Clinical trial results:
A Randomized, Observer-blind, Active-controlled Phase 3 Study to Investigate the Safety, Immunogenicity, and Relative Vaccine Efficacy of mRNA-1283 Compared With mRNA-1273 in Participants Aged 12 Years for the Prevention of COVID-19

Summary

EudraCT number	2023-000884-30
Trial protocol	Outside EU/EEA
Global end of trial date	12 April 2025

Results information

Result version number	v1 (current)
This version publication date	26 October 2025
First version publication date	26 October 2025

Trial information

Trial identification

Sponsor protocol code	mRNA-1283-P301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05815498
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ModernaTX, Inc.
Sponsor organisation address	325 Binney Street, Cambridge, United States, 02142
Public contact	Moderna WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com
Scientific contact	Moderna WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-003426-PIP01-23
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 June 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 April 2025
Global end of trial reached?	Yes
Global end of trial date	12 April 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study were:
- To demonstrate a non-inferior neutralizing antibody (nAb) response of mRNA-1283.222 compared to mRNA-1273.222 against Omicron BA.4/5 and ancestral Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) D614G based on geometric mean ratio (GMR) and seroresponse rate (SRR) difference at Day 29.
- To demonstrate non-inferior relative vaccine efficacy (rVE) of mRNA-1283 compared to mRNA-1273 (variant formulations) to prevent COVID 19.
- To evaluate the safety and reactogenicity of mRNA-1283.222.

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, Council for International Organizations of Medical Sciences, International Ethical Guidelines, applicable International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, and other applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 March 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: 8634
Country: Number of subjects enrolled	Canada: 213
Country: Number of subjects enrolled	United Kingdom: 2569
Worldwide total number of subjects	11416
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)	992
Adults (18-64 years)	7150
From 65 to 84 years	3227
85 years and over	47

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 11453 participants were randomized, and 11416 participants were dosed, of which 5706 participants were in the mRNA-1283.222 group and 5710 participants were in the mRNA-1273.222 group.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	mRNA-1283.222

Arm description:

Participants received a single intramuscular (IM) injection of mRNA-1283.222 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1283.222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1283.222 was administered per schedule specified in the arm description.

Arm title	mRNA-1273.222

Arm description:

Participants received a single IM injection of mRNA-1273.222 on Day 1.

Arm type	Active comparator
Investigational medicinal product name	mRNA-1273.222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.222 was administered per schedule specified in the arm description.

Number of subjects in period 1	mRNA-1283.222	mRNA-1273.222
Started	5706	5710
Completed	5312	5373
Not completed	394	337
Adverse event, serious fatal	7	11
Physician decision	14	10
Consent withdrawn by subject	181	157
Other Than Specified	4	4
Adverse event, non-fatal	4	2
Pregnancy	2	-
Lost to follow-up	180	152
Protocol deviation	2	1

Baseline characteristics

Reporting groups	
Reporting group title	mRNA-1283.222
Reporting group description:	
Participants received a single intramuscular (IM) injection of mRNA-1283.222 on Day 1.	
Reporting group title	mRNA-1273.222
Reporting group description:	
Participants received a single IM injection of mRNA-1273.222 on Day 1.	

Reporting group values	mRNA-1283.222	mRNA-1273.222	Total
Number of subjects	5706	5710	11416
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	51.1	51.2	
standard deviation	± 18.58	± 18.32	-
Gender Categorical Units: Subjects			
Female	3120	3079	6199
Male	2586	2631	5217
Race Units: Subjects			
White	4670	4711	9381
Black or African American	640	634	1274
Asian	225	183	408
American Indian or Alaska Native	20	26	46
Native Hawaiian or Other Pacific Islander	9	6	15
Multiple	81	94	175
Other	20	20	40
Not Reported	36	26	62
Unknown	5	10	15
Ethnicity Units: Subjects			
Hispanic or Latino	769	741	1510
Not Hispanic or Latino	4860	4863	9723
Not Reported	59	87	146
Unknown	18	19	37

End points

End points reporting groups	
Reporting group title	mRNA-1283.222
Reporting group description:	
Participants received a single intramuscular (IM) injection of mRNA-1283.222 on Day 1.	
Reporting group title	mRNA-1273.222
Reporting group description:	
Participants received a single IM injection of mRNA-1273.222 on Day 1.	

Primary: Geometric Mean (GM) of Omicron BA.4/5 at Day 29	
End point title	Geometric Mean (GM) of Omicron BA.4/5 at Day 29
End point description:	
Antibody values reported as below the lower limit of quantification (LLOQ) were replaced by 0.5*LLOQ. Values greater than the upper limit of quantification (ULOQ) were replaced by the ULOQ if actual values were not available. LLOQ was 103 arbitrary units (AU)/milliliter (mL) and ULOQ was 28571 AU/mL. Per-Protocol Immunogenicity Set (PPIS) included all randomized participants who received the planned dose of study vaccination, had baseline and Day 29 nAb data, and had no major protocol deviations that impacted key or critical data.	
End point type	Primary
End point timeframe:	
Day 29	

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	621	568		
Units: AU/mL				
geometric mean (confidence interval 95%)	2340.9 (2167.0 to 2528.8)	1753.8 (1618.2 to 1900.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Geometric mean ratio (GMR) of Omicron BA.4/5 mRNA-1283.222 over the Omicron BA.4/5 mRNA-1273.222 was the primary endpoint.	
Comparison groups	mRNA-1283.222 v mRNA-1273.222
Number of subjects included in analysis	1189
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	GMR
Point estimate	1.335

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.194
upper limit	1.492

Notes:

[1] - Noninferiority margin for GMR was 0.667 (1/1.5).

Primary: Seroresponse Rate (SRR) Omicron BA.4/5 at Day 29

End point title	Seroresponse Rate (SRR) Omicron BA.4/5 at Day 29

End point description:

Seroresponse was defined as an antibody value change from baseline below the LLOQ to ≥4*LLOQ, or at least a 4-fold rise if baseline was ≥LLOQ and <4*LLOQ, or at least a 2-fold rise if baseline was ≥4*LLOQ, where baseline referred to pre-booster. LLOQ was 103 AU/mL and ULOQ was 28571 AU/mL. PPIS included all randomized participants who received the planned dose of study vaccination, had baseline and Day 29 (occurring between 21 and 42 days after vaccination) nAb data, and had no major protocol deviations that impacted key or critical data.

End point type	Primary

End point timeframe:

Day 29

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	621	568		
Units: percentage of participants				
number (confidence interval 95%)	79.9 (76.5 to 83.0)	65.5 (61.4 to 69.4)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

SRR difference of Omicron BA.4/5 between mRNA-1283.222 and mRNA-1273.222 was the primary endpoint.

Comparison groups	mRNA-1283.222 v mRNA-1273.222
Number of subjects included in analysis	1189
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	SRR Difference
Point estimate	14.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.3
upper limit	19.4

Notes:

[2] - Noninferiority margin for SRR difference was 10%.

Primary: GM of the Ancestral Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) D614G at Day 29

End point title	GM of the Ancestral Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) D614G at Day 29

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PPIS included all randomized participants who received the planned dose of study vaccination, had baseline and Day 29 nAb data, and had no major protocol deviations that impacted key or critical data.

End point type	Primary

End point timeframe:

Day 29

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	621	568		
Units: AU/mL				
geometric mean (confidence interval 95%)	10631.9 (9960.2 to 11348.9)	8576.5 (8012.5 to 9180.1)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

GMR of the ancestral SARS-CoV-2 D614G mRNA-1283.222 over the ancestral SARS-CoV-2 D614G mRNA-1273.222 was the primary endpoint.

Comparison groups	mRNA-1283.222 v mRNA-1273.222
Number of subjects included in analysis	1189
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	GMR
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.128
upper limit	1.362

Notes:

[3] - Noninferiority margin for GMR was 0.667 (1/1.5).

Primary: SRR of Ancestral SARS-CoV-2 D641G at Day 29

End point title	SRR of Ancestral SARS-CoV-2 D641G at Day 29

End point description:

Seroresponse was defined as an antibody value change from baseline below the LLOQ to ≥4*LLOQ, or at least a 4-fold rise if baseline was ≥LLOQ and <4*LLOQ, or at least a 2-fold rise if baseline was ≥4*LLOQ, where baseline referred to pre-booster. LLOQ was 10 AU/mL and ULOQ was 111433AU/mL. PPIS included all randomized participants who received the planned dose of study vaccination, had baseline and Day 29 nAb data, and had no major protocol deviations that impacted key or critical data.

End point type	Primary

End point timeframe:

Day 29

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	621	568		
Units: percentage of participants				
number (confidence interval 95%)	83.6 (80.4 to 86.4)	72.9 (69.0 to 76.5)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

SRR difference of ancestral SARS-CoV-2 D641G between mRNA-1283.222 and mRNA-1273.222 was the primary endpoint.

Comparison groups	mRNA-1283.222 v mRNA-1273.222
Number of subjects included in analysis	1189
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	SRR Difference
Point estimate	10.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	6
upper limit	15.4

Notes:

[4] - Noninferiority margin for SRR difference was 10%.

Primary: Number of Participants With First Event of Centers for Disease Control and Prevention (CDC)-defined COVID-19

End point title	Number of Participants With First Event of Centers for Disease Control and Prevention (CDC)-defined COVID-19

End point description:

CDC COVID-19 definition: the presence of at least 1 CDC listed symptom and positive reverse transcriptase polymerase chain reaction (RT-PCR) test on a respiratory sample. The Per-Protocol Set for Efficacy (PPSE) included all randomized participants who received the planned dose of study drug and had no major protocol deviations that impacted vaccine efficacy data.

End point type	Primary

End point timeframe:

From 14 days after injection up to Day 365

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5679	5687		
Units: participants	560	617		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Relative vaccine efficacy (rVE) of mRNA-1283 and mRNA-1273 (variant formulations) to prevent the first event of CDC-defined COVID-19 was the primary endpoint.
rVE was defined as 1 - hazard ratio (mRNA-1283.222 versus mRNA-1273.222).

Comparison groups	mRNA-1283.222 v mRNA-1273.222
Number of subjects included in analysis	11366
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
P-value	= 0.0005
Method	Cox proportional hazard model
Parameter estimate	rVE
Point estimate	9.31
Confidence interval	
level	Other: 99.4 %
sides	2-sided
lower limit	-6.58
upper limit	22.83

Notes:

[5] - Noninferiority margin for rVE was 10%.

Primary: Number of Participants with Solicited Local and Systemic Reactogenicity Adverse Reactions (ARs)

End point title	Number of Participants with Solicited Local and Systemic Reactogenicity Adverse Reactions (ARs)[6]

End point description:

Solicited ARs were recorded daily using electronic diaries (eDiaries). Local ARs: injection site pain, erythema (redness), swelling/induration (hardness); and axillary (underarm) swelling or tenderness ipsilateral to the side of injection. Systemic ARs: fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Note, not all solicited ARs were considered adverse events (AEs). Investigator reviewed whether the solicited AR was also to be recorded as an AE. A Summary of serious AEs (SAEs) and nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. The Solicited Safety Set included all randomized participants who received study drug and contributed any solicited AR data.

End point type	Primary

End point timeframe:

Up to Day 7 (7-day follow-up after vaccination)

Notes:

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

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5702	5705		
Units: participants	4571	4781		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Unsolicited Adverse Events (AEs)

End point title	Number of Participants with Unsolicited Adverse Events (AEs)[7]

End point description:

An unsolicited AE was defined as any AE reported by the participant that was not specified as a solicited AR in the protocol. An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. A summary of all Serious Adverse Events and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. The Safety Set included all randomized participants who received study drug.

End point type	Primary

End point timeframe:

Up to Day 28 (28-day follow-up 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: The endpoint is descriptive in nature.

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5706	5710		
Units: participants	706	683		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Any Serious AEs (SAEs), Medically Attended AEs (MAAEs), AEs Leading to Withdrawal From Study, and AEs of Special Interest (AESIs)

End point title	Number of Participants with Any Serious AEs (SAEs), Medically Attended AEs (MAAEs), AEs Leading to Withdrawal From Study, and AEs of Special Interest (AESIs)[8]

End point description:

SAEs were AEs that resulted in death, were life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly or birth defect, or was a

medically important event. MAAEs were AEs that lead to an unscheduled visit to a healthcare provider. AESIs were AEs (serious or nonserious) of scientific and medical concern specific to the Sponsor's product or program for which ongoing monitoring and immediate notification by the investigator to the Sponsor was required. A summary of all Serious Adverse Events and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. The Safety Set included all randomized participants who received study drug.

End point type	Primary

End point timeframe:

Day 1 up to Day 365

Notes:

[8] - 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: The endpoint is descriptive in nature.

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5706	5710		
Units: participants				
SAEs	203	197		
MAAEs	2165	2120		
AEs Leading to Withdrawal From Study	11	13		
AESIs	79	75		

Statistical analyses

No statistical analyses for this end point

Secondary: GMs of Omicron BA.4/5 and Ancestral SARS-CoV-2 D614G

End point title	GMs of Omicron BA.4/5 and Ancestral SARS-CoV-2 D614G

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available. LLOQ was 103 AU/mL and ULOQ was 28571 AU/mL for Omicron BA.4/5. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL for ancestral SARS-CoV-2 D614G. PPIS included all randomized participants who received the planned dose of study vaccination, had baseline and Day 29 nAb data, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary

End point timeframe:

Days 91, 181, and 365

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	605	552		
Units: AU/mL				
geometric mean (confidence interval 95%)				

Omicron BA.4/5: Day 91 (n=605,552)	1513.2 (1400.9 to 1634.5)	1137.8 (1049.8 to 1233.3)		
Omicron BA.4/5: Day 181 (n=541,520)	1113.3 (1022.4 to 1212.3)	863.7 (792.1 to 941.9)		
Omicron BA.4/5: Day 365 (n=506,488)	753.3 (690.2 to 822.2)	625.9 (572.8 to 684.0)		
SARS-CoV-2 D614G: Day 91 (n=605,552)	6537.7 (6086.0 to 7023.0)	5414.0 (5023.9 to 5834.3)		
SARS-CoV-2 D614G: Day 181 (n=540,520)	4753.2 (4381.5 to 5156.5)	3861.8 (3555.3 to 4194.6)		
SARS-CoV-2 D614G: Day 365 (n=506,488)	2878.9 (2645.2 to 3133.3)	2545.0 (2335.6 to 2773.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: SRR Against Omicron BA.4/5 and Ancestral SARS-CoV-2 D614G at Days 91, 181, and 365

End point title	SRR Against Omicron BA.4/5 and Ancestral SARS-CoV-2 D614G at Days 91, 181, and 365

End point description:

Seroresponse was defined as an antibody value change from baseline below the LLOQ to ≥4*LLOQ, or at least a 4-fold rise if baseline was ≥LLOQ and <4*LLOQ, or at least a 2-fold rise if baseline was ≥4*LLOQ, where baseline referred to pre-booster. LLOQ was 103 AU/mL and ULOQ was 28571 AU/mL for Omicron BA.4/5. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL for ancestral SARS-CoV-2 D614G. PPIS included all randomized participants who received the planned dose of study vaccination, had baseline and Day 29 nAb data, and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified category.

End point type	Secondary

End point timeframe:

Days 91, 181, and 365

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	605	552		
Units: percentage of participants				
number (confidence interval 95%)				
Omicron BA.4/5: Day 91 (n=605,552)	59.5 (55.5 to 63.4)	45.8 (41.6 to 50.1)		
Omicron BA.4/5: Day 181 (n=541,520)	45.7 (41.4 to 50.0)	37.1 (33.0 to 41.4)		
Omicron BA.4/5: Day 365 (n=506,488)	30.0 (26.1 to 34.2)	26.4 (22.6 to 30.6)		
SARS-CoV-2 D614G Day 91 (n=605,552)	64.8 (60.8 to 68.6)	52.9 (48.6 to 57.1)		

SARS-CoV-2 D614G Day 181 (n=540,520)	45.6 (41.3 to 49.9)	39.0 (34.8 to 43.4)		
SARS-CoV-2 D614G Day 365 (n=506,488)	26.3 (22.5 to 30.4)	25.4 (21.6 to 29.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with a SARS-CoV-2 Infection (Symptomatic or Asymptomatic)

End point title	Number of Participants with a SARS-CoV-2 Infection (Symptomatic or Asymptomatic)

End point description:

SARS-CoV-2 infection (symptomatic or asymptomatic) was defined as (1) negative binding antibody (bAb) level against SARS-CoV-2 nucleocapsid protein and negative RT-PCR at baseline that became positive bAb level against SARS-CoV-2 nucleocapsid protein post-baseline, or (2) positive RT-PCR post-baseline. Asymptomatic SARS-CoV-2 infection was characterized by the absence of COVID-19 symptoms. The PPSE included all randomized participants who received the planned dose of study drug and had no major protocol deviations that impacted vaccine efficacy data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From 14 days after injection up to Day 365

End point values	mRNA-1283.222	mRNA-1273.222		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5676	5684		
Units: participants	1249	1290		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 1 up to Day 365	
Adverse event reporting additional description:	
The Safety Set included all randomized participants who received study drug. 'Subject Disposition module' reported the number of participants who discontinued from the study due to death. 'Adverse Events module' reported "Total number of Deaths (all causes)".	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups	
Reporting group title	mRNA-1273.222
Reporting group description:	
Participants received a single IM injection of mRNA-1273.222 on Day 1.	
Reporting group title	mRNA-1283.222
Reporting group description:	
Participants received a single IM injection of mRNA-1283.222 on Day 1.	

Serious adverse events	mRNA-1273.222	mRNA-1283.222	
Total subjects affected by serious adverse events			
subjects affected / exposed	197 / 5710 (3.45%)	203 / 5706 (3.56%)	
number of deaths (all causes)	11	9	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Chronic myeloid leukaemia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer recurrent			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoma benign			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular lymphoma			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage III			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal cancer			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	2 / 5710 (0.04%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal carcinoma			
subjects affected / exposed	2 / 5710 (0.04%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ovarian cancer			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer stage II			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma stage I			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma stage IV			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia vera			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic gastric cancer			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	4 / 5710 (0.07%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular germ cell cancer			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Orthostatic hypotension			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Deep vein thrombosis			
subjects affected / exposed	3 / 5710 (0.05%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial vein thrombosis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 5710 (0.02%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death	Additional description: Arm mRNA-1273.222: >70 year-old participant with significant cardiovascular disease; cause of death at Day 7 was reported as unknown and related to vaccine by PI due to temporality. Sponsor assessed this and all other fatal events as unrelated.		
subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	1 / 2	0 / 2	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 5710 (0.02%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Cystic lung disease				
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Combined pulmonary fibrosis and emphysema				
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Chronic obstructive pulmonary disease				
subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Asthma				
subjects affected / exposed	1 / 5710 (0.02%)	5 / 5706 (0.09%)		
occurrences causally related to treatment / all	0 / 1	0 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
Acute respiratory failure				
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 1		
Pleural effusion				
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Pulmonary embolism				
subjects affected / exposed	3 / 5710 (0.05%)	5 / 5706 (0.09%)		
occurrences causally related to treatment / all	0 / 3	0 / 5		
deaths causally related to treatment / all	0 / 1	0 / 0		
Pneumothorax spontaneous				

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	3 / 5710 (0.05%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 5710 (0.04%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anxiety			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression suicidal			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 5710 (0.00%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal behaviour			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	3 / 5710 (0.05%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed	2 / 5710 (0.04%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 5710 (0.00%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniofacial fracture			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle injury			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	2 / 5710 (0.04%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Traumatic arthritis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic fracture			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Urachal abnormality			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute left ventricular failure			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	3 / 5710 (0.05%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Angina pectoris			
subjects affected / exposed	4 / 5710 (0.07%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	2 / 5710 (0.04%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	7 / 5710 (0.12%)	4 / 5706 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	2 / 5710 (0.04%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			

subjects affected / exposed	1 / 5710 (0.02%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cardiac failure congestive			
subjects affected / exposed	2 / 5710 (0.04%)	4 / 5706 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery occlusion			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tachycardia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			

subjects affected / exposed	6 / 5710 (0.11%)	7 / 5706 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pericarditis	Additional description: In arm mRNA-1283.222, a participant of >50 year-old, the event was reported at Day 343 after vaccination as not related to vaccination by the Principal investigator (PI).		
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bell's palsy			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	3 / 5710 (0.05%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	2 / 5710 (0.04%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	3 / 5710 (0.05%)	5 / 5706 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 5710 (0.02%)	4 / 5706 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Speech disorder			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postictal paralysis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	2 / 5710 (0.04%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
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			
Blood loss anaemia			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	1 / 5710 (0.02%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	2 / 5710 (0.04%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinal tear			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia obstructive			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal mass			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Abdominal wall haematoma			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	2 / 5710 (0.04%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilic oesophagitis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	3 / 5710 (0.05%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hiatus hernia strangulated			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	2 / 5710 (0.04%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	2 / 5710 (0.04%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer perforation			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 5710 (0.02%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 5710 (0.04%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Gallbladder rupture			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	3 / 5710 (0.05%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatic failure			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis alcoholic			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic mass			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	2 / 5710 (0.04%)	6 / 5706 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Pituitary enlargement			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute aseptic arthritis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Back pain			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	6 / 5710 (0.11%)	10 / 5706 (0.18%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oligoarthritis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (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			
Arthritis bacterial			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			

subjects affected / exposed	0 / 5710 (0.00%)	4 / 5706 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial food poisoning			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	4 / 5710 (0.07%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bordetella infection			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coccidioidomycosis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	5 / 5710 (0.09%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			

subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bite			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningoencephalitis viral			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	4 / 5710 (0.07%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	11 / 5710 (0.19%)	6 / 5706 (0.11%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			

subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	3 / 5710 (0.05%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 5710 (0.00%)	4 / 5706 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	2 / 5710 (0.04%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 5710 (0.00%)	2 / 5706 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 5710 (0.00%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Electrolyte imbalance			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	3 / 5710 (0.05%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	2 / 5710 (0.04%)	3 / 5706 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 5710 (0.02%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	1 / 5710 (0.02%)	0 / 5706 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypomagnesaemia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 5710 (0.00%)	1 / 5706 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	mRNA-1273.222	mRNA-1283.222	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	636 / 5710 (11.14%)	607 / 5706 (10.64%)	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	636 / 5710 (11.14%)	607 / 5706 (10.64%)	
occurrences (all)	820	813	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 May 2023	This amendment introduced the primary rVE objective (noninferior efficacy of mRNA-1283 versus mRNA-1273) with a sample size increase up to 10748 participants. rVE was a key secondary study objective in the original study protocol.
08 August 2023	This amendment introduced a sample size increase specifically for the adolescent group, to enroll approximately 1000 adolescents.
20 December 2023	This amendment prespecified a noninferiority rVE margin of 10% (mRNA-1283 versus mRNA-1273) for the primary rVE objective.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported