



Clinical trial results:

An Open-Label, Phase 3 Study to Evaluate the Safety and Immunogenicity of mRNA Vaccines for SARS-CoV-2 Variants in Participants Aged 6 Months to < 6 Years

Summary

EudraCT number	2024-000165-25
Trial protocol	Outside EU/EEA
Global end of trial date	20 October 2025

Results information

Result version number	v1 (current)
This version publication date	06 May 2026
First version publication date	06 May 2026

Trial information

Trial identification

Sponsor protocol code	mRNA-1273-P306
-----------------------	----------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05436834
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ModernaTX, Inc.
Sponsor organisation address	325 Binney Street, Cambridge, MA, United States, 02142
Public contact	Moderna Clinical Trials Support Center, ModernaTX, Inc., 1 866-663-3762, WeCareClinicalTrials@modernatx.com
Scientific contact	Moderna Clinical Trials Support Center, ModernaTX, Inc., 1 866-663-3762, WeCareClinicalTrials@modernatx.com

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	20 October 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 October 2025
Global end of trial reached?	Yes
Global end of trial date	20 October 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study evaluated the safety and immunogenicity of the mRNA-1273.214 vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variant of concerns (VOCs) in participants aged 6 months to <6 years, when administered as a primary series in SARS-CoV-2 vaccine-naïve participants (Part 1) and a single booster dose (BD) given to participants who previously received 2 doses of the mRNA-1273 vaccine as a primary series (Part 2); and evaluated the safety and immunogenicity of the mRNA-1273.815 vaccine, when administered as a BD in participants aged 6 months to <6 years (Part 3) and when administered to SARS-CoV-2 vaccine-naïve participants aged 2 years to <5 years of age (Part 4).

Protection of trial subjects:

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki, and Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, and other applicable laws and regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 June 2022
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1802
Worldwide total number of subjects	1802
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	677

months)	
Children (2-11 years)	1125
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study mRNA-1273-P306 (P306): Part 1 enrolled vaccine-naïve participants; Part 2 enrolled participants who had previously been vaccinated with mRNA-1273 primary series; Part 3 enrolled participants who had previously been vaccinated with an authorized/approved COVID-19 vaccine; Part 4 enrolled SARS-CoV-2 vaccine-naïve participants.

Pre-assignment

Screening details:

Four participants were enrolled in the study but were not dosed and data are not included for these participants. Data from participants from study mRNA-1273-P204 (P204, NCT04796896) of the same age group, vaccinated with a mRNA-1273 primary series were used for comparison of immune response.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: mRNA-1273.214

Arm description:

Participants, 6 months to <6 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 micrograms (µg) intramuscular (IM) injections of mRNA-1273.214 vaccine as a 2-dose series on Day 1 and Day 29.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.214 was administered per dose and schedule specified in the arm description.

Arm title	Part 2: mRNA-1273.214
------------------	-----------------------

Arm description:

Participants, 6 months to <6 years of age, who had previously been vaccinated with a mRNA-1273 primary series, received a single IM 10 µg booster dose (BD) of mRNA-1273.214 vaccine at least 4 months after completion of the mRNA-1273 primary series.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.214 was administered per dose and schedule specified in the arm description.

Arm title	Part 3: mRNA-1273.815
------------------	-----------------------

Arm description:

Participants, 6 months to <6 years of age, who had previously been vaccinated with an authorized/approved COVID-19 vaccine, received a single IM 25 µg BD of mRNA-1273.815 vaccine on BD Day 1, at least 4 months after the last dose of a COVID-19 vaccine.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.815
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.815 was administered per dose and schedule specified in the arm description.

Arm title	Part 4: mRNA-1273.815 Cohort A
------------------	--------------------------------

Arm description:

Participants, 2 to <5 years of age, who had not been previously vaccinated against SARS-CoV-2, received a single 25 µg IM injection of mRNA-1273.815 vaccine on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.815
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.815 was administered per dose and schedule specified in the arm description.

Arm title	Part 4: mRNA-1273.815 Cohort B
------------------	--------------------------------

Arm description:

Participants, 6 months to <2 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injections of mRNA-1273.815 vaccine as a 2-dose series on Day 1 and Day 29.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.815
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.815 was administered per dose and schedule specified in the arm description.

Number of subjects in period 1	Part 1: mRNA-1273.214	Part 2: mRNA-1273.214	Part 3: mRNA-1273.815
Started	391	539	274
Received at Least 1 Dose of Study Drug	391	539	274
Solicited Safety Set	391	539	271
Per-protocol Immunogenicity Set (PPIS)	304 ^[1]	468 ^[2]	252 ^[3]
Safety Set	391	539	274
PPIS-Pos	240 ^[4]	149 ^[5]	211 ^[6]
PPIS-Neg	64 ^[7]	319 ^[8]	41 ^[9]
Completed	318	493	267
Not completed	73	46	7
Consent withdrawn by subject	18	21	4
Physician decision	3	-	-

Protocol Deviation	1	-	-
Other than Specified	8	-	-
Lost to follow-up	43	25	3

Number of subjects in period 1	Part 4: mRNA-1273.815 Cohort A	Part 4: mRNA-1273.815 Cohort B
Started	199	399
Received at Least 1 Dose of Study Drug	199	399
Solicited Safety Set	199	399
Per-protocol Immunogenicity Set (PPIS)	148 ^[10]	352 ^[11]
Safety Set	199	399
PPIS-Pos	143 ^[12]	276 ^[13]
PPIS-Neg	5 ^[14]	76 ^[15]
Completed	197	383
Not completed	2	16
Consent withdrawn by subject	-	10
Physician decision	-	-
Protocol Deviation	2	-
Other than Specified	-	-
Lost to follow-up	-	6

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: Analysis set population

[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: Analysis set population

[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: Analysis set population

[4] - 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: Analysis set population

[5] - 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: Analysis set population

[6] - 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: Analysis set population

[7] - 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: Analysis set population

[8] - 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: Analysis set population

[9] - 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: Analysis set population

[10] - 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: Analysis set population

[11] - 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: Analysis set population

[12] - 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: Analysis set population

[13] - 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: Analysis set population

[14] - 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: Analysis set population

[15] - 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: Analysis set population

Baseline characteristics

Reporting groups

Reporting group title	Part 1: mRNA-1273.214
Reporting group description: Participants, 6 months to <6 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 micrograms (µg) intramuscular (IM) injections of mRNA-1273.214 vaccine as a 2-dose series on Day 1 and Day 29.	
Reporting group title	Part 2: mRNA-1273.214
Reporting group description: Participants, 6 months to <6 years of age, who had previously been vaccinated with a mRNA-1273 primary series, received a single IM 10 µg booster dose (BD) of mRNA-1273.214 vaccine at least 4 months after completion of the mRNA-1273 primary series.	
Reporting group title	Part 3: mRNA-1273.815
Reporting group description: Participants, 6 months to <6 years of age, who had previously been vaccinated with an authorized/approved COVID-19 vaccine, received a single IM 25 µg BD of mRNA-1273.815 vaccine on BD Day 1, at least 4 months after the last dose of a COVID-19 vaccine.	
Reporting group title	Part 4: mRNA-1273.815 Cohort A
Reporting group description: Participants, 2 to <5 years of age, who had not been previously vaccinated against SARS-CoV-2, received a single 25 µg IM injection of mRNA-1273.815 vaccine on Day 1.	
Reporting group title	Part 4: mRNA-1273.815 Cohort B
Reporting group description: Participants, 6 months to <2 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injections of mRNA-1273.815 vaccine as a 2-dose series on Day 1 and Day 29.	

Reporting group values	Part 1: mRNA-1273.214	Part 2: mRNA-1273.214	Part 3: mRNA-1273.815
Number of subjects	391	539	274
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	2.51	2.73	3.06
standard deviation	± 1.488	± 1.277	± 1.319
Gender Categorical Units: Subjects			
Female	189	263	138
Male	202	276	136

Reporting group values	Part 4: mRNA-	Part 4: mRNA-	Total
------------------------	---------------	---------------	-------

	1273.815 Cohort A	1273.815 Cohort B	
Number of subjects	199	399	1802
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	2.91	0.89	
standard deviation	± 0.860	± 0.158	-
Gender Categorical Units: Subjects			
Female	99	191	880
Male	100	208	922

End points

End points reporting groups

Reporting group title	Part 1: mRNA-1273.214
Reporting group description: Participants, 6 months to <6 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 micrograms (µg) intramuscular (IM) injections of mRNA-1273.214 vaccine as a 2-dose series on Day 1 and Day 29.	
Reporting group title	Part 2: mRNA-1273.214
Reporting group description: Participants, 6 months to <6 years of age, who had previously been vaccinated with a mRNA-1273 primary series, received a single IM 10 µg booster dose (BD) of mRNA-1273.214 vaccine at least 4 months after completion of the mRNA-1273 primary series.	
Reporting group title	Part 3: mRNA-1273.815
Reporting group description: Participants, 6 months to <6 years of age, who had previously been vaccinated with an authorized/approved COVID-19 vaccine, received a single IM 25 µg BD of mRNA-1273.815 vaccine on BD Day 1, at least 4 months after the last dose of a COVID-19 vaccine.	
Reporting group title	Part 4: mRNA-1273.815 Cohort A
Reporting group description: Participants, 2 to <5 years of age, who had not been previously vaccinated against SARS-CoV-2, received a single 25 µg IM injection of mRNA-1273.815 vaccine on Day 1.	
Reporting group title	Part 4: mRNA-1273.815 Cohort B
Reporting group description: Participants, 6 months to <2 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injections of mRNA-1273.815 vaccine as a 2-dose series on Day 1 and Day 29.	
Subject analysis set title	Part 1: mRNA-1273.214
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <6 years of age, who had not been previously vaccinated against SARS-CoV-2, were to receive 25 µg IM injections of mRNA-1273.214 vaccine as a 2-dose series on Day 1 and Day 29.	
Subject analysis set title	Part 1: mRNA-1273.214 First Injection
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <6 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injection of mRNA-1273.214 vaccine on Day 1.	
Subject analysis set title	Part 1: mRNA-1273.214 Second Injection
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <6 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injection of mRNA-1273.214 vaccine on Day 29.	
Subject analysis set title	Part 2: mRNA-1273.214
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <6 years of age, who had previously been vaccinated with a mRNA-1273 primary series, received a single IM 10 µg BD of mRNA-1273.214 vaccine at least 4 months after completion of the mRNA-1273 primary series.	
Subject analysis set title	Part 3: mRNA-1273.815
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <6 years of age, who had previously been vaccinated with an authorized/approved COVID-19 vaccine, received a single IM 25 µg BD of mRNA-1273.815 vaccine on BD Day 1, at least 4 months after the last dose of a COVID-19 vaccine.	
Subject analysis set title	Part 4: mRNA-1273.815 Cohort A

Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 2 to <5 years of age, who had not been previously vaccinated against SARS-CoV-2, received a single 25 µg IM injection of mRNA-1273.815 vaccine on Day 1.	
Subject analysis set title	Part 4: mRNA-1273.815 Cohort B
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <2 years of age, who had not been previously vaccinated against SARS-CoV-2, were to receive 25 µg IM injections of mRNA-1273.815 vaccine as a 2-dose series on Day 1 and Day 29.	
Subject analysis set title	Part 4: mRNA-1273.815 Cohort B First Injection
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <2 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injection of mRNA-1273.815 vaccine on Day 1.	
Subject analysis set title	Part 4: mRNA-1273.815 Cohort B Second Injection
Subject analysis set type	Safety analysis
Subject analysis set description: Participants, 6 months to <2 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injection of mRNA-1273.815 vaccine on Day 29.	
Subject analysis set title	P204 mRNA-1273 Primary Series
Subject analysis set type	Per protocol
Subject analysis set description: Participants received 25 µg mRNA-1273 25 µg primary series in Study P204.	

Primary: Parts 1, 2, 3, 4 Cohort A, 4 Cohort B: Number of Participants With Solicited Local and Systemic Adverse Reactions (ARs)

End point title	Parts 1, 2, 3, 4 Cohort A, 4 Cohort B: Number of Participants With Solicited Local and Systemic Adverse Reactions (ARs) ^[1]
End point description: Solicited AR were reported by participants daily via electronic diary. Solicited local (injection site pain, injection site erythema [redness]), injection site swelling/induration [hardness], axillary [or groin] swelling or tenderness) and systemic AR (fever [all age groups], irritability/crying, sleepiness, and loss of appetite [6-36 months], and headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills [37 months-<6 years] and assessed by toxicity grading (Grades 0-4) modified from Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials. Lower score indicated lower severity. Solicited Safety Set: participants who received at least 1 dose of study drug and contributed any solicited AR data.	
End point type	Primary
End point timeframe: Up to 7 days after any injection	

Notes:

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

Justification: Date reported for applicable reporting arms.

End point values	Part 1: mRNA-1273.214 First Injection	Part 1: mRNA-1273.214 Second Injection	Part 2: mRNA-1273.214	Part 3: mRNA-1273.815
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	391	377	539	271
Units: participants				
Grade 1	153	132	253	92
Grade 2	56	61	99	37
Grade 3	7	11	19	17
Grade 4	0	1	0	0

Any AR	216	205	371	146
--------	-----	-----	-----	-----

End point values	Part 4: mRNA-1273.815 Cohort A	Part 4: mRNA-1273.815 Cohort B First Injection	Part 4: mRNA-1273.815 Cohort B Second Injection	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	199	399	386	
Units: participants				
Grade 1	60	106	84	
Grade 2	13	34	31	
Grade 3	9	12	15	
Grade 4	0	0	0	
Any AR	82	152	130	

Statistical analyses

No statistical analyses for this end point

Primary: Parts 1, 2, 3, 4 Cohort A, 4 Cohort B: Number of Participants With Unsolicited Adverse Events (AEs) After Any Injection

End point title	Parts 1, 2, 3, 4 Cohort A, 4 Cohort B: Number of Participants With Unsolicited Adverse Events (AEs) After Any Injection ^[2]
-----------------	--

End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. Abnormal laboratory test result or other safety assessment, including one that worsened from baseline and considered clinically significant by investigator was recorded as an AE. Active surveillance for COVID-19 was included in Parts 1 and 2, but not in Parts 3 and 4, so COVID-19/SARS-CoV-2 infections were considered clinical events and not AEs in Parts 1 and 2, and considered as AEs in Parts and Part 4. Summary of SAEs and nonserious AEs, regardless of causality, are located in AE section. Safety Set: received at least 1 dose of study drug.

End point type	Primary
----------------	---------

End point timeframe:

28 days after any injection

Notes:

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

Justification: Date reported for applicable reporting arms.

End point values	Part 1: mRNA-1273.214	Part 2: mRNA-1273.214	Part 3: mRNA-1273.815	Part 4: mRNA-1273.815 Cohort A
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	391	539	274	199
Units: participants	138	112	49	39

End point values	Part 4: mRNA-			
------------------	---------------	--	--	--

	1273.815 Cohort B			
Subject group type	Subject analysis set			
Number of subjects analysed	399			
Units: participants	207			

Statistical analyses

No statistical analyses for this end point

Primary: Parts 1, 2, 3, 4 Cohort A, 4 Cohort B: Number of Participants with Serious AEs (SAEs), Medically Attended AEs (MAAEs), AEs of Special Interest (AESIs), and AEs Leading to Discontinuation from Participation in the Study

End point title	Parts 1, 2, 3, 4 Cohort A, 4 Cohort B: Number of Participants with Serious AEs (SAEs), Medically Attended AEs (MAAEs), AEs of Special Interest (AESIs), and AEs Leading to Discontinuation from Participation in the Study ^[3]
-----------------	---

End point description:

SAE: AE resulting in death, life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in disability/permanent damage, a congenital anomaly/birth defect, or important medical event. MAAE: AE that led to unscheduled visit to doctor included visits to a site for unscheduled assessments. AESI identified based on medical concepts that may be related to COVID-19 or were of interest in COVID-19 vaccine safety surveillance. Active surveillance for COVID-19 was included in Parts 1 and 2, but not in Parts 3 and 4, so COVID-19/SARS-CoV-2 infections were considered clinical events and not AEs in Parts 1 and 2, and considered as AEs in Parts and Part 4. Safety Set: received at least 1 dose of study drug.

End point type	Primary
----------------	---------

End point timeframe:

Up to Day 394

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: Date reported for applicable reporting arms.

End point values	Part 1: mRNA-1273.214	Part 2: mRNA-1273.214	Part 3: mRNA-1273.815	Part 4: mRNA-1273.815 Cohort A
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	391	539	274	199
Units: participants				
SAE	10	9	5	0
MAAE	242	310	66	31
AESI	4	4	2	0
AEs Leading to Discontinuation from the Study	0	0	0	0

End point values	Part 4: mRNA-1273.815 Cohort B			
Subject group type	Subject analysis set			
Number of subjects analysed	399			
Units: participants				

SAE	13			
MAAE	172			
AESI	1			
AEs Leading to Discontinuation from the Study	0			

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 Geometric Mean Concentration (GMC) of Pseudovirus Neutralizing Antibody (nAb) Against Omicron BA.1 after mRNA-1273.214 Administration Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group

End point title	Part 1 Geometric Mean Concentration (GMC) of Pseudovirus Neutralizing Antibody (nAb) Against Omicron BA.1 after mRNA-1273.214 Administration Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group
-----------------	--

End point description:

Measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 arbitrary units (AU)/milliliter (mL), ULOQ: 24503 AU/mL. Analysis Set: P306 Part 1 PPIS and P204 PPIS was used for comparison of immune response. PPIS: all participants, regardless of Baseline SARS-CoV-2 status, who had baseline and P306 Day 57/P204 Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint. n = participants evaluable for the specified category.

End point type	Primary
----------------	---------

End point timeframe:

P306 Day 57/P204 Day 57

End point values	Part 1: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	300	607		
Units: AU/mL				
geometric mean (confidence interval 95%)	3949.4 (3567.3 to 4372.4)	77.7 (72.3 to 83.5)		

Statistical analyses

Statistical analysis title	Statistical Analysis Test 1
Comparison groups	P204 mRNA-1273 Primary Series v Part 1: mRNA-1273.214

Number of subjects included in analysis	907
Analysis specification	Pre-specified
Analysis type	superiority ^[4]
Method	ANCOVA
Parameter estimate	Geometric mean ratio (GMR)
Point estimate	50.829
Confidence interval	
level	95 %
sides	2-sided
lower limit	44.884
upper limit	57.562

Notes:

[4] - Superiority criterion: lower bound of 95% CI of GMR >1.0

Primary: Part 1 Geometric Mean Concentration (GMC) of Pseudovirus Neutralizing Antibody (nAb) Against Ancestral SARS-CoV-2 (D614G) after mRNA-1273.214 Administration Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group

End point title	Part 1 Geometric Mean Concentration (GMC) of Pseudovirus Neutralizing Antibody (nAb) Against Ancestral SARS-CoV-2 (D614G) after mRNA-1273.214 Administration Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group
-----------------	--

End point description:

Measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL. Analysis Set: P306 Part 1 PPIS and P204 PPIS was used for comparison of immune response. PPIS: all participants, regardless of Baseline SARS-CoV-2 status, who had baseline and P306 Day 57/P204 Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint. n = participants evaluable for the specified category.

End point type	Primary
End point timeframe:	
P306 Day 57/P204 Day 57	

End point values	Part 1: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	301	594		
Units: AU/mL				
geometric mean (confidence interval 95%)	2068.2 (1859.3 to 2300.6)	1732.5 (1606.0 to 1868.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis Test 1
Comparison groups	Part 1: mRNA-1273.214 v P204 mRNA-1273 Primary Series

Number of subjects included in analysis	895
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
Method	ANCOVA
Parameter estimate	GMR
Point estimate	1.194
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.048
upper limit	1.36

Notes:

[5] - Noninferiority criterion: lower bound of 95% CI of GMR >0.667

Primary: Part 2: GMC of the Pseudovirus nAb Against Omicron BA.1 After mRNA-1273.214 Administration at BD-Day 29 Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group

End point title	Part 2: GMC of the Pseudovirus nAb Against Omicron BA.1 After mRNA-1273.214 Administration at BD-Day 29 Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group
-----------------	---

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL). Analysis Set: P306 Part 2 PPIS-Neg and P204 PPIS-Neg was used for comparison of immune response. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P306 BD-Day 29/P204 Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint. n = participants evaluable for specified category.

End point type	Primary
----------------	---------

End point timeframe:

P306 BD-Day 29/P204 Day 57

End point values	Part 2: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	316	567		
Units: AU/mL				
geometric mean (confidence interval 95%)	805.2 (731.2 to 886.8)	66.6 (62.0 to 71.6)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2: mRNA-1273.214 v P204 mRNA-1273 Primary Series

Number of subjects included in analysis	883
Analysis specification	Pre-specified
Analysis type	superiority ^[6]
Method	ANCOVA
Parameter estimate	GMR
Point estimate	12.085
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.715
upper limit	13.631

Notes:

[6] - Superiority criterion: lower bound of 95% CI of GMR >1.0

Primary: Part 2: GMC of the Pseudovirus nAb Against Ancestral SARS-CoV-2 (D614G) After mRNA-1273.214 Administration at BD-Day 29 Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group

End point title	Part 2: GMC of the Pseudovirus nAb Against Ancestral SARS-CoV-2 (D614G) After mRNA-1273.214 Administration at BD-Day 29 Compared with GMC After P204 mRNA-1273 Primary Series of Same Age Group
-----------------	---

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). Analysis Set: P306 Part 2 PPIS-Neg and P204 PPIS-Neg was used for comparison of immune response. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P306 BD-Day 29/P204 Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint. n = participants evaluable for specified category.

End point type	Primary
----------------	---------

End point timeframe:

P306 BD-Day 29/P204 Day 57

End point values	Part 2: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	316	557		
Units: AU/mL				
geometric mean (confidence interval 95%)	4754.7 (4346.9 to 5200.7)	1559.4 (1457.6 to 1668.4)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2: mRNA-1273.214 v P204 mRNA-1273 Primary Series

Number of subjects included in analysis	873
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[7]
Method	ANCOVA
Parameter estimate	GMR
Point estimate	3.049
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.725
upper limit	3.411

Notes:

[7] - Noninferiority criterion: lower bound of 95% CI of GMR >0.667

Primary: Part 2: Seroresponse Rate (SRR) Against Omicron BA.1 After mRNA-1273.214 at BD-29 Compared with SRR after P204 mRNA-1273 Primary Series of Same Age Group

End point title	Part 2: Seroresponse Rate (SRR) Against Omicron BA.1 After mRNA-1273.214 at BD-29 Compared with SRR after P204 mRNA-1273 Primary Series of Same Age Group
-----------------	---

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse relative to baseline (pre-Dose of primary series) SRR at a participant level was defined as a change from Baseline (pre-Dose 1 of P204 primary series) below the LLOQ to $\geq 4 \times \text{LLOQ}$, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL). Analysis Set: P306 Part 2 PPIS-Neg and P204 PPIS-Neg was used for comparison of immune response. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P306 BD-Day 29/P204 Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint. n = participants evaluable for specified category.

End point type	Primary
----------------	---------

End point timeframe:

P306 BD-Day 29/P204 Day 57

End point values	Part 2: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	312	562		
Units: percentage of participants				
number (confidence interval 95%)	99.0 (97.2 to 99.8)	84.9 (81.6 to 87.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2: mRNA-1273.214 v P204 mRNA-1273 Primary Series

Number of subjects included in analysis	874
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[8]
Method	Miettinen-Nurminen Score
Parameter estimate	SRR difference
Point estimate	14.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.1
upper limit	17.5

Notes:

[8] - Noninferiority: Lower bound of the 95% CI of the SRR difference > -5% with noninferiority margin of 5%

Primary: Part 2: SRR Against Ancestral SARS-CoV-2 (D614G) After mRNA-1273.214 at BD-29 Compared with SRR after P204 mRNA-1273 Primary Series of Same Age Group

End point title	Part 2: SRR Against Ancestral SARS-CoV-2 (D614G) After mRNA-1273.214 at BD-29 Compared with SRR after P204 mRNA-1273 Primary Series of Same Age Group
-----------------	---

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse relative to baseline (pre-Dose of primary series) SRR at a participant level was defined as a change from Baseline (pre-Dose 1 of P204 primary series) below the LLOQ to $\geq 4 \times \text{LLOQ}$, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). Analysis Set: P306 Part 2 PPIS-Neg and P204 PPIS-Neg was used for comparison of immune response. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P306 BD-Day 29/P204 Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint. n = participants evaluable for specified category.

End point type	Primary
----------------	---------

End point timeframe:

P306 BD-Day29/P204 Day 57

End point values	Part 2: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	312	548		
Units: percentage of participants				
number (confidence interval 95%)	100.0 (98.8 to 100.0)	99.5 (98.4 to 99.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2: mRNA-1273.214 v P204 mRNA-1273 Primary Series

Number of subjects included in analysis	860
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[9]
Method	Miettinen-Nurminen Score
Parameter estimate	SRR difference
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	1.6

Notes:

[9] - Noninferiority: Lower bound of the 95% CI of the SRR difference >-10% with noninferiority margin of 10%

Primary: Part 4: GMC of the Pseudovirus nAb Against SARS-CoV-2 VOC (Omicron XBB.1.5) After a Single Dose of mRNA-1273.815 (Cohort A) Compared with GMC after 2 Doses of mRNA-1273.815 (Cohort B)

End point title	Part 4: GMC of the Pseudovirus nAb Against SARS-CoV-2 VOC (Omicron XBB.1.5) After a Single Dose of mRNA-1273.815 (Cohort A) Compared with GMC after 2 Doses of mRNA-1273.815 (Cohort B)
-----------------	---

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150 for XBB.1.5 AU/mL, LLOQ: 38 AU/mL, ULOQ: 6960 AU/mL). Analysis Set: P306 Part 4 Cohort A PPIS-Pos and P306 Part 4 Cohort B PPIS-Neg was used for comparison of immune response. PPIS-Pos: all participants who were SARS-CoV-2 positive at baseline who had baseline and Day 29 Cohort A/Day 57 Cohort B Ab assessments and had no major protocol deviations that impacted key or critical data. PPIS-Neg: all participants who were SARS-CoV-2 negative at baseline, who had baseline Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Primary
----------------	---------

End point timeframe:

Day 29 Cohort A/Day 57 Cohort B

End point values	Part 4: mRNA-1273.815 Cohort A	Part 4: mRNA-1273.815 Cohort B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	143	76		
Units: AU/mL				
geometric mean (confidence interval 95%)	2074.1 (1637.8 to 2626.7)	1736.3 (1255.8 to 2400.6)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
-----------------------------------	------------------------

Statistical analysis description:

Cohort A versus Cohort B

Comparison groups	Part 4: mRNA-1273.815 Cohort A v Part 4: mRNA-1273.815 Cohort B
Number of subjects included in analysis	219
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[10]
Method	ANCOVA
Parameter estimate	GMR
Point estimate	1.195
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.784

Notes:

[10] - Noninferiority criterion: lower bound of the 95% CI >0.667

Secondary: Part 1: SRR Against Omicron BA.1 and Ancestral SARS-CoV-2 (D614G) Strain After mRNA-1273.214 Compared with SRR After P204 mRNA-1273 primary Series in Same Age Group

End point title	Part 1: SRR Against Omicron BA.1 and Ancestral SARS-CoV-2 (D614G) Strain After mRNA-1273.214 Compared with SRR After P204 mRNA-1273 primary Series in Same Age Group
-----------------	--

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse relative to baseline (pre-Dose of primary series) SRR at a participant level was defined as a change from Baseline (pre-Dose 1 of P204 primary series) below the LLOQ to $\geq 4 \times \text{LLOQ}$, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL and VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). Analysis Set: P306 Part 1 PPIS and P204 PPIS was used for comparison of immune response. PPIS: all participants, regardless of Baseline SARS-CoV-2 status, who had baseline and P306 Day 57/P204 Day 57 Ab assessments, and met protocol-defined criteria for inclusion. "Number of subjects analyzed" = participants evaluable for this endpoint. n = participants evaluable for specified category.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 Day 57/P204 Day 57

End point values	Part 1: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	297	602		
Units: percentage of participants				
number (confidence interval 95%)				
BA.1 (n= 293, 602)	95.6 (92.5 to 97.6)	85.7 (82.7 to 88.4)		
D614G (n= 297, 585)	92.9 (89.4 to 95.6)	99.5 (98.5 to 99.9)		

Statistical analyses

Secondary: Part 1: nAb GMC Against Omicron BA.1 Compared with GMC of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group

End point title	Part 1: nAb GMC Against Omicron BA.1 Compared with GMC of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group
-----------------	---

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL and VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). Analysis Set: P306 Part 1 PPIS and P204 PPIS was used for comparison of immune response. PPIS: all participants, regardless of Baseline SARS-CoV-2 status, who had baseline and P306 Day 57/P204 Day 57 Ab assessments, and met protocol-defined criteria for inclusion. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 Day 57/P204 Day 57

End point values	Part 1: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	300	594		
Units: AU/mL				
geometric mean (confidence interval 95%)	3949.4 (3411.5 to 4572.0)	1732.5 (1611.5 to 1862.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: SRR Against Omicron BA.1 Compared with SRR of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group

End point title	Part 1: SRR Against Omicron BA.1 Compared with SRR of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group
-----------------	---

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse at a participant level was defined as a change from Baseline (pre-Dose 1 of P204 primary series) below the LLOQ to $\geq 4 \times$ LLOQ, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL and VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). Analysis Set: P306 Part 1 PPIS and P204 PPIS was used for comparison of immune response. PPIS: all participants, regardless of Baseline SARS-CoV-2 status, who had baseline and P306 Day 57/P204 Day 57 Ab assessments, and met protocol-defined criteria for inclusion. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:
P306 Day 57/P204 Day 57

End point values	Part 1: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	293	585		
Units: percentage of participants				
number (confidence interval 95%)	95.6 (92.5 to 97.6)	99.5 (98.5 to 99.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: nAb GMC Against Omicron BA.1 Compared with GMC of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group

End point title	Part 2: nAb GMC Against Omicron BA.1 Compared with GMC of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group
-----------------	---

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL and VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL. Analysis Set: P306 Part 2 PPIS-Neg and P204 PPIS-Neg was used for comparison of immune response. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P306 BD-Day 29/P204 Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 BD-Day 29/P204 Day 57

End point values	Part 2: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	316	557		
Units: AU/mL				
geometric mean (confidence interval 95%)	805.2 (730.0 to 888.2)	1559.4 (1448.4 to 1679.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: SRR Against Omicron BA.1 Compared with SRR of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group

End point title	Part 2: SRR Against Omicron BA.1 Compared with SRR of P204 mRNA-1273 2-dose Primary Series Against Ancestral (D614G) Strain in Participants of Same Age Group
-----------------	---

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse relative to baseline (pre-Dose of primary series) SRR at a participant level was defined as a change from Baseline (pre-Dose 1 of P204 primary series) below the LLOQ to $\geq 4 \times$ LLOQ, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC122 for BA.1 [B.1.1.529], LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL and VAC62 for D614G [original strain], LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL. Analysis Set: P306 Part 2 PPIS-Neg and P204 PPIS-Neg was used for comparison of immune response. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P306 BD-Day 29/P204 Day 57 Ab assessments, and met protocol-defined criteria for inclusion. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 BD-Day 29/P204 Day 57

End point values	Part 2: mRNA-1273.214	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	312	548		
Units: percentage of participation				
number (confidence interval 95%)	99.0 (97.2 to 99.8)	99.5 (98.4 to 99.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: nAb GMC Against Omicron XBB.1.5 After mRNA-1273.815 Administration

End point title	Part 3: nAb GMC Against Omicron XBB.1.5 After mRNA-1273.815 Administration
-----------------	--

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported $<$ LLOQ replaced by $0.5 \times$ LLOQ. Values $>$ ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150), LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL. Analysis Set: P306 Part 3 PPIS. PPIS: all participants, regardless of Baseline SARS-CoV-2 status, who had baseline and BD-Day 29 Ab assessments, and met protocol-defined criteria for inclusion. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

BD-Day 29

End point values	Part 3: mRNA-1273.815			
Subject group type	Subject analysis set			
Number of subjects analysed	274			
Units: AU/mL				
geometric mean (confidence interval 95%)	2827.4 (2389.9 to 3345.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: SRR Against Omicron XBB.1.5 After mRNA-1273.815 Administration

End point title	Part 3: SRR Against Omicron XBB.1.5 After mRNA-1273.815 Administration
End point description:	
Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse at a participant level was defined as a change from Baseline below the LLOQ to $\geq 4 \times \text{LLOQ}$, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150), LLOQ: 8 AU/mL, ULOQ: 24503 AU/mL. Analysis Set: P306 Part 3 PPIS. PPIS: all participants, regardless of Baseline SARS-CoV-2 status, who had baseline and BD-Day 29 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint.	
End point type	Secondary
End point timeframe:	
BD-Day 29	

End point values	Part 3: mRNA-1273.815			
Subject group type	Subject analysis set			
Number of subjects analysed	274			
Units: percentage of participants				
number (confidence interval 95%)	79.0 (73.4 to 83.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 4: SRR Against Omicron XBB.1.5 After mRNA-1273.815 Single Dose (Cohort A) Compared with SRR After 2 Doses of mRNA-1273.815 (Cohort B)

End point title	Part 4: SRR Against Omicron XBB.1.5 After mRNA-1273.815
-----------------	---

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse at a participant level was defined as a change from Baseline below the LLOQ to $\geq 4 \times \text{LLOQ}$, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150 for XBB.1.5, LLOQ: 38 AU/mL, ULOQ: 6960 AU/mL). Analysis Set: P306 Part 4 Cohort A PPIS-Pos and P306 Part 4 Cohort B PPIS-Neg was used for comparison of immune response: PPIS-Pos: all participants who were SARS-CoV-2 positive at baseline who had baseline and P306 Cohort A Day 29 Ab assessments and had no major protocol deviations that impacted key or critical data. PPIS-Neg: all participants who were SARS-CoV-2 negative at baseline, who had baseline P306 Cohort B Day 57 Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 Cohort A Day 29/P306 Cohort B Day 57

End point values	Part 4: mRNA-1273.815 Cohort A	Part 4: mRNA-1273.815 Cohort B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	139	76		
Units: percentage of participants				
number (confidence interval 95%)	73.4 (65.2 to 80.5)	96.1 (88.9 to 99.2)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 4: mRNA-1273.815 Cohort A v Part 4: mRNA-1273.815 Cohort B
Number of subjects included in analysis	215
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[11]
Method	Miettinen-Nurminen Score
Parameter estimate	SRR difference
Point estimate	-22.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.3
upper limit	-13.5

Notes:

[11] - Noninferiority criterion for SRR difference = lower bound of the 95% CI $> -10\%$

Secondary: Part 4: GMC Against Omicron XBB.1.5 After mRNA-1273.815 Single Dose (Cohort A) Compared with GMC After P204 mRNA-1273 2-dose Primary Series Against Ancestral SARS-CoV-2 (D614G) Strain

End point title	Part 4: GMC Against Omicron XBB.1.5 After mRNA-1273.815 Single Dose (Cohort A) Compared with GMC After P204 mRNA-
-----------------	---

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150 for XBB.1.5 AU/mL, LLOQ: 38 AU/mL, ULOQ: 6960 AU/mL and VAC62 for D614G, LLOQ: 10, ULOQ: 111433 AU/mL). Analysis Set: P306 Part 4 Cohort A PPIS-Pos and P204 PPIS-Neg was used for comparison of immune response. PPIS-Pos: all participants with positive Baseline SARS-CoV-2 status, who had baseline and P306 Cohort A Day 29 Ab assessments, and met protocol-defined criteria for inclusion. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P204 Day 57 Ab assessments, and met protocol-defined criteria for inclusion. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 Cohort A Day 29/P204 Day 57

End point values	Part 4: mRNA-1273.815 Cohort A	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	143	258		
Units: AU/mL				
geometric mean (confidence interval 95%)	2074.1 (1722.5 to 2497.5)	1439.1 (1253.3 to 1652.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 4: GMC Against Omicron XBB.1.5 After mRNA-1273.815 Single Dose (Cohort A) Compared with GMC After 2 Doses of mRNA-1273.815 (Cohort B), Regardless of Prior Infection

End point title	Part 4: GMC Against Omicron XBB.1.5 After mRNA-1273.815 Single Dose (Cohort A) Compared with GMC After 2 Doses of mRNA-1273.815 (Cohort B), Regardless of Prior Infection
-----------------	---

End point description:

Pseudovirus nAb measured using PsVNA assay. Antibody values reported <LLOQ replaced by 0.5*LLOQ. Values >ULOQ replaced by ULOQ if actual values not available. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150 for XBB.1.5, LLOQ: 38 AU/mL, ULOQ: 6960 AU/mL). Analysis Set: P306 Part 4 Cohort A PPIS-Pos and P306 Part 4 Cohort B PPIS-Neg was used for comparison of immune response. PPIS-Pos: all participants who were SARS-CoV-2 positive at baseline who had baseline and P306 Day 29 Cohort A Ab assessments and had no major protocol deviations that impacted key or critical data. PPIS-Neg: all participants who were SARS-CoV-2 negative at baseline, who had baseline P306 Day 57 Cohort B Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 Day 29 Cohort A/P306 Day 57 Cohort B

End point values	Part 4: mRNA-1273.815 Cohort A	Part 4: mRNA-1273.815 Cohort B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	148	352		
Units: AU/mL				
geometric mean (confidence interval 95%)	1975.5 (1593.2 to 2449.6)	3768.9 (3278.2 to 4333.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 4: SRR Against Omicron XBB.1.5 After mRNA-1273.815 Single Dose (Cohort A) Compared with SRR of P204 mRNA-1273 2-dose Primary Series Against Ancestral SARS-CoV-2 (D614G) Strain

End point title	Part 4: SRR Against Omicron XBB.1.5 After mRNA-1273.815 Single Dose (Cohort A) Compared with SRR of P204 mRNA-1273 2-dose Primary Series Against Ancestral SARS-CoV-2 (D614G) Strain
-----------------	--

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse at a participant level was defined as a change from Baseline below the LLOQ to $\geq 4 \times \text{LLOQ}$, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150 for XBB.1.5 AU/mL, LLOQ: 38 AU/mL, ULOQ: 6960 AU/mL and VAC62 for D614G, LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL). Analysis Set: P306 Part 4 PPIS-Pos and P204 PPIS-Neg was used for comparison of immune response. PPIS-Pos: all participants with positive Baseline SARS-CoV-2 status, who had baseline and P306 Cohort A Day 29 Ab assessments, and met protocol-defined criteria for inclusion. PPIS-Neg: all participants with negative Baseline SARS-CoV-2 status, who had baseline and P204 Day 57 Ab assessments, and met protocol-defined criteria for inclusion. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 Cohort A Day 29/P204 Day 57

End point values	Part 4: mRNA-1273.815 Cohort A	P204 mRNA-1273 Primary Series		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	139	253		
Units: percentage of participants				
number (confidence interval 95%)	73.4 (65.2 to 80.5)	99.2 (97.2 to 99.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 4: SRR against Omicron XBB.1.5 after mRNA-1273.815 Single Dose

(Cohort A) Compared with SRR After 2 Doses of mRNA-1273.815 (Cohort B), Regardless of Prior Infection

End point title	Part 4: SRR against Omicron XBB.1.5 after mRNA-1273.815 Single Dose (Cohort A) Compared with SRR After 2 Doses of mRNA-1273.815 (Cohort B), Regardless of Prior Infection
-----------------	---

End point description:

Percentage of participants with seroresponse for pseudovirus nAb measured using PsVNA assay are reported. Seroresponse at a participant level was defined as a change from Baseline below the LLOQ to $\geq 4 \times \text{LLOQ}$, or at least a 4-fold rise if Baseline was $\geq$ the LLOQ. Serum nAb level against SARS-CoV-2 were measured by pseudotyped virus neutralization (VAC150 for XBB.1.5, LLOQ: 38 AU/mL, ULOQ: 6960 AU/mL). Analysis Set: P306 Part 4 Cohort A PPIS-Pos and P306 Part 4 Cohort B PPIS-Neg was used for comparison of immune response. PPIS-Pos: all participants who were SARS-CoV-2 positive at baseline who had baseline and P306 Day 29 Cohort A Ab assessments and had no major protocol deviations that impacted key or critical data. PPIS-Neg: all participants who were SARS-CoV-2 negative at baseline, who had baseline P306 Day 57 Cohort B Ab assessments, and had no major protocol deviations that impacted key or critical data. "Number of subjects analyzed" = participants evaluable for this endpoint.

End point type	Secondary
----------------	-----------

End point timeframe:

P306 Day 29 Cohort A/P306 Day 57 Cohort B

End point values	Part 4: mRNA-1273.815 Cohort A	Part 4: mRNA-1273.815 Cohort B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	144	347		
Units: percentage of participants				
number (confidence interval 95%)	73.6 (65.6 to 80.6)	89.0 (85.3 to 92.1)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Day 394

Adverse event reporting additional description:

Safety Set: received at least 1 dose of study drug..

Active surveillance for COVID-19 was included in Parts 1 and 2, but not in Parts 3 and 4, so COVID-19/SARS-CoV-2 infections were considered clinical events and not AEs in Parts 1 and 2, and considered as AEs in Parts and Part 4.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	23.0
--------------------	------

Reporting groups

Reporting group title	Part 2: mRNA-1273.214
-----------------------	-----------------------

Reporting group description:

Participants, 6 months to <6 years of age, who had previously been vaccinated with a mRNA-1273 primary series, received a single IM 10 µg BD of mRNA-1273.214 vaccine at least 4 months after completion of the mRNA-1273 primary series.

Reporting group title	Part 1: mRNA-1273.214
-----------------------	-----------------------

Reporting group description:

Participants, 6 months to <6 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injections of mRNA-1273.214 vaccine as a 2-dose series on Day 1 and Day 29.

Reporting group title	Part 4: mRNA-1273.815 Cohort A
-----------------------	--------------------------------

Reporting group description:

Participants, 2 to <5 years of age, who had not been previously vaccinated against SARS-CoV-2, received a single 25 µg IM injection of mRNA-1273.815 vaccine on Day 1.

Reporting group title	Part 4: mRNA-1273.815 Cohort B
-----------------------	--------------------------------

Reporting group description:

Participants, 6 months to <2 years of age, who had not been previously vaccinated against SARS-CoV-2, received 25 µg IM injections of mRNA-1273.815 vaccine as a 2-dose series on Day 1 and Day 29.

Reporting group title	Part 3: mRNA-1273.815
-----------------------	-----------------------

Reporting group description:

Participants, 6 months to <6 years of age, who had previously been vaccinated with an authorized/approved COVID-19 vaccine, received a single IM 25 µg BD of mRNA-1273.815 vaccine on BD Day 1, at least 4 months after the last dose of a COVID-19 vaccine.

Serious adverse events	Part 2: mRNA-1273.214	Part 1: mRNA-1273.214	Part 4: mRNA-1273.815 Cohort A
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 539 (1.67%)	10 / 391 (2.56%)	0 / 199 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Cardiac murmur			

subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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
Congenital, familial and genetic disorders			
Aberrant aortic arch			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 539 (0.19%)	0 / 391 (0.00%)	0 / 199 (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
Cerebellar ataxia			
subjects affected / exposed	1 / 539 (0.19%)	0 / 391 (0.00%)	0 / 199 (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
Seizure			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Status epilepticus			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 539 (0.00%)	2 / 391 (0.51%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	1 / 539 (0.19%)	0 / 391 (0.00%)	0 / 199 (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
Bronchial obstruction			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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			
Pneumonia			

subjects affected / exposed	1 / 539 (0.19%)	1 / 391 (0.26%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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 syncytial virus infection			
subjects affected / exposed	1 / 539 (0.19%)	2 / 391 (0.51%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	2 / 539 (0.37%)	0 / 391 (0.00%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Gastroenteritis clostridial			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Herpangina			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Otitis media			
subjects affected / exposed	1 / 539 (0.19%)	0 / 391 (0.00%)	0 / 199 (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
Respiratory tract infection			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Parainfluenzae virus infection			
subjects affected / exposed	1 / 539 (0.19%)	0 / 391 (0.00%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Tooth infection			
subjects affected / exposed	0 / 539 (0.00%)	0 / 391 (0.00%)	0 / 199 (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
Staphylococcal scalded skin syndrome			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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			
Hypoglycaemia			
subjects affected / exposed	0 / 539 (0.00%)	1 / 391 (0.26%)	0 / 199 (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
Dehydration			

subjects affected / exposed	1 / 539 (0.19%)	1 / 391 (0.26%)	0 / 199 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 4: mRNA-1273.815 Cohort B	Part 3: mRNA-1273.815	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 399 (3.26%)	5 / 274 (1.82%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Aberrant aortic arch			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (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			
Febrile convulsion			
subjects affected / exposed	0 / 399 (0.00%)	1 / 274 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar ataxia			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			

subjects affected / exposed	1 / 399 (0.25%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	0 / 399 (0.00%)	1 / 274 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoidal hypertrophy			

subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial obstruction			
subjects affected / exposed	1 / 399 (0.25%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	5 / 399 (1.25%)	1 / 274 (0.36%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	3 / 399 (0.75%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	3 / 399 (0.75%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 399 (0.25%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis clostridial			

subjects affected / exposed	1 / 399 (0.25%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpangina			
subjects affected / exposed	1 / 399 (0.25%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 399 (0.00%)	1 / 274 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 399 (0.00%)	1 / 274 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 399 (0.00%)	1 / 274 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth infection			
subjects affected / exposed	0 / 399 (0.00%)	1 / 274 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal scalded skin syndrome			

subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 2: mRNA-1273.214	Part 1: mRNA-1273.214	Part 4: mRNA-1273.815 Cohort A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	245 / 539 (45.45%)	178 / 391 (45.52%)	37 / 199 (18.59%)
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	18 / 539 (3.34%)	10 / 391 (2.56%)	31 / 199 (15.58%)
occurrences (all)	22	12	33
Gastroenteritis viral			
subjects affected / exposed	9 / 539 (1.67%)	22 / 391 (5.63%)	0 / 199 (0.00%)
occurrences (all)	9	23	0
Otitis media acute			
subjects affected / exposed	34 / 539 (6.31%)	24 / 391 (6.14%)	0 / 199 (0.00%)
occurrences (all)	44	52	0
Otitis media			
subjects affected / exposed	71 / 539 (13.17%)	55 / 391 (14.07%)	1 / 199 (0.50%)
occurrences (all)	99	89	1
Pharyngitis streptococcal			
subjects affected / exposed	33 / 539 (6.12%)	38 / 391 (9.72%)	1 / 199 (0.50%)
occurrences (all)	40	50	1
Respiratory syncytial virus infection			

subjects affected / exposed	27 / 539 (5.01%)	11 / 391 (2.81%)	0 / 199 (0.00%)
occurrences (all)	28	11	0
Respiratory tract infection			
subjects affected / exposed	1 / 539 (0.19%)	0 / 391 (0.00%)	0 / 199 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	119 / 539 (22.08%)	84 / 391 (21.48%)	4 / 199 (2.01%)
occurrences (all)	179	168	4
Viral upper respiratory tract infection			
subjects affected / exposed	20 / 539 (3.71%)	38 / 391 (9.72%)	1 / 199 (0.50%)
occurrences (all)	22	47	1

Non-serious adverse events	Part 4: mRNA-1273.815 Cohort B	Part 3: mRNA-1273.815	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	161 / 399 (40.35%)	48 / 274 (17.52%)	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	117 / 399 (29.32%)	20 / 274 (7.30%)	
occurrences (all)	148	26	
Gastroenteritis viral			
subjects affected / exposed	0 / 399 (0.00%)	4 / 274 (1.46%)	
occurrences (all)	0	4	
Otitis media acute			
subjects affected / exposed	4 / 399 (1.00%)	6 / 274 (2.19%)	
occurrences (all)	4	6	
Otitis media			
subjects affected / exposed	7 / 399 (1.75%)	2 / 274 (0.73%)	
occurrences (all)	7	2	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 399 (0.00%)	2 / 274 (0.73%)	
occurrences (all)	0	2	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 399 (0.00%)	0 / 274 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			

subjects affected / exposed	23 / 399 (5.76%)	0 / 274 (0.00%)	
occurrences (all)	30	0	
Upper respiratory tract infection			
subjects affected / exposed	16 / 399 (4.01%)	18 / 274 (6.57%)	
occurrences (all)	16	21	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 399 (0.25%)	1 / 274 (0.36%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 December 2022	Updated the coprimary endpoints for Part 1 and Part 2
28 November 2023	Added Parts 3 and 4 (mRNA- 1273.815) to the study
17 January 2024	- Updated study endpoints - Updated immunogenicity and vaccine effective assessments - Additional statistical analysis added

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported