



Clinical trial results:

A Phase 2/3, Randomized, Observer-blind, Active-controlled, Multicenter Study to Evaluate the Immunogenicity and Safety of Omicron Variant Vaccines in Comparison with mRNA-1273 (Prototype) Booster Vaccine Summary

EudraCT number	2022-000063-51
Trial protocol	Outside EU/EEA
Global end of trial date	23 June 2023

Results information

Result version number	v1 (current)
This version publication date	06 June 2024
First version publication date	06 June 2024

Trial information

Trial identification

Sponsor protocol code	mRNA-1273-P305
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05249829
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., +1 877-777-7187, clinicaltrials@modernatx.com
Scientific contact	Moderna Clinical Trials Support Center, ModernaTX, Inc., +1 877-777-7187, clinicaltrials@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	23 June 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

mRNA-1273-P305 is a Phase 2/3, 2-part, randomized, observer-blind, active-controlled, multicentre study to evaluate the immunogenicity and safety of the mRNA-1273.529 vaccine and mRNA-1273.214 vaccine, and the original mRNA-1273 vaccine in medically stable individuals 16 years and older.

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 February 2022
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 Kingdom: 3548
Worldwide total number of subjects	3548
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)	1
Adults (18-64 years)	2349
From 65 to 84 years	1193
85 years and over	5

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Of the 3779 participants who were screened for Part 1 and Part 2 of the study, 220 participants failed screening and 11 did not receive study vaccine.

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	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Phase A of this study was observer blinded. Phase B of the study was open label and blinding was not applicable.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: mRNA-1273.529

Arm description:

Phase A: Participants will receive 1 intramuscular (IM) dose of mRNA-1273.529 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.529
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Sterile liquid for injection.

Arm title	Part 1: mRNA-1273
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Arm description:

Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Arm type	Active comparator
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Sterile liquid for injection.

Arm title	Part 2: mRNA-1273.214
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Arm description:

Phase A: Participants will receive 1 IM dose of mRNA-1273.214 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Arm type	Experimental
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Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Sterile liquid for injection.	
Arm title	Part 2: mRNA-1273

Arm description:

Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Arm type	Active comparator
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Sterile liquid for injection.

Number of subjects in period 1	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214
Started	367	357	1422
Received at Least 1 Dose of Study Drug	367	357	1422
Full Analysis Set (FAS)	363	357	1422
Completed	337	320	1314
Not completed	30	37	108
Consent withdrawn by subject	9	17	40
Physician decision	1	-	-
Adverse event, non-fatal	2	2	2
Death	-	1	2
Participant Relocation	-	1	2
Lost to follow-up	16	16	57
COVID-19 Non-Infection Related	-	-	-
Protocol deviation	2	-	5

Number of subjects in period 1	Part 2: mRNA-1273
Started	1402
Received at Least 1 Dose of Study Drug	1402
Full Analysis Set (FAS)	1402
Completed	1295
Not completed	107
Consent withdrawn by subject	35
Physician decision	-

Adverse event, non-fatal	2
Death	4
Participant Relocation	2
Lost to follow-up	60
COVID-19 Non-Infection Related	1
Protocol deviation	3

Baseline characteristics

Reporting groups

Reporting group title	Part 1: mRNA-1273.529
Reporting group description:	
Phase A: Participants will receive 1 intramuscular (IM) dose of mRNA-1273.529 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	
Reporting group title	Part 1: mRNA-1273
Reporting group description:	
Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	
Reporting group title	Part 2: mRNA-1273.214
Reporting group description:	
Phase A: Participants will receive 1 IM dose of mRNA-1273.214 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	
Reporting group title	Part 2: mRNA-1273
Reporting group description:	
Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	

Reporting group values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214
Number of subjects	367	357	1422
Age Categorical Units: Participants			
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	57.6	57.3	57.4
standard deviation	± 12.93	± 13.22	± 12.53
Gender Categorical Units: Participants			
Female	200	202	695
Male	167	155	727
Race Units: Subjects			
White	353	335	1347
Mixed or Multiple Ethnic Groups	3	5	21
Asian or Asian British	10	10	31
Black, African, Caribbean, or Black British	0	0	6

Other Ethnic Group	1	5	4
Not Reported	0	2	11
Unknown	0	0	2

Reporting group values	Part 2: mRNA-1273	Total	
Number of subjects	1402	3548	
Age Categorical Units: Participants			
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	57.0		
standard deviation	± 12.81	-	
Gender Categorical Units: Participants			
Female	694	1791	
Male	708	1757	
Race Units: Subjects			
White	1313	3348	
Mixed or Multiple Ethnic Groups	27	56	
Asian or Asian British	41	92	
Black, African, Caribbean, or Black British	6	12	
Other Ethnic Group	7	17	
Not Reported	7	20	
Unknown	1	3	

End points

End points reporting groups

Reporting group title	Part 1: mRNA-1273.529
Reporting group description: Phase A: Participants will receive 1 intramuscular (IM) dose of mRNA-1273.529 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	
Reporting group title	Part 1: mRNA-1273
Reporting group description: Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	
Reporting group title	Part 2: mRNA-1273.214
Reporting group description: Phase A: Participants will receive 1 IM dose of mRNA-1273.214 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	
Reporting group title	Part 2: mRNA-1273
Reporting group description: Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.	
Subject analysis set title	PPSI-Neg
Subject analysis set type	Per protocol
Subject analysis set description: The Per-Protocol Set for Immunogenicity–SARS-CoV-2 negative (PPSI-Neg) included all randomized participants who received the planned dose of the study vaccine, had no major protocol deviations that had an impact on critical or key study data, and had no serologic or virologic evidence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection at Baseline and up to the day of the analysis visit.	
Subject analysis set title	Solicited Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All randomized participants who received the study vaccine and contributed any solicited adverse reaction (AR) data within the first 7 days after study vaccine administration.	
Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All randomized participants who received the study vaccine. Participants were included in the study vaccine arm that they actually received.	
Subject analysis set title	Per-Protocol Set for Efficacy
Subject analysis set type	Per protocol
Subject analysis set description: All participants with a pre-vaccination/Baseline SARS-CoV-2 negative status who received the planned dose of study vaccination and had no major protocol deviations that had an impact on key or critical data.	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description: All randomized participants who received the study vaccine. Participants were analysed according to their randomized study vaccine arm.	

Primary: Part 1: Geometric Mean Concentration (GMC) of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 29

End point title	Part 1: Geometric Mean Concentration (GMC) of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 29 ^[1]
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End point description:

Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. Results are reported as absorbance units/millilitre (AU/mL). The GMC 95% confidence interval (CI) was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Primary
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End point timeframe:

Day 29 (post vaccination)

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 1, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	274 ^[2]	277 ^[3]		
Units: AU/mL				
geometric mean (confidence interval 95%)	537.7 (478.2 to 604.6)	302.8 (274.8 to 333.6)		

Notes:

[2] - PPSI-Neg

[3] - PPSI-Neg

Statistical analyses

Statistical analysis title	Day 29: mRNA-1273.529 Non-Inferiority
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Statistical analysis description:

Geometric Mean Ratio = GMCmRNA-1273.529/GMCmRNA-1273 against the B.1.1.529 strain at Day 29 after study vaccine administration.

Comparison groups	Part 1: mRNA-1273.529 v Part 1: mRNA-1273
Number of subjects included in analysis	551
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.73
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	1.493
upper limit	2.005

Notes:

[4] - Non-inferiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >0.667.

Primary: Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 85

End point title	Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 85 ^[5]
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End point description:

Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Primary
End point timeframe:	
Day 85 (post vaccination)	
Notes:	
[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.	
Justification: Only statistics are reported for Part 1, as prespecified in the statistical analysis plan.	

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	234 ^[6]	226 ^[7]		
Units: AU/mL				
geometric mean (confidence interval 95%)	284.7 (248.0 to 326.7)	152.6 (135.1 to 172.3)		

Notes:

[6] - PPSI-Neg

[7] - PPSI-Neg

Statistical analyses

Statistical analysis title	Day 85: mRNA-1273.529 Non-Inferiority
Statistical analysis description:	
Geometric Mean Ratio = GMCmRNA-1273.529/GMCmRNA-1273 against the B.1.1.529 strain at Day 85 after study vaccine administration.	
Comparison groups	Part 1: mRNA-1273.529 v Part 1: mRNA-1273
Number of subjects included in analysis	460
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[8]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.763
Confidence interval	
level	Other: 96 %
sides	2-sided
lower limit	1.546
upper limit	2.01

Notes:

[8] - Non-inferiority was demonstrated if the lower bound of the 96% CI of the Geometric Mean Ratio was >0.667.

Primary: Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the B1.1.529 Strain at Day 29

End point title	Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the B1.1.529 Strain at Day 29 ^[9]
End point description:	
Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.	
End point type	Primary
End point timeframe:	
Day 29 (post vaccination)	

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	968 ^[10]	894 ^[11]		
Units: AU/mL				
geometric mean (confidence interval 95%)	465.7 (437.0 to 496.3)	311.0 (292.9 to 330.1)		

Notes:

[10] - PPSI-Neg

[11] - PPSI-Neg

Statistical analyses

Statistical analysis title	Day 29: Geometric Mean Ratio
Statistical analysis description: Geometric Mean Ratio = GMCmRNA-1273.214/GMCmRNA-1273 against the B.1.1.529 strain at Day 29 after study vaccine administration.	
Comparison groups	Part 2: mRNA-1273.214 v Part 2: mRNA-1273
Number of subjects included in analysis	1862
Analysis specification	Pre-specified
Analysis type	other ^[12]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.535
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	1.409
upper limit	1.672

Notes:

[12] - Non-inferiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >0.667. Superiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >1.

Primary: Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the B1.1.529 Strain at Day 85

End point title	Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the B1.1.529 Strain at Day 85 ^[13]
End point description: Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.	
End point type	Primary
End point timeframe: Day 85 (post vaccination)	

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	761 ^[14]	688 ^[15]		
Units: AU/mL				
geometric mean (confidence interval 95%)	258.2 (239.3 to 278.7)	153.0 (142.2 to 164.6)		

Notes:

[14] - PPSI-Neg

[15] - PPSI-Neg

Statistical analyses

Statistical analysis title	Day 85: Geometric Mean Ratio
Statistical analysis description:	
Geometric Mean Ratio = GMCmRNA-1273.214/GMCmRNA-1273 against the B.1.1.529 strain at Day 85 after study vaccine administration.	
Comparison groups	Part 2: mRNA-1273.214 v Part 2: mRNA-1273
Number of subjects included in analysis	1449
Analysis specification	Pre-specified
Analysis type	other ^[16]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.713
Confidence interval	
level	Other: 96 %
sides	2-sided
lower limit	1.583
upper limit	1.853

Notes:

[16] - Non-inferiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >0.667. Superiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >1.

Primary: Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the Ancestral Strain at Day 29

End point title	Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the Ancestral Strain at Day 29 ^[17]
End point description:	
Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. The ancestral (prototype) strain was Wuhan-Hu-1. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.	
End point type	Primary
End point timeframe:	
Day 29 (post vaccination)	

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	951 ^[18]	880 ^[19]		
Units: AU/mL				
geometric mean (confidence interval 95%)	2998.8 (2825.4 to 3182.8)	2933.6 (2772.3 to 3104.4)		

Notes:

[18] - PPSI-Neg

[19] - PPSI-Neg

Statistical analyses

Statistical analysis title	Day 29: mRNA-1273.214 Non-Inferiority
Statistical analysis description:	
Geometric Mean Ratio = GMCmRNA-1273.214/GMCmRNA-1273 against the ancestral strain at Day 29 after study vaccine administration. Reported statistical analysis based upon the number of participants with non-missing data at baseline and the corresponding timepoint (N=1818).	
Comparison groups	Part 2: mRNA-1273.214 v Part 2: mRNA-1273
Number of subjects included in analysis	1831
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[20]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.048
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	0.958
upper limit	1.147

Notes:

[20] - Non-inferiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >0.667.

Primary: Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the Ancestral Strain ay Day 85

End point title	Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against the Ancestral Strain ay Day 85 ^[21]
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End point description:

Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. The ancestral strain was Wuhan-Hu-1. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Primary
End point timeframe:	
Day 85 (post vaccination)	

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	761 ^[22]	685 ^[23]		
Units: AU/mL				
geometric mean (confidence interval 95%)	1753.1 (1650.0 to 1862.6)	1610.2 (1519.6 to 1706.2)		

Notes:

[22] - PPSI-Neg

[23] - PPSI-Neg

Statistical analyses

Statistical analysis title	Day 85: mRNA-1273.214 Non-Inferiority
Statistical analysis description:	
Geometric Mean Ratio = GMCmRNA-1273.214/GMCmRNA-1273 against the ancestral strain at Day 85 after study vaccine administration. Reported statistical analysis based upon the number of participants with non-missing data at baseline and the corresponding timepoint (N=1418).	
Comparison groups	Part 2: mRNA-1273.214 v Part 2: mRNA-1273
Number of subjects included in analysis	1446
Analysis specification	Pre-specified
Analysis type	other ^[24]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.104
Confidence interval	
level	Other: 96 %
sides	2-sided
lower limit	1.032
upper limit	1.18

Notes:

[24] - Non-inferiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >0.667.

Primary: Parts 1 and 2: Percentage of Participants with Solicited Local and Systemic Reactogenicity ARs

End point title	Parts 1 and 2: Percentage of Participants with Solicited Local and Systemic Reactogenicity ARs ^[25]
End point description:	
Reactogenicity refers to the occurrence and intensity of selected signs and symptoms (ARs) occurring after vaccine injection. Participants recorded such occurrences in an electronic diary on the day of study vaccine injection and for the 7 days after the day of dosing. Solicited local ARs were injection site pain, injection site erythema (redness), injection site swelling/induration (hardness), and axillary (underarm) swelling or tenderness ipsilateral to the side of the injection. Solicited systemic ARs were headache, fatigue, myalgia (muscle aches all over the body), arthralgia (joint aches in several joints), nausea/vomiting, chills, and fever (oral temperature). The Investigator determined if a solicited AR was also to be recorded as an adverse event (AE). A summary of all Serious and Non Serious AEs, regardless of causality, is located in the 'Adverse Events' section. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.	
End point type	Primary
End point timeframe:	
Up to Day 8 (7 days post-vaccination)	

Notes:

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

Justification: Only descriptive statistics (percentage of participants plus confidence interval) are reported for this primary end point, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214	Part 2: mRNA-1273
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	367 ^[26]	357 ^[27]	1421 ^[28]	1398 ^[29]
Units: percentage of participants				
number (confidence interval 95%)				
Any Solicited Local ARs	84.5 (80.4 to 88.0)	89.1 (85.4 to 92.1)	83.6 (81.6 to 85.5)	89.9 (88.2 to 91.4)
Any Solicited Systemic ARs	69.8 (64.8 to 74.4)	74.2 (69.4 to 78.7)	70.2 (67.7 to 72.5)	75.3 (73.0 to 77.6)

Notes:

[26] - Solicited Safety Set

[27] - Solicited Safety Set

[28] - Solicited Safety Set

[29] - Solicited Safety Set

Statistical analyses

No statistical analyses for this end point

Primary: Parts 1 and 2: Number of Participants with Unsolicited AEs

End point title	Parts 1 and 2: Number of Participants with Unsolicited AEs ^[30]
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End point description:

An AE was any untoward medical occurrence associated with the use of a drug/vaccine, whether or not considered related to the drug/vaccine. An unsolicited AE was any AE reported by the participant that is not specified as a solicited AR in the protocol or is specified as a solicited AR but starts outside the protocol-defined period for reporting solicited ARs (that is, 7 days after vaccination). A summary of all Serious and Non Serious AEs, regardless of causality, is located in the 'Adverse Events' section.

End point type	Primary
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End point timeframe:

Up to Day 29 (28 days post-vaccination)

Notes:

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

Justification: Only descriptive statistics (percentage of participants plus confidence interval) are reported for this primary end point, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214	Part 2: mRNA-1273
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	367 ^[31]	357 ^[32]	1422 ^[33]	1402 ^[34]
Units: participants	142	124	442	429

Notes:

[31] - Safety Set

[32] - Safety Set

[33] - Safety Set

[34] - Safety Set

Statistical analyses

No statistical analyses for this end point

Primary: Parts 1 and 2: Number of Participants with Serious AEs (SAEs)

End point title	Parts 1 and 2: Number of Participants with Serious AEs
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End point description:

An AE was considered an SAE if, in the view of either the investigator or Sponsor, it resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization (hospitalization or prolongation of hospitalization in the absence of a precipitating event was not in itself an SAE), resulted in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, was a congenital anomaly/birth defect, or was a medically important event. A summary of all Serious and Non Serious AEs, regardless of causality, is located in the 'Adverse Events' section.

End point type	Primary
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End point timeframe:

Day 1 to end of study (Day 359)

Notes:

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

Justification: Only descriptive statistics (percentage of participants plus confidence interval) are reported for this primary end point, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214	Part 2: mRNA-1273
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	367 ^[36]	357 ^[37]	1422 ^[38]	1402 ^[39]
Units: participants	20	13	60	72

Notes:

[36] - Safety Set

[37] - Safety Set

[38] - Safety Set

[39] - Safety Set

Statistical analyses

No statistical analyses for this end point

Primary: Parts 1 and 2: Number of Participants with Medically Attended AEs (MAAEs)

End point title	Parts 1 and 2: Number of Participants with Medically Attended AEs (MAAEs) ^[40]
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End point description:

An MAAE is an AE that leads to an unscheduled visit to a healthcare practitioner (HCP). This would include visits to a clinic for unscheduled assessments (for example, rash assessment, abnormal laboratory follow-up, coronavirus disease 2019 [COVID-19]) and visits to HCPs external to the clinic (for example, urgent care, primary care physician). A summary of all Serious and Non Serious AEs, regardless of causality, is located in the 'Adverse Events' section.

End point type	Primary
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End point timeframe:

Day 1 to end of study (Day 359)

Notes:

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

Justification: Only descriptive statistics (percentage of participants plus confidence interval) are reported for this primary end point, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214	Part 2: mRNA-1273
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	367 ^[41]	357 ^[42]	1422 ^[43]	1402 ^[44]
Units: participants	242	257	956	964

Notes:

[41] - Safety Set

[42] - Safety Set

[43] - Safety Set

[44] - Safety Set

Statistical analyses

No statistical analyses for this end point

Primary: Parts 1 and 2: Number of Participants with AEs Leading to Withdrawal

End point title	Parts 1 and 2: Number of Participants with AEs Leading to Withdrawal ^[45]
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End point description:

An AE leading to withdrawal was defined as any AE that caused the participant to withdraw from the study, regardless of whether the decision to withdraw from the study was made by the participant or by the Investigator. A summary of all Serious and Non Serious AEs, regardless of causality, is located in the 'Adverse Events' section.

End point type	Primary
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End point timeframe:

Day 1 to end of study (Day 359)

Notes:

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

Justification: Only descriptive statistics (percentage of participants plus confidence interval) are reported for this primary end point, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214	Part 2: mRNA-1273
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	367 ^[46]	357 ^[47]	1422 ^[48]	1402 ^[49]
Units: participants	2	3	3	6

Notes:

[46] - Safety Set

[47] - Safety Set

[48] - Safety Set

[49] - Safety Set

Statistical analyses

No statistical analyses for this end point

Primary: Parts 1 and 2: Number of Participants with AEs of Special Interest (AESIs)

End point title	Parts 1 and 2: Number of Participants with AEs of Special Interest (AESIs) ^[50]
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End point description:

An AESI is an AE (serious or non serious) 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 are required. Such events may require further investigation to characterize and understand them. A summary of all Serious and Non Serious AEs, regardless of causality, is located in the 'Adverse Events' section.

End point type	Primary
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End point timeframe:

Day 1 to end of study (Day 359)

Notes:

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

Justification: Only descriptive statistics (percentage of participants plus confidence interval) are reported for this primary end point, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214	Part 2: mRNA-1273
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	367 ^[51]	357 ^[52]	1422 ^[53]	1402 ^[54]
Units: participants	42	28	60	60

Notes:

[51] - Safety Set

[52] - Safety Set

[53] - Safety Set

[54] - Safety Set

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 29 and Day 85

End point title	Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 29 and Day 85 ^[55]
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End point description:

Blood samples for immunogenicity assessments were collected during protocol specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then backtransformed to the original scale for presentation. Superiority at Day 29 was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >1. Superiority at Day 85 was demonstrated if the lower bound of the 96% CI of the Geometric Mean Ratio was >1. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
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End point timeframe:

Day 29 and Day 85 (post vaccination)

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 1, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	274 ^[56]	277 ^[57]		
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 29	537.7 (478.2 to 604.6)	302.8 (274.8 to 333.6)		
Day 85	284.7 (248.0 to 326.7)	152.6 (135.1 to 172.3)		

Notes:

[56] - PPSI-Neg; Day 29 (N=274); Day 85 (N=234)

[57] - PPSI-Neg; Day 29 (N=277); Day 85 (N=226)

Statistical analyses

Statistical analysis title	Day 85: mRNA-1273.529 Superiority
Statistical analysis description: Geometric Mean Ratio = GMCmRNA-1273.529/GMCmRNA-1273 against the B.1.1.529 strain at Day 85 after study vaccine administration. Reported statistical analysis based upon the number of participants with non-missing data at baseline and the corresponding timepoint (N=460).	
Comparison groups	Part 1: mRNA-1273.529 v Part 1: mRNA-1273
Number of subjects included in analysis	551
Analysis specification	Pre-specified
Analysis type	superiority ^[58]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.763
Confidence interval	
level	Other: 96 %
sides	2-sided
lower limit	1.546
upper limit	2.01

Notes:

[58] - Superiority was demonstrated if the lower bound of the 96% CI of the Geometric Mean Ratio was >1.

Statistical analysis title	Day 29: mRNA-1273.529 Superiority
Statistical analysis description: Geometric Mean Ratio = GMCmRNA-1273.529/GMCmRNA-1273 against the B.1.1.529 strain at Day 29 after study vaccine administration.	
Comparison groups	Part 1: mRNA-1273.529 v Part 1: mRNA-1273
Number of subjects included in analysis	551
Analysis specification	Pre-specified
Analysis type	superiority ^[59]
Parameter estimate	Geometric Mean Ratio
Point estimate	1.73
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	1.493
upper limit	2.005

Notes:

[59] - Superiority was demonstrated if the lower bound of the 99% CI of the Geometric Mean Ratio was >1.

Secondary: Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 179

End point title	Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the B.1.1.529 Strain at Day 179 ^[60]
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End point description:

Blood samples for immunogenicity assessments were collected during protocol specified study visits. The

serum neutralizing antibody levels were measured by pseudovirus neutralization assays. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
End point timeframe:	
Day 179 (post vaccination)	

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 1, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	160 ^[61]	138 ^[62]		
Units: AU/mL				
geometric mean (confidence interval 95%)	144.3 (119.4 to 174.5)	70.1 (59.0 to 83.4)		

Notes:

[61] - PPSI-Neg

[62] - PPSI-Neg

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the Ancestral Strain at Day 29, Day 85, and Day 179

End point title	Part 1: GMC of mRNA-1273.529 and mRNA-1273 Against the Ancestral Strain at Day 29, Day 85, and Day 179 ^[63]
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End point description:

Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. The ancestral strain was Wuhan-Hu-1. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
End point timeframe:	
Day 29, Day 85, Day 179 (post vaccination)	

Notes:

[63] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 1, as prespecified in the statistical analysis plan.

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	270 ^[64]	272 ^[65]		
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 29	2699.7 (2431.3 to 2997.7)	3020.6 (2776.5 to 3286.2)		

Day 85	1401.2 (1236.9 to 1587.4)	1559.4 (1401.2 to 1735.5)		
Day 179	734.6 (621.8 to 867.9)	747.6 (644.1 to 867.7)		

Notes:

[64] - PPSI-Neg; Day 29 (N=270); Day 85 (N=234); Day 179 (N=160)

[65] - PPSI-Neg; Day 29 (N=272); Day 85 (N=226); Day 179 (N=133)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts 1 and 2: Percentage of Participants with Seroresponse Against SARS-CoV-2

End point title	Parts 1 and 2: Percentage of Participants with Seroresponse Against SARS-CoV-2
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End point description:

Seroresponse was defined by an increase of the GMC from pre-study vaccination (booster) below the lower limit of quantitation (LLOQ) to at least 4×LLOQ, or a 4-fold or greater rise if pre-study vaccination was ≥LLOQ. The number of participants analysed from the PPSI-Neg population include those with non-missing data at Baseline and the corresponding timepoint. 95% CI calculated using the Clopper-Pearson method. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
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End point timeframe:

Days 29, 85, 179, and 359

End point values	Part 1: mRNA-1273.529	Part 1: mRNA-1273	Part 2: mRNA-1273.214	Part 2: mRNA-1273
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	274 ^[66]	277 ^[67]	968 ^[68]	894 ^[69]
Units: percentage of participants				
number (confidence interval 95%)				
Day 29 - B.1.1.529 Strain	83.2 (78.2 to 87.4)	55.2 (49.2 to 61.2)	84.7 (82.3 to 86.9)	70.4 (67.2 to 73.3)
Day 85 - B.1.1.529 Strain	48.3 (41.7 to 54.9)	15.9 (11.4 to 21.4)	60.6 (57.0 to 64.1)	32.3 (28.8 to 35.9)
Day 179 - B.1.1.529 Strain	18.1 (12.5 to 25.0)	2.9 (0.8 to 7.3)	37.5 (33.5 to 41.8)	25.8 (22.1 to 29.9)
Day 359 - B.1.1.529 Strain	36.5 (25.6 to 48.5)	26.2 (15.8 to 39.1)	32.5 (27.1 to 38.3)	25.1 (19.9 to 30.9)
Day 29 - Ancestral Strain	43.1 (37.1 to 49.2)	59.0 (52.9 to 65.0)	70.9 (67.9 to 73.8)	68.4 (65.2 to 71.5)
Day 85 - Ancestral Strain	14.3 (10.0 to 19.5)	21.8 (16.6 to 27.7)	38.8 (35.3 to 42.4)	33.4 (29.8 to 37.1)
Day 179 - Ancestral Strain	2.5 (0.7 to 6.4)	6.1 (2.7 to 11.6)	25.0 (21.4 to 29.0)	23.8 (20.1 to 27.9)
Day 359 - Ancestral Strain	2.7 (0.3 to 9.5)	8.2 (2.7 to 18.1)	8.9 (5.9 to 12.9)	12.6 (8.7 to 17.3)

Notes:

[66] - PPSI-Neg; Day 29 (N=274/267); Day 85 (N=234/231); Day 179 (N=160/158); Day 359 (N=74/73)

[67] - PPSI-Neg; Day 29 (N=277/271); Day 85 (N=226/225); Day 179 (N=138/132); Day 359 (N=61)

[68] - PPSI-Neg; Day 29 (N=968/945); Day 85 (N=761/747); Day 179 (N=546/531); Day 359 (N=286/280)

[69] - PPSI-Neg; Day 29 (N=894/873); Day 85 (N=688/671); Day 179 (N=507/487); Day 359 (N=251/247)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against Other Variant Strains

End point title	Part 2: GMC of mRNA-1273.214 and mRNA-1273 Against Other Variant Strains ^[70]
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End point description:

Blood samples for immunogenicity assessments were collected during protocol-specified study visits. The serum neutralizing antibody levels were measured by pseudovirus neutralization assays. Results are reported as AU/mL. The GMC 95% CI was calculated based on the t-distribution of the log-transformed values then back-transformed to the original scale for presentation. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
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End point timeframe:

Days 29 and 85

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	968 ^[71]	895 ^[72]		
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 29 - B.1.1.7 Strain	236533.1 (227116.7 to 246340.0)	225834.1 (216536.7 to 235530.8)		
Day 85 - B.1.1.7 Strain	133951.9 (127594.4 to 140626.1)	124778.3 (118785.1 to 131073.9)		
Day 29 - AY.4 Strain	244715.5 (234951.9 to 254884.8)	236066.3 (226310.8 to 246242.3)		
Day 85 - AY.4 Strain	134119.3 (127672.7 to 140891.4)	127263.6 (121106.4 to 133733.8)		
Day 29 - P.1 Strain	182396.9 (175235 to 189850.9)	175216.7 (168018.0 to 182723.9)		
Day 85 - P.1 Strain	103438.9 (98607.6 to 108506.8)	97927.0 (93264.0 to 102823.2)		

Notes:

[71] - PPSI-Neg; Day 29 (N=968); Day 85 (N=761)

[72] - PPSI-Neg; Day 29 (N=895); Day 85 (N=688)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants with Asymptomatic SARS-CoV-2 Infection Measured by Reverse Transcriptase Polymerase-chain Reaction (RT-PCR)

End point title	Part 2: Percentage of Participants with Asymptomatic SARS-CoV-2 Infection Measured by Reverse Transcriptase Polymerase-chain Reaction (RT-PCR) ^[73]
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End point description:

Asymptomatic SARS-CoV-2 infection was defined as a positive RT-PCR test on a respiratory sample in the absence of symptoms or a positive serologic test for antinucleocapsid antibody after a negative test at time of enrollment. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
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End point timeframe:

Day 14 through the end of study (Day 359)

Notes:

[73] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	995 ^[74]	932 ^[75]		
Units: percentage of participants				
number (not applicable)	16.9	17.7		

Notes:

[74] - PPSE

[75] - PPSE

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants with Symptomatic SARS-CoV-2 Infection Measured by RT-PCR

End point title	Part 2: Percentage of Participants with Symptomatic SARS-CoV-2 Infection Measured by RT-PCR ^[76]
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End point description:

Symptomatic SARS-CoV-2 infection was defined 2 ways: protocol-defined COVID-19 and Center for Disease Control (CDC) COVID-19. Protocol-defined COVID-19 required at least 2 of the following systemic symptoms: fever, chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), or at least 1 of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical/radiographical evidence of pneumonia, and at least 1 positive nasopharyngeal swab, nasal swab, or saliva sample (RT-PCR). CDC-defined COVID-19 was based on a positive respiratory sample (RT-PCR) and at least 1 of the following systemic or respiratory symptoms: fever, chills, cough, shortness of breath, and/or difficulty breathing, fatigue, muscle and/or body aches, headache, new loss of taste/smell, sore throat, congestion, runny nose, nausea, vomiting, or diarrhoea. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
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End point timeframe:

Time Frame: Day 1 through the end of study (Day 359)

Notes:

[76] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	995 ^[77]	932 ^[78]		
Units: percentage of participants				
number (not applicable)	50.8	48.6		

Notes:

[77] - PPSE

[78] - PPSE

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants with Primary Case Definition of COVID-19

End point title	Part 2: Percentage of Participants with Primary Case Definition of COVID-19 ^[79]
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End point description:

The primary case definition of COVID-19 (protocol-defined COVID-19) required the participant to have experienced at least 2 of the following systemic symptoms: fever, chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), or the participant must have experienced at least 1 of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia, and must have at least 1 nasopharyngeal swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
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End point timeframe:

Day 14 through the end of study (Day 359)

Notes:

[79] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	995 ^[80]	932 ^[81]		
Units: percentage of participants				
number (not applicable)	30.5	29.1		

Notes:

[80] - PPSE

[81] - PPSE

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants with Secondary Case Definition of

COVID-19

End point title	Part 2: Percentage of Participants with Secondary Case Definition of COVID-19 ^[82]
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End point description:

The secondary case definition of COVID-19 (CDC case definition) was based on a positive RT-PCR test on a respiratory sample and at least 1 of the following systemic or respiratory symptoms: fever, chills, cough, shortness of breath, and/or difficulty breathing, fatigue, muscle and/or body aches (not related to exercise), headache, new loss of taste/smell, sore throat, congestion, runny nose, nausea, vomiting, or diarrhoea. Here, Number of Subjects Analysed signifies those participants who were evaluable for this End Point.

End point type	Secondary
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End point timeframe:

Day 14 through the end of study (Day 359)

Notes:

[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only statistics are reported for Part 2, as prespecified in the statistical analysis plan.

End point values	Part 2: mRNA-1273.214	Part 2: mRNA-1273		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	995 ^[83]	932 ^[84]		
Units: percentage of participants				
number (not applicable)	33.5	30.9		

Notes:

[83] - PPSE

[84] - PPSE

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 to end of study (Day 359)

Adverse event reporting additional description:

Reported adverse events are based upon the Safety Set: all randomized participants who received the study vaccine. Note, not all solicited ARs were considered AEs. Investigator determined if solicited AR was also to be recorded as an AE.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

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

Phase A: Participants will receive 1 IM dose of mRNA-1273.214 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Reporting group title	Part 1: mRNA-1273
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Reporting group description:

Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Reporting group title	Part 1: mRNA-1273.529
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Reporting group description:

Phase A: Participants will receive 1 intramuscular (IM) dose of mRNA-1273.529 on Day 1. Phase B: After Day 179, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Reporting group title	Part 2: mRNA-1273
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Reporting group description:

Phase A: Participants will receive 1 IM dose of mRNA-1273 on Day 1. Phase B: After Day 85, eligible participants may choose to be unblinded and to receive an additional booster outside of the study.

Serious adverse events	Part 2: mRNA-1273.214	Part 1: mRNA-1273	Part 1: mRNA-1273.529
Total subjects affected by serious adverse events			
subjects affected / exposed	60 / 1422 (4.22%)	13 / 357 (3.64%)	20 / 367 (5.45%)
number of deaths (all causes)	2	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal carcinoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Colorectal cancer metastatic			

subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Brain neoplasm malignant			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
High-grade B- cell lymphoma			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Metastases to liver			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Meningioma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Malignant melanoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Lung neoplasm malignant			
subjects affected / exposed	2 / 1422 (0.14%)	1 / 357 (0.28%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Small cell lung cancer			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Malignant glioma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ovarian tumor			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Breast cancer			
subjects affected / exposed	1 / 1422 (0.07%)	1 / 357 (0.28%)	0 / 367 (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
Colon cancer			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Glioblastoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Benign lung neoplasm			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Malignant pleural effusion			

subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Oesophageal carcinoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Plasma cell myeloma			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Prostate cancer			
subjects affected / exposed	3 / 1422 (0.21%)	1 / 357 (0.28%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Thyroid adenoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Thrombophlebitis superficial			

subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Aortic aneurysm			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Poor peripheral circulation			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Sudden unexplained death in epilepsy			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Pyrexia			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Incarcerated hernia			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Immune system disorders			

Food allergy			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Vaginal haemorrhage			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Prostatitis			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Prostatomegaly			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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, thoracic and mediastinal disorders			
Epistaxis			

subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Pulmonary embolism			
subjects affected / exposed	2 / 1422 (0.14%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Anxiety			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Completed suicide			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Suicide attempt			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Depression			

subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Femur fracture			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Delayed recovery from anaesthesia			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Cartilage injury			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Joint dislocation			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Ligament rupture			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Subdural haematoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			

subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Road traffic accident			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Wrist fracture			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Cervical vertebral fracture			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Craniocerebral injury			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Hip fracture			

subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Intentional overdose			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Open fracture			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Clavicle fracture			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Rib fracture			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Tendon rupture			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Right aortic arch			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Bicuspid aortic valve			

subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Angina pectoris			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Extrasystoles			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Sinus tachycardia			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Coronary artery stenosis			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Myocardial infarction			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	2 / 367 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			

subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Arrhythmia			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Atrial fibrillation			
subjects affected / exposed	3 / 1422 (0.21%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Anosmia			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Intracranial hypotension			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Ischaemic stroke			

subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Epilepsy			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Myasthenia gravis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Cauda equina syndrome			

subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Haemorrhagic stroke			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Motor neurone disease			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Oromandibular dystonia			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Parkinson's disease			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Syncope			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Vertigo			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Eye disorders			

Cataract			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal tear			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Retinal detachment			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Hiatus hernia			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Mesenteric panniculitis			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Intestinal obstruction			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Colitis			

subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Richter's hernia			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Pancreatitis chronic			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Anal fistula			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Colitis ischaemic			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Abdominal pain			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Umbilical hernia			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Hepatobiliary disorders			
Portal vein thrombosis			

subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Liver injury			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Idiopathic angioedema			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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 retention			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Ureterolithiasis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Osteoarthritis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Arthritis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Infections and infestations			
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Herpes zoster			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 1422 (0.00%)	1 / 357 (0.28%)	0 / 367 (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
Nail infection			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary tract infection			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Systemic viral infection			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Pyelonephritis			
subjects affected / exposed	3 / 1422 (0.21%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Appendicitis			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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 externa			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Cellulitis			

subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Gastroenteritis viral			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (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
Mastoiditis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
COVID-19			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Pneumonia			
subjects affected / exposed	2 / 1422 (0.14%)	2 / 357 (0.56%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection staphylococcal			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			

subjects affected / exposed	1 / 1422 (0.07%)	0 / 357 (0.00%)	0 / 367 (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
Dehydration			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	1 / 367 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 1422 (0.00%)	0 / 357 (0.00%)	0 / 367 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: mRNA-1273		
Total subjects affected by serious adverse events			
subjects affected / exposed	72 / 1402 (5.14%)		
number of deaths (all causes)	4		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal carcinoma			
subjects affected / exposed	2 / 1402 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Colorectal cancer metastatic			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain neoplasm malignant			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

High-grade B- cell lymphoma subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to liver subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningioma subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small cell lung cancer subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant glioma subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign ovarian tumor				

subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glioblastoma			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign lung neoplasm			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant pleural effusion			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal carcinoma			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			

subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid adenoma			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis superficial			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Poor peripheral circulation			

subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sudden unexplained death in epilepsy			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pyrexia			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incarcerated hernia			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postmenopausal haemorrhage			

subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal haemorrhage			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostatomegaly			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	4 / 1402 (0.29%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			

Alcohol withdrawal syndrome				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Completed suicide				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mixed anxiety and depressive disorder				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Suicide attempt				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Hand fracture				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Delayed recovery from anaesthesia subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cartilage injury subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint dislocation subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ligament rupture subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sternal fracture subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb injury subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				

subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical vertebral fracture			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	2 / 1402 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Craniocerebral injury			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intentional overdose			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Open fracture			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			

subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Corneal dystrophy			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Right aortic arch			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bicuspid aortic valve			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Atrial flutter				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extrasystoles				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Atrial fibrillation				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tachycardia				

subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anosmia			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial hypotension			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			

subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myasthenia gravis			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cauda equina syndrome			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic stroke			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Motor neurone disease			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Oromandibular dystonia			

subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal tear			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uveitis			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			

subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	2 / 1402 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mesenteric panniculitis			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Richter's hernia			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis chronic			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wall haematoma			

subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaundice			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver injury			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			

Idiopathic angioedema			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	2 / 1402 (0.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Rotator cuff syndrome				
subjects affected / exposed	2 / 1402 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nail infection				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic viral infection				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Pyelonephritis				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pilonidal cyst				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Otitis externa				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	2 / 1402 (0.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 1402 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	1 / 1402 (0.07%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mastoiditis				

subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital cellulitis			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Wound infection staphylococcal			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 1402 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gout			
subjects affected / exposed	1 / 1402 (0.07%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part 2: mRNA-1273.214	Part 1: mRNA-1273	Part 1: mRNA-1273.529
Total subjects affected by non-serious adverse events			
subjects affected / exposed	207 / 1422 (14.56%)	70 / 357 (19.61%)	68 / 367 (18.53%)
Nervous system disorders			
Headache			
subjects affected / exposed	40 / 1422 (2.81%)	9 / 357 (2.52%)	6 / 367 (1.63%)
occurrences (all)	43	12	6
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	19 / 1422 (1.34%)	4 / 357 (1.12%)	4 / 367 (1.09%)
occurrences (all)	19	4	4
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	11 / 1422 (0.77%)	3 / 357 (0.84%)	1 / 367 (0.27%)
occurrences (all)	11	3	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	16 / 1422 (1.13%)	5 / 357 (1.40%)	1 / 367 (0.27%)
occurrences (all)	17	6	1
Nausea			
subjects affected / exposed	5 / 1422 (0.35%)	4 / 357 (1.12%)	0 / 367 (0.00%)
occurrences (all)	5	4	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	13 / 1422 (0.91%)	4 / 357 (1.12%)	3 / 367 (0.82%)
occurrences (all)	13	4	3
Asthma			
subjects affected / exposed	4 / 1422 (0.28%)	1 / 357 (0.28%)	4 / 367 (1.09%)
occurrences (all)	4	1	5
Nasal congestion			
subjects affected / exposed	4 / 1422 (0.28%)	0 / 357 (0.00%)	6 / 367 (1.63%)
occurrences (all)	4	0	6
Dyspnoea			

subjects affected / exposed occurrences (all)	5 / 1422 (0.35%) 5	4 / 357 (1.12%) 4	0 / 367 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	22 / 1422 (1.55%) 23	5 / 357 (1.40%) 5	1 / 367 (0.27%) 1
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	8 / 1422 (0.56%) 8	4 / 357 (1.12%) 4	2 / 367 (0.54%) 2
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	5 / 1422 (0.35%) 5	9 / 357 (2.52%) 10	15 / 367 (4.09%) 15
Nasopharyngitis subjects affected / exposed occurrences (all)	26 / 1422 (1.83%) 26	2 / 357 (0.56%) 2	3 / 367 (0.82%) 3
COVID-19 subjects affected / exposed occurrences (all)	60 / 1422 (4.22%) 60	30 / 357 (8.40%) 30	28 / 367 (7.63%) 28
Asymptomatic COVID-19 subjects affected / exposed occurrences (all)	12 / 1422 (0.84%) 12	4 / 357 (1.12%) 4	2 / 367 (0.54%) 2

Non-serious adverse events	Part 2: mRNA-1273		
Total subjects affected by non-serious adverse events subjects affected / exposed	198 / 1402 (14.12%)		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	29 / 1402 (2.07%) 29		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	10 / 1402 (0.71%) 10		
Immune system disorders			

Seasonal allergy subjects affected / exposed occurrences (all)	19 / 1402 (1.36%) 20		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	12 / 1402 (0.86%) 12		
Nausea subjects affected / exposed occurrences (all)	4 / 1402 (0.29%) 4		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	13 / 1402 (0.93%) 13		
Asthma subjects affected / exposed occurrences (all)	7 / 1402 (0.50%) 7		
Nasal congestion subjects affected / exposed occurrences (all)	6 / 1402 (0.43%) 6		
Dyspnoea subjects affected / exposed occurrences (all)	4 / 1402 (0.29%) 4		
Oropharyngeal pain subjects affected / exposed occurrences (all)	24 / 1402 (1.71%) 26		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	13 / 1402 (0.93%) 14		
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	12 / 1402 (0.86%) 12		
Nasopharyngitis			

subjects affected / exposed	19 / 1402 (1.36%)		
occurrences (all)	19		
COVID-19			
subjects affected / exposed	51 / 1402 (3.64%)		
occurrences (all)	51		
Asymptomatic COVID-19			
subjects affected / exposed	8 / 1402 (0.57%)		
occurrences (all)	8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 March 2022	- Added an objective and end point table for the new Part 2 (mRNA-1273.214 and mRNA-1273). - For the primary non-inferiority of the immune response of mRNA-1273.529 compared to mRNA-1273 booster administered as a 4th dose against the B.1.1.529 strain endpoint in Part 1, Month 3 was added as an assessment timepoint. - For the other secondary end points of the evaluation of the immunogenicity of mRNA-1273.529 booster compared to mRNA-1273 booster administered at the 3rd or 4th dose in Part 1, immunogenicity will be evaluated at all measured timepoints. - Changed the end point of evaluating the immunogenicity of mRNA-1273.529 and mRNA-1273 booster at all evaluable end points against the B.1.1.529 strain (and ancestral strain) rather than against other strains. - Removed the other secondary end points to evaluate the immunogenicity of mRNA-1273.529 and mRNA-1273 booster at all evaluable time points after the vaccination administration. - Removed the exploratory end point/objective to evaluate cellular immunogenicity of a subset of participants in Part 1. - Modified (Part 1) and added (Part 2) details for targeted enrollment and other sample size assumptions.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/37348519>