Vomiting: moderate	0 (0.0 to 7.0)	2.0 (0.0 to 10.4)	1.0 (0.0 to 5.3)	
Vomiting: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Vomiting: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Diarrhoea: any	11.8 (4.4 to 23.9)	7.8 (2.2 to 18.9)	9.8 (4.8 to 17.3)	
Diarrhoea: mild	7.8 (2.2 to 18.9)	7.8 (2.2 to 18.9)	7.8 (3.4 to 14.9)	
Diarrhoea: moderate	3.9 (0.5 to 13.5)	0 (0.0 to 7.0)	2.0 (0.2 to 6.9)	
Diarrhoea: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
Diarrhoea: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
New or worsened muscle pain: any	33.3 (20.8 to 47.9)	9.8 (3.3 to 21.4)	21.6 (14.0 to 30.8)	
New or worsened muscle pain: mild	17.6 (8.4 to 30.9)	7.8 (2.2 to 18.9)	12.7 (7.0 to 20.8)	
New or worsened muscle pain: moderate	15.7 (7.0 to 28.6)	2.0 (0.0 to 10.4)	8.8 (4.1 to 16.1)	
New or worsened muscle pain: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
New or worsened muscle pain: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
New or worsened joint pain: any	13.7 (5.7 to 26.3)	3.9 (0.5 to 13.5)	8.8 (4.1 to 16.1)	
New or worsened joint pain: mild	11.8 (4.4 to 23.9)	2.0 (0.0 to 10.4)	6.9 (2.8 to 13.6)	
New or worsened joint pain: moderate	2.0 (0.0 to 10.4)	2.0 (0.0 to 10.4)	2.0 (0.2 to 6.9)	
New or worsened joint pain: severe	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	
New or worsened joint pain: grade 4	0 (0.0 to 7.0)	0 (0.0 to 7.0)	0 (0.0 to 3.6)	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSC Cohort 3

End point title	Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSC Cohort 3[41][42]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with use of study intervention, whether or not considered related to study intervention. Percentage of participants reporting AEs from study vaccination on Day 1 up to 1 month after the study vaccination were reported in this outcome measure. Exact 2-sided CI was based on Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this outcome measure. Safety population: All participants who received the study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years	SSC: Cohort 3 Combined: All Age Groups	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	51	51	102	
Units: Percentage of participants				
number (confidence interval 95%)	13.7 (5.7 to 26.3)	5.9 (1.2 to 16.2)	9.8 (4.8 to 17.3)	

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARS-CoV-2 Omi JN.1 and XBB.1.5 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohorts 1 + 2 Combined and Historical Control Group From SSA Respectively

End point title	GMTs of SARS-CoV-2 Omi JN.1 and XBB.1.5 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohorts 1 + 2 Combined and Historical Control Group From SSA Respectively[43][44]

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, "n" signifies participants evaluable at specific variant.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSA Total Study Participants: C4591054
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	91	103	200
Units: Titers				
geometric mean (confidence interval 95%)				
Omicron JN.1(n=18,91,103,212,17,84,98,199)	3920.4 (2296.3 to 6693.2)	1895.8 (1456.8 to 2467.0)	2275.2 (1771.0 to 2923.1)	1133.8 (950.7 to 1352.2)
Omicron XBB.1.5(n=18,91,103,212,17,85,98,200)	5893.1 (3472.2 to 10002.0)	1926.7 (1361.8 to 2725.9)	2415.2 (1815.5 to 3213.1)	2848.1 (2341.9 to 3463.8)

End point values	SSA Historical Control: 12-17 years	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	85	98	212
Units: Titers				
geometric mean (confidence interval 95%)				
Omicron JN.1(n=18,91,103,212,17,84,98,199)	1979.1 (928.5 to 4218.1)	1060.1 (841.8 to 1335.1)	1090.4 (829.7 to 1433.1)	2203.3 (1855.7 to 2616.0)
Omicron XBB.1.5(n=18,91,103,212,17,85,98,200)	5744.9 (3040.8 to 10853.8)	2566.8 (1963.2 to 3355.9)	2759.8 (2028.9 to 3753.9)	2364.4 (1917.4 to 2915.6)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSC Cohort 3

End point title	Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSC Cohort 3[45][46]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An SAE was defined as any untoward medical occurrence at any dose that resulted in any of the following outcomes: death; life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; or considered as an important medical event. Percentage of participants reporting SAEs from study vaccination on Day 1 up to 6 months after the study vaccination were reported in this outcome measure. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: all participants who received study intervention.

End point type	Primary

End point timeframe:

From vaccination on Day 1 up to 6 months after vaccination

Notes:

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

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years	SSC: Cohort 3 Combined: All Age Groups	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	51	51	102	
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 7.0)	2.0 (0.0 to 10.4)	1.0 (0.0 to 5.3)	

Statistical analyses

No statistical analyses for this end point

Primary: GMFR of SARS-CoV-2 Omi JN.1 and XBB.1.5 Variant-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination in SSC Cohorts 1 + 2 Combined and Historical Control Group From SSA Respectively

End point title	GMFR of SARS-CoV-2 Omi JN.1 and XBB.1.5 Variant-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination in SSC Cohorts 1 + 2 Combined and Historical Control Group From SSA Respectively[47][48]

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, "n" signifies participants evaluable for specific variant.

End point type	Primary

End point timeframe:

From before vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSA Total Study Participants: C4591054
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	91	103	200
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron JN.1 (n=17,91,103,211,17,83,97,197)	15.5 (5.8 to 41.5)	11.2 (8.3 to 15.0)	11.4 (8.4 to 15.4)	7.2 (6.0 to 8.7)
Omicron XBB.1.5 (n=18,91,103,212,17,85,98,200)	15.9 (6.3 to 40.1)	7.0 (5.0 to 9.8)	8.3 (6.0 to 11.4)	13.0 (10.9 to 15.5)

End point values	SSA Historical Control: 12-17 years	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	85	98	212
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron JN.1 (n=17,91,103,211,17,83,97,197)	3.9 (2.5 to 6.1)	5.8 (4.5 to 7.6)	9.6 (7.2 to 12.9)	11.6 (9.4 to 14.2)
Omicron XBB.1.5 (n=18,91,103,212,17,85,98,200)	10.2 (6.2 to 16.8)	12.3 (9.4 to 16.1)	14.2 (11.0 to 18.4)	8.1 (6.5 to 10.2)

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Seroresponse to SARS-CoV-2 OMI JN.1 and XBB.1.5 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohorts 1 + 2 Combined and Historical Control Group From SSA Respectively

End point title	Percentage of Participants With Seroresponse to SARS-CoV-2 OMI JN.1 and XBB.1.5 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohorts 1 + 2 Combined and Historical Control Group From SSA Respectively[49][50]

End point description:

Seroresponse was defined as achieving a >=4-fold rise from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, a postvaccination assay result >=4 *LLOQ is considered a seroresponse. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, "n" signifies participants evaluable for specific variant.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSA Total Study Participants: C4591054
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	91	103	200
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron JN.1 (n=17,91,103,211,17,83,97,197)	70.6 (44.0 to 89.7)	73.6 (63.3 to 82.3)	68.0 (58.0 to 76.8)	65.5 (58.4 to 72.1)
Omicron XBB.1.5 (n=18,91,103,212,17,85,98,200)	66.7 (41.0 to 86.7)	58.2 (47.4 to 68.5)	61.2 (51.1 to 70.6)	82.0 (76.0 to 87.1)

End point values	SSA Historical Control: 12-17 years	SSA Historical Control: 18-55 years	SSA Historical Control: >55 years	SSC: Cohort 1 and Cohort 2 Combined: All Age Groups
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	85	98	212
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron JN.1 (n=17,91,103,211,17,83,97,197)	47.1 (23.0 to 72.2)	63.9 (52.6 to 74.1)	70.1 (60.0 to 79.0)	70.6 (64.0 to 76.7)
Omicron XBB.1.5 (n=18,91,103,212,17,85,98,200)	82.4 (56.6 to 96.2)	82.4 (72.6 to 89.8)	81.6 (72.5 to 88.7)	60.4 (53.5 to 67.0)

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of SARS-CoV-2 Omi KP.2 and Omi JN.1 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohort 3 and Cohorts 1 + 2 Combined

End point title	GMTs of SARS-CoV-2 Omi KP.2 and Omi JN.1 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohort 3 and Cohorts 1 + 2 Combined[51][52]

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. SSC combined cohorts 1 and 2 acted as control for this outcome measure.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	103	50	50
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron KP.2	890.4 (648.6 to 1222.2)	858.5 (641.5 to 1148.8)	2037.8 (1326.3 to 3130.9)	2498.8 (1590.4 to 3926.0)
Omicron JN.1	1895.8 (1456.8 to 2467.0)	2275.2 (1771.0 to 2923.1)	3738.8 (2566.9 to 5445.6)	4990.5 (3309.3 to 7525.7)

End point values	SSC: Cohort 3 Combined: All Age Groups	SSC Cohort 1 and Cohort 2 Combined BNT162b2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	100	194		
Units: Titer				
geometric mean (confidence interval 95%)				
Omicron KP.2	2256.5 (1660.2 to 3067.0)	873.3 (706.1 to 1080.2)		
Omicron JN.1	4319.5 (3280.7 to 5687.2)	2088.6 (1743.9 to 2501.5)		

Statistical analyses

No statistical analyses for this end point

Primary: GMFR of SARS-CoV-2 Omi KP.2 and Omi JN.1 Variant-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination in SSC Cohort 3 and Cohorts 1 + 2 Combined

End point title	GMFR of SARS-CoV-2 Omi KP.2 and Omi JN.1 Variant-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination in SSC Cohort 3 and Cohorts 1 + 2 Combined[53][54]

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician . SSC combined cohorts 1 and 2 acted as control for this outcome measure.

End point type	Primary

End point timeframe:

From before vaccination on Day 1 up to 1 month after vaccination

Notes:

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

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	103	50	50
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron KP.2 (n=49,50,91,103,99,194)	11.4 (8.5 to 15.4)	10.9 (8.1 to 14.7)	8.9 (6.3 to 12.5)	13.4 (8.1 to 22.1)
Omicron JN.1 (n=50,50,91,103,100,194)	11.2 (8.3 to 15.0)	11.4 (8.4 to 15.4)	6.6 (4.7 to 9.2)	11.7 (6.7 to 20.3)

End point values	SSC: Cohort 3 Combined: All Age Groups	SSC Cohort 1 and Cohort 2 Combined BNT162b2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	100	194		
Units: Fold rise				
geometric mean (confidence interval 95%)				
Omicron KP.2 (n=49,50,91,103,99,194)	11.0 (8.1 to 14.8)	11.1 (9.0 to 13.7)		
Omicron JN.1 (n=50,50,91,103,100,194)	8.8 (6.4 to 12.1)	11.3 (9.1 to 13.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Seroresponse to SARS-CoV-2 Omi KP.2 and

Omi JN.1 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohort 3 and Cohorts 1 + 2 Combined

End point title	Percentage of Participants With Seroresponse to SARS-CoV-2 Omi KP.2 and Omi JN.1 Variant-Neutralizing Titers at 1 Month After Vaccination in SSC Cohort 3 and Cohorts 1 + 2 Combined[55][56]

End point description:

Seroresponse was defined as achieving a >=4-fold rise from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, a postvaccination assay result >=4 *LLOQ is considered a seroresponse. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, "n" signifies participants evaluable at specific variant.

End point type	Primary

End point timeframe:

At 1 month after vaccination

Notes:

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

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be analysed only for the specified reporting arms

End point values	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years	SSC: Cohort 3: 18-55 Years	SSC: Cohort 3: > 55 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	103	49	50
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron KP.2 (n=49,50,91,103,99,194)	71.4 (61.0 to 80.4)	63.1 (53.0 to 72.4)	77.6 (63.4 to 88.2)	76.0 (61.8 to 86.9)
Omicron JN.1 (n=50,50,91,103,100,194)	73.6 (63.3 to 82.3)	68.0 (58.0 to 76.8)	64.0 (49.2 to 77.1)	64.0 (49.2 to 77.1)

End point values	SSC: Cohort 3 Combined: All Age Groups	SSC Cohort 1 and Cohort 2 Combined BNT162b2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	99	194		
Units: Percentage of participants				
number (confidence interval 95%)				
Omicron KP.2 (n=49,50,91,103,99,194)	76.8 (67.2 to 84.7)	67.0 (59.9 to 73.6)		
Omicron JN.1 (n=50,50,91,103,100,194)	64.0 (53.8 to 73.4)	70.6 (63.7 to 76.9)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SSA,B&C: Systematic assessment (SA): Local reactions, systemic events: Day 1 to 7 after vaccination(vax); Non-SA: SAEs (including all cause mortality): Day 1 of vax up to 6 months after study vax & Non-SAEs: Day 1 of vax up to 1 month after study vax

Adverse event reporting additional description:

Same event may appear as both AE and SAE but are distinct events. An event may be categorized as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE. Safety population included all participants who received the study intervention.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	SSA: Group 1: 12-17 years

Reporting group description:

Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via intramuscular (IM) route on Day 1 of this study.

Reporting group title	SSA: Group 2: 18-55 years

Reporting group description:

Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSA: Group 3: >55 years

Reporting group description:

Participants aged greater than (>) 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 1: 12-17 years

Reporting group description:

Participants aged 12-17 years who were previously exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSB: Group 2: 18-55 years

Reporting group description:

Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 3: > 55 Years

Reporting group description:

Participants aged >55 years were randomized to receive a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years

Reporting group description:

Participants aged 12-17 years were randomized to receive a single dose of BNT162b2 (Omi JN.1)30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years

Reporting group description:

Participants aged 18-55 years were randomized to receive a single dose of BNT162b2 (Omi JN.1)30 mcg via IM route on Day 1 of this study.

Reporting group title	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years
Reporting group description:	
Participants aged >55 years were randomized to receive a single dose of BNT162b2 (Omi JN.1)30 mcg via IM route on Day 1 of this study.	

Reporting group title	SSC: Cohort 3: 18-55 Years
Reporting group description:	
Participants aged 18-55 years were randomized to receive a single dose of BNT162b2 (Omi KP.2) 30 mcg via IM route on Day 1 of this study.	

Reporting group title	SSB: Group 3: >55 years
Reporting group description:	
Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine–naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this	

Serious adverse events	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	4 / 208 (1.92%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive lobular breast carcinoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	1 / 208 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Subdural haematoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (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
Road traffic accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (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
Cervical vertebral fracture	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (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			
Cardiac arrest	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	1 / 208 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Cerebrovascular accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	1 / 208 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	1 / 208 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paroxysmal nocturnal haemoglobinuria	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	1 / 208 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (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
Viral infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (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
Appendicitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Hyponatraemia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	1 / 208 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (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	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSC: Cohort 3: > 55 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)	2 / 253 (0.79%)	1 / 51 (1.96%)
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)			
Invasive lobular breast carcinoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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			
Subdural haematoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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
Road traffic accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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
Cervical vertebral fracture	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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			
Cardiac arrest	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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
Dyspnoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	1 / 253 (0.40%)	0 / 51 (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
Respiratory failure	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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
Paroxysmal nocturnal haemoglobinuria	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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			
Cellulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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
Viral infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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
Appendicitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	1 / 253 (0.40%)	0 / 51 (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
Metabolism and nutrition disorders			

Hyponatraemia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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
Dehydration	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (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	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)	1 / 92 (1.09%)	3 / 106 (2.83%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive lobular breast carcinoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (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			
Subdural haematoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (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
Dyspnoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Renal and urinary disorders			
Acute kidney injury	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (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
Paroxysmal nocturnal haemoglobinuria	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (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			
Cellulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	1 / 92 (1.09%)	0 / 106 (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
Viral infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Hyponatraemia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (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
Dehydration	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	1 / 106 (0.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SSC: Cohort 3: 18-55 Years	SSB: Group 3: >55 years	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	1 / 49 (2.04%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive lobular breast carcinoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Subdural haematoma	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac arrest	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Small intestinal obstruction	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paroxysmal nocturnal haemoglobinuria	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			

Hyponatraemia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	SSA: Group 1: 12-17 years	SSA: Group 2: 18-55 years	SSA: Group 3: >55 years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 30 (90.00%)	154 / 174 (88.51%)	134 / 208 (64.42%)
Nervous system disorders			
Restless arm syndrome	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	1	0	0
Headache (HEADACHE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	11 / 30 (36.67%)	76 / 174 (43.68%)	54 / 208 (25.96%)
occurrences (all)	11	76	54
Somnolence	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Lymphadenopathy	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	2 / 174 (1.15%)	0 / 208 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Fatigue (FATIGUE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	17 / 30 (56.67%)	99 / 174 (56.90%)	73 / 208 (35.10%)
occurrences (all)	17	99	73
Chills (CHILLS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	6 / 30 (20.00%)	16 / 174 (9.20%)	19 / 208 (9.13%)
occurrences (all)	6	16	19
Axillary pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	2 / 174 (1.15%)	2 / 208 (0.96%)
occurrences (all)	0	2	2
Injection site erythema (REDNESS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	3 / 30 (10.00%)	7 / 174 (4.02%)	12 / 208 (5.77%)
occurrences (all)	3	7	12
Pyrexia (FEVER)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	5 / 30 (16.67%)	7 / 174 (4.02%)	8 / 208 (3.85%)
occurrences (all)	5	7	8
Injection site swelling (SWELLING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	5 / 30 (16.67%)	13 / 174 (7.47%)	12 / 208 (5.77%)
occurrences (all)	5	13	12
Injection site pruritus	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	1	0	0
Injection site pain (PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	24 / 30 (80.00%)	132 / 174 (75.86%)	107 / 208 (51.44%)
occurrences (all)	24	132	107
Injection site pain alternative dictionary used: MedDRA 27.1 alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	4 / 208 (1.92%)
occurrences (all)	0	0	4
Non-cardiac chest pain alternative dictionary used: MedDRA 27.1 alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	2 / 174 (1.15%)	1 / 208 (0.48%)
occurrences (all)	0	2	1
Ear and labyrinth disorders			
Vertigo	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Ear pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Ear disorder	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting (VOMITING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	4 / 174 (2.30%)	0 / 208 (0.00%)
occurrences (all)	0	4	0
Diarrhoea (DIARRHEA)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	21 / 174 (12.07%)	18 / 208 (8.65%)
occurrences (all)	0	21	18
Gastrooesophageal reflux disease	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	0 / 30 (0.00%)	2 / 174 (1.15%)	0 / 208 (0.00%)
occurrences (all)	0	2	0
Diarrhoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	3 / 174 (1.72%)	0 / 208 (0.00%)
occurrences (all)	0	3	0
Abdominal pain upper	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast tenderness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	1	0	0
Heavy menstrual bleeding			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Myalgia (MUSCLE PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	7 / 30 (23.33%)	38 / 174 (21.84%)	25 / 208 (12.02%)
occurrences (all)	7	38	25
Back pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	5 / 30 (16.67%)	25 / 174 (14.37%)	16 / 208 (7.69%)
occurrences (all)	5	25	16
Pain in extremity			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Sialoadenitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Ear infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Sinusitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Pneumonia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 30 (3.33%)	0 / 174 (0.00%)	0 / 208 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	SSB: Group 1: 12-17 years	SSB: Group 2: 18-55 years	SSC: Cohort 3: > 55 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 9 (44.44%)	167 / 253 (66.01%)	35 / 51 (68.63%)

Nervous system disorders			
Restless arm syndrome	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	76 / 253 (30.04%)	9 / 51 (17.65%)
occurrences (all)	1	76	9
Somnolence	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphadenopathy	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	1 / 253 (0.40%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue (FATIGUE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	87 / 253 (34.39%)	17 / 51 (33.33%)
occurrences (all)	1	87	17
Chills (CHILLS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	30 / 253 (11.86%)	5 / 51 (9.80%)
occurrences (all)	1	30	5
Axillary pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Pyrexia (FEVER)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	6 / 253 (2.37%)	2 / 51 (3.92%)
occurrences (all)	1	6	2
Injection site swelling (SWELLING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	30 / 253 (11.86%)	2 / 51 (3.92%)
occurrences (all)	1	30	2
Injection site pruritus	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injection site pain (PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	4 / 9 (44.44%)	142 / 253 (56.13%)	23 / 51 (45.10%)
occurrences (all)	4	142	23
Injection site pain			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	5 / 253 (1.98%)	0 / 51 (0.00%)
occurrences (all)	0	5	0
Non-cardiac chest pain			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			

Vertigo	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Ear pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear disorder	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting (VOMITING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	12 / 253 (4.74%)	2 / 51 (3.92%)
occurrences (all)	0	12	2
Diarrhoea (DIARRHEA)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	42 / 253 (16.60%)	4 / 51 (7.84%)
occurrences (all)	1	42	4
Gastrooesophageal reflux disease	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Diarrhoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast tenderness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia (MUSCLE PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	45 / 253 (17.79%)	5 / 51 (9.80%)
occurrences (all)	1	45	5
Back pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Arthralgia (JOINT PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 9 (11.11%)	32 / 253 (12.65%)	2 / 51 (3.92%)
occurrences (all)	1	32	2
Pain in extremity			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Sialoadenitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sinusitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pneumonia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 9 (0.00%)	0 / 253 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	SSC: Cohort 1 and Cohort 2 Combined: 12-17 Years	SSC: Cohort 1 and Cohort 2 Combined: 18-55 Years	SSC: Cohort 1 and Cohort 2 Combined: > 55 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 18 (88.89%)	77 / 92 (83.70%)	66 / 106 (62.26%)
Nervous system disorders			
Restless arm syndrome	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	11 / 18 (61.11%)	33 / 92 (35.87%)	19 / 106 (17.92%)
occurrences (all)	11	33	19
Somnolence	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	1 / 92 (1.09%)	0 / 106 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue (FATIGUE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	10 / 18 (55.56%)	44 / 92 (47.83%)	31 / 106 (29.25%)
occurrences (all)	10	44	31
Chills (CHILLS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	8 / 18 (44.44%)	16 / 92 (17.39%)	9 / 106 (8.49%)
occurrences (all)	8	16	9
Axillary pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 18 (0.00%)	1 / 92 (1.09%)	0 / 106 (0.00%)
occurrences (all)	0	1	0
Pyrexia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	1 / 92 (1.09%)	0 / 106 (0.00%)
occurrences (all)	0	1	0
Fatigue	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	1 / 92 (1.09%)	0 / 106 (0.00%)
occurrences (all)	0	1	0
Injection site erythema (REDNESS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	2 / 18 (11.11%)	8 / 92 (8.70%)	10 / 106 (9.43%)
occurrences (all)	2	8	10
Pyrexia (FEVER)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	2 / 18 (11.11%)	4 / 92 (4.35%)	2 / 106 (1.89%)
occurrences (all)	2	4	2
Injection site swelling (SWELLING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	12 / 92 (13.04%)	12 / 106 (11.32%)
occurrences (all)	0	12	12
Injection site pruritus	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	1 / 92 (1.09%)	0 / 106 (0.00%)
occurrences (all)	0	1	0
Injection site pain (PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Ear pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Ear disorder	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting (VOMITING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	2 / 18 (11.11%)	2 / 92 (2.17%)	1 / 106 (0.94%)
occurrences (all)	2	2	1
Diarrhoea (DIARRHEA)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	9 / 92 (9.78%)	8 / 106 (7.55%)
occurrences (all)	0	9	8
Gastrooesophageal reflux disease	Additional description: MedDRA version 26.1 was used for SSA and SSB		

	Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Diarrhoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast tenderness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia (MUSCLE PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	6 / 18 (33.33%)	16 / 92 (17.39%)	11 / 106 (10.38%)
occurrences (all)	6	16	11
Back pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	2 / 18 (11.11%)	8 / 92 (8.70%)	8 / 106 (7.55%)
occurrences (all)	2	8	8
Pain in extremity			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Sialoadenitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Ear infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Sinusitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0
Pneumonia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 18 (5.56%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 18 (0.00%)	0 / 92 (0.00%)	0 / 106 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	SSC: Cohort 3: 18-55 Years	SSB: Group 3: >55 years	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 51 (84.31%)	25 / 49 (51.02%)	

Nervous system disorders			
Restless arm syndrome	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Headache (HEADACHE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	20 / 51 (39.22%)	8 / 49 (16.33%)	
occurrences (all)	20	8	
Somnolence	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 51 (1.96%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Dizziness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 51 (1.96%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Headache	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Lymphadenopathy	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Fatigue (FATIGUE)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	30 / 51 (58.82%)	12 / 49 (24.49%)	
occurrences (all)	30	12	
Chills (CHILLS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	4 / 51 (7.84%)	5 / 49 (10.20%)	
occurrences (all)	4	5	
Axillary pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative dictionary used: MedDRA 27.1			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Pyrexia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Fatigue	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Injection site erythema (REDNESS)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	3 / 51 (5.88%)	0 / 49 (0.00%)	
occurrences (all)	3	0	
Pyrexia (FEVER)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	2 / 51 (3.92%)	3 / 49 (6.12%)	
occurrences (all)	2	3	
Injection site swelling (SWELLING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	5 / 51 (9.80%)	5 / 49 (10.20%)	
occurrences (all)	5	5	
Injection site pruritus	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Injection site pain (PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	37 / 51 (72.55%)	18 / 49 (36.73%)	
occurrences (all)	37	18	
Injection site pain			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			

Vertigo	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Ear pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 51 (1.96%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Ear disorder	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 51 (1.96%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Vomiting (VOMITING)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 51 (1.96%)	1 / 49 (2.04%)	
occurrences (all)	1	1	
Diarrhoea (DIARRHEA)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	6 / 51 (11.76%)	4 / 49 (8.16%)	
occurrences (all)	6	4	
Gastrooesophageal reflux disease	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Diarrhoea	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 51 (1.96%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Breast tenderness	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	1 / 51 (1.96%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Dysmenorrhoea			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Heavy menstrual bleeding			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Depression			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Myalgia (MUSCLE PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	17 / 51 (33.33%)	9 / 49 (18.37%)	
occurrences (all)	17	9	
Back pain	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Arthralgia (JOINT PAIN)	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	7 / 51 (13.73%)	6 / 49 (12.24%)	
occurrences (all)	7	6	
Pain in extremity			
alternative dictionary used: MedDRA 27.1			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 51 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Infections and infestations			
Sialoadenitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		

subjects affected / exposed	1 / 51 (1.96%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Ear infection	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	2 / 51 (3.92%)	0 / 49 (0.00%)	
occurrences (all)	2	0	
Sinusitis	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	2 / 51 (3.92%)	0 / 49 (0.00%)	
occurrences (all)	2	0	
Pneumonia	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite	Additional description: MedDRA version 26.1 was used for SSA and SSB Cohorts. MedDRA v27.1 was used for SSC Cohort.		
subjects affected / exposed	0 / 51 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 March 2024	This protocol was amended due to the addition of Substudy C to evaluate the BNT162b2 vaccine targeting the SARS-CoV-2 variant selected for the 2024-2025 respiratory virus season.
06 August 2024	This protocol was amended to add Cohort 3 to Substudy C to evaluate the BNT162b2 (Omi KP.2) vaccine. Cohort 1 was also modified to remove the planned second investigational vaccine, since the evaluation is performed in Cohort 3 instead.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported