



Clinical trial results:

A Phase 2, Two-Part Study (Open-Label [Part 1] Followed by Observer-Blind/Randomized [Part 2]) to Evaluate the Safety, Tolerability, Reactogenicity, and Effectiveness of mRNA-1273.214 SARS-CoV-2 Vaccine in Participants Aged 12 Weeks to <6 Months (BabyCOVE)

Summary

EudraCT number	2023-000482-14
Trial protocol	Outside EU/EEA
Global end of trial date	15 November 2024

Results information

Result version number	v1 (current)
This version publication date	29 May 2025
First version publication date	29 May 2025

Trial information

Trial identification

Sponsor protocol code	mRNA-1273-P206
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05584202
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 WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com
Scientific contact	Moderna WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002893-PIP01-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 February 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 November 2024
Global end of trial reached?	Yes
Global end of trial date	15 November 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The study evaluated the safety, tolerability, reactogenicity, and effectiveness of mRNA-1273.214 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine in infants aged 12 weeks to < 6 months. The study was planned to be conducted in 2 parts (open-label in Part 1 and observer-blind, randomized, placebo-controlled in Part 2).

Enrollment for the study was paused after an updated COVID-19 vaccine in children 6 months to <12 years of age was granted emergency use authorization (EUA) in the United (US). Enrollment in the study was subsequently discontinued based on immunogenicity results from Part 1, and accordingly Part 2 of the study was not initiated. This discontinuation was not related to any safety concerns.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2022
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 68
Worldwide total number of subjects	68
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	68

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

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants eligible for enrollment in Part 1 of this study included male and female infants aged 12 weeks to <6 months at the time of administration of first dose who were in good general health.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	mRNA-1273.214 5 µg

Arm description:

Participants received at least 1 of the 2 doses of mRNA-1273.214 5 micrograms (µg) by intramuscular (IM) injection approximately 8 weeks apart (Day 1 and Day 57).

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

Dosage and administration details:

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

Arm title	mRNA-1273.214 10 µg
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Arm description:

Participants received at least 1 of the 2 doses of mRNA-1273.214 10 µg by IM injection approximately 8 weeks apart (Day 1 and Day 57).

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

Dosage and administration details:

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

Number of subjects in period 1	mRNA-1273.214 5 µg	mRNA-1273.214 10 µg
Started	50	18
Received First Injection	50	18
Received Second Injection	49	15
Safety Set	50	18

Solicited Safety Set First Injection	50	18
Solicited Safety Set Second Injection	49	15
Per-Protocol Immunogenicity Set (PPIS)	37 ^[1]	11 ^[2]
Completed	45	14
Not completed	5	4
Withdrawal of Consent	3	2
Death	-	1
Lost to follow-up	2	1

Notes:

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

Justification: PPIS analysis population

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

Justification: PPIS analysis population

Baseline characteristics

Reporting groups

Reporting group title	mRNA-1273.214 5 µg
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Reporting group description:

Participants received at least 1 of the 2 doses of mRNA-1273.214 5 micrograms (µg) by intramuscular (IM) injection approximately 8 weeks apart (Day 1 and Day 57).

Reporting group title	mRNA-1273.214 10 µg
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Reporting group description:

Participants received at least 1 of the 2 doses of mRNA-1273.214 10 µg by IM injection approximately 8 weeks apart (Day 1 and Day 57).

Reporting group values	mRNA-1273.214 5 µg	mRNA-1273.214 10 µg	Total
Number of subjects	50	18	68
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	50	18	68
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Subjects			
Female	26	4	30
Male	24	14	38

End points

End points reporting groups

Reporting group title	mRNA-1273.214 5 µg
Reporting group description: Participants received at least 1 of the 2 doses of mRNA-1273.214 5 micrograms (µg) by intramuscular (IM) injection approximately 8 weeks apart (Day 1 and Day 57).	
Reporting group title	mRNA-1273.214 10 µg
Reporting group description: Participants received at least 1 of the 2 doses of mRNA-1273.214 10 µg by IM injection approximately 8 weeks apart (Day 1 and Day 57).	
Subject analysis set title	mRNA-1273.214 5 µg (Safety Set)
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received at least 1 of 2 doses of mRNA-1273.214 5 µg by IM injection approximately 8 weeks apart (Day 1 and Day 57).	
Subject analysis set title	mRNA-1273.214 10 µg (Safety Set)
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received at least 1 of 2 doses of mRNA-1273.214 10 µg by IM injection approximately 8 weeks apart (Day 1 and Day 57).	
Subject analysis set title	mRNA-1273.214 5 µg First Injection (Solicited Safety Set)
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received first injection of mRNA-1273.214 5 µg.	
Subject analysis set title	mRNA-1273.214 10 µg First Injection (Solicited Safety Set)
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received first injection of mRNA-1273.214 10 µg.	
Subject analysis set title	mRNA-1273.214 5 µg Second Injection (Solicited Safety Set)
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received second injection of mRNA-1273.214 5 µg.	
Subject analysis set title	mRNA-1273.214 10 µg Second Injection (Solicited Safety Set)
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received second injection of mRNA-1273.214 10 µg.	
Subject analysis set title	mRNA-1273.214 5 µg (PPIS)
Subject analysis set type	Per protocol
Subject analysis set description: Participants received the planned doses of mRNA-1273.214 5 µg per schedule, complied with immunogenicity testing schedule, had Baseline (Day 1) and Day 85 antibody assessments, and had no major protocol deviations that impacted key or critical data.	
Subject analysis set title	mRNA-1273.214 10 µg (PPIS)
Subject analysis set type	Per protocol
Subject analysis set description: Participants received the planned doses of mRNA-1273.214 10 µg per schedule, complied with immunogenicity testing schedule, had Baseline (Day 1) and Day 85 antibody assessments, and had no major protocol deviations that impacted key or critical data.	

Primary: Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) After First Injection

End point title	Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) After First Injection ^[1]
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End point description:

Solicited ARs (local and systemic) were collected in an electronic diary (eDiary). Local ARs included injection site pain/tenderness, injection site erythema (redness), injection site swelling/induration (hardness), and groin or underarm swelling or tenderness ipsilateral to the side of injection. Systemic ARs included fever, irritability/crying, sleepiness, and loss of appetite. Solicited AR severity was graded according to a modified version (relevant to age 12 weeks to <6 months) of the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials. ARs graded 1-4 are presented. Lower scores indicated lower severity, and higher scores indicated greater severity. Solicited Safety Set included participants who received the first injection of study drug and contributed any solicited AR data.

A summary of SAEs and nonserious AEs (Safety Set), regardless of causality, is located in the AE section.

End point type	Primary
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End point timeframe:

Day 1 up to 7 days after first vaccination (up to Day 8)

Notes:

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

Justification: As prespecified in the the protocol, no statistical analysis was conducted for this endpoint.

End point values	mRNA-1273.214 5 µg First Injection (Solicited Safety Set)	mRNA-1273.214 10 µg First Injection (Solicited Safety Set)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	50	18		
Units: participants				
number (not applicable)				
Grade 1	23	7		
Grade 2	8	3		
Grade 3	1	0		
Grade 4	0	0		
Any solicited ARs (Grade 1-4)	32	10		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Local and Systemic ARs After Second Injection

End point title	Number of Participants With Solicited Local and Systemic ARs After Second Injection ^[2]
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End point description:

Solicited ARs (local and systemic) were collected in an electronic diary (eDiary). Local ARs included injection site pain/tenderness, injection site erythema (redness), injection site swelling/induration (hardness), and groin or underarm swelling or tenderness ipsilateral to the side of injection. Systemic ARs included fever, irritability/crying, sleepiness, and loss of appetite. Solicited AR severity was graded according to a modified version (relevant to age 12 weeks to <6 months) of the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials. ARs graded 1-4 are presented. Lower scores indicated lower severity, and higher scores indicated greater severity.

Solicited Safety Set included participants who received the second injection of study drug and contributed any solicited AR data.

A summary of SAEs and nonserious AEs (Safety Set), regardless of causality, is located in the AE section.

End point type	Primary
End point timeframe:	
Day 57 up to 7 days after second vaccination (up to Day 64)	

Notes:

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

Justification: As prespecified in the the protocol, no statistical analysis was conducted for this endpoint.

End point values	mRNA-1273.214 5 µg Second Injection (Solicited Safety Set)	mRNA-1273.214 10 µg Second Injection (Solicited Safety Set)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	49	15		
Units: participants				
number (not applicable)				
Grade 1	18	6		
Grade 2	7	2		
Grade 3	1	0		
Grade 4	0	0		
Any solicited ARs (Grade 1-4)	26	8		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited Adverse Events (AEs) After Any Injection

End point title	Number of Participants With Unsolicited Adverse Events (AEs) After Any Injection ^[3]
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End point description:

An unsolicited AE was any AE reported by the participant that was not specified as a solicited AR in the protocol or was specified as a solicited AR but started outside the protocol-defined period for reporting solicited ARs (onset after Day 7 of dosing). An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. Any abnormal laboratory test result or other safety assessment, including one that worsened from baseline and was considered clinically significant by the Investigator was recorded as an AE.

Safety Set included participants who received at least 1 dose of study drug.

A summary of SAEs and nonserious AEs (Safety Set), regardless of causality, is located in the AE section.

COVID-19/SARS-CoV-2 infections were considered clinical events and not AEs.

End point type	Primary
End point timeframe:	
Day 1 up to 28 days after any vaccination (up to Day 85)	

Notes:

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

Justification: As prespecified in the the protocol, no statistical analysis was conducted for this endpoint.

End point values	mRNA- 1273.214 5 µg (Safety Set)	mRNA- 1273.214 10 µg (Safety Set)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	50	18		
Units: participants				
number (not applicable)	24	8		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With SAEs, AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs Leading to Study or Treatment Discontinuation

End point title	Number of Participants With SAEs, AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs Leading to Study or Treatment Discontinuation ^[4]
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End point description:

SAE was defined as any AE that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in disability/permanent damage, was a congenital anomaly/birth defect, or was an important medical event. AESIs were identified based upon medical concepts that may be related to COVID19 or were of interest in COVID19 vaccine safety surveillance. MAAE was an AE that led to an unscheduled visit to a healthcare practitioner, included visits to a study site for unscheduled assessments (for example, abnormal laboratory follow-up, and visits to healthcare practitioners external to the study site [for example, urgent care, primary care physician]). A summary of SAEs and nonserious AEs (Safety Set), regardless of causality, is located in the AE section. COVID-19/SARS-CoV-2 infections were considered clinical events and not AEs.

End point type	Primary
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End point timeframe:

Day 1 up to Day 422

Notes:

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

Justification: As prespecified in the the protocol, no statistical analysis was conducted for this endpoint.

End point values	mRNA- 1273.214 5 µg (Safety Set)	mRNA- 1273.214 10 µg (Safety Set)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	50	18		
Units: participants				
number (not applicable)				
SAEs	1	1		
AESIs	1	0		
MAAEs	39	16		
AEs Leading to Study or Treatment Discontinuation	0	1		

Statistical analyses

Secondary: Geometric Mean Concentration (GMC) of Serum Pseudovirus Neutralizing Antibody (nAb) Titers Against SARS-CoV-2 Omicron BA.1 Variant (B.1.1.529) After Second Dose of mRNA-1273.214

End point title	Geometric Mean Concentration (GMC) of Serum Pseudovirus Neutralizing Antibody (nAb) Titers Against SARS-CoV-2 Omicron BA.1 Variant (B.1.1.529) After Second Dose of mRNA-1273.214
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End point description:

Pseudovirus nAb were measured using pseudovirus neutralization assay (PsVNA). Antibody values reported as below the lower limit of quantification (LLOQ) were replaced by 0.5*LLOQ. Values greater than the upper limit of quantification (ULOQ) were replaced by the ULOQ if actual values were not available. VAC122 Neutralizing Antibody against the SARS-CoV-2 B.1.1.529 variant (LLOQ: 8 arbitrary unit (AU)/milliliter (mL), ULOQ: 24503 AU/mL).

Per-protocol Immunogenicity Set (PPIS): participants who received the planned doses of investigational product per schedule, complied with immunogenicity testing schedule, had Baseline (Day 1) and Day 85 antibody assessments, and had no major protocol deviations that impacted key or critical data.

End point type	Secondary
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End point timeframe:

Baseline and 28 days after second dose (Day 85)

End point values	mRNA-1273.214 5 µg (PPIS)	mRNA-1273.214 10 µg (PPIS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	37 ^[5]	11 ^[6]		
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline	64.9 (42.3 to 99.6)	84.2 (42.8 to 165.5)		
Day 85	163.0 (91.0 to 292.2)	228.6 (97.0 to 538.9)		

Notes:

[5] - Baseline n=37, Day 85 n=37

[6] - Baseline n=11, Day 85 n=11

Statistical analyses

No statistical analyses for this end point

Secondary: GMC of Serum Pseudovirus nAb Titers Against SARS-CoV-2 Original Strain (D614G) After Second Dose of mRNA-1273.214

End point title	GMC of Serum Pseudovirus nAb Titers Against SARS-CoV-2 Original Strain (D614G) After Second Dose of mRNA-1273.214
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End point description:

Pseudovirus nAb were measured using PsVNA assay. Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ if actual values were not available. VAC62 Neutralizing Antibody against D614G (LLOQ: 10 AU/mL, ULOQ: 111433 AU/mL).

PPIS: participants who received the planned doses of investigational product per schedule, complied with immunogenicity testing schedule, had Baseline (Day 1) and Day 85 antibody assessments, and had no major protocol deviations that impacted key or critical data. Overall number of participants analyzed = participants evaluable for the endpoint.

End point type	Secondary
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End point timeframe:

Baseline and 28 days after second dose (Day 85)

End point values	mRNA- 1273.214 5 µg (PPIS)	mRNA- 1273.214 10 µg (PPIS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	37 ^[7]	11 ^[8]		
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline	236.4 (150.8 to 370.6)	203.6 (76.6 to 540.9)		
Day 85	178.1 (133.3 to 237.9)	96.0 (72.2 to 127.6)		

Notes:

[7] - Baseline n=37, Day 85 n=36

[8] - Baseline n=11, Day 85 n=11

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to Day 422

Adverse event reporting additional description:

Safety Set included participants who received at least 1 dose of study drug.

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	mRNA-1273.214 10 ug
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Reporting group description:

Participants received at least 1 of 2 doses of mRNA-1273.214 10 µg by IM injection approximately 8 weeks apart (Day 1 and Day 57).

Reporting group title	mRNA-1273.214 5 ug
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Reporting group description:

Participants received at least 1 of 2 doses of mRNA-1273.214 5 µg by IM injection approximately 8 weeks apart (Day 1 and Day 57).

Serious adverse events	mRNA-1273.214 10 ug	mRNA-1273.214 5 ug	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 18 (5.56%)	1 / 50 (2.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	1	0	
Cardiac disorders			
Cardiac arrest	Additional description: Cardiac arrest resulting from drowning.		
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Hypoxic-ischaemic encephalopathy	Additional description: Hypoxic-ischaemic encephalopathy resulting from drowning.		
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
General disorders and administration site conditions			
Drowning			

subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Rhinovirus infection			
subjects affected / exposed	0 / 18 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	mRNA-1273.214 10 ug	mRNA-1273.214 5 ug	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 18 (88.89%)	40 / 50 (80.00%)	
Investigations			
Blood lead increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Speech disorder developmental			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 18 (11.11%)	5 / 50 (10.00%)	
occurrences (all)	4	5	
Ear and labyrinth disorders			
Otorrhoea			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			

Constipation			
subjects affected / exposed	1 / 18 (5.56%)	3 / 50 (6.00%)	
occurrences (all)	1	4	
Diarrhoea			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Teething			
subjects affected / exposed	1 / 18 (5.56%)	6 / 50 (12.00%)	
occurrences (all)	1	6	
Vomiting			
subjects affected / exposed	1 / 18 (5.56%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	3 / 18 (16.67%)	5 / 50 (10.00%)	
occurrences (all)	8	7	
Nasal congestion			
subjects affected / exposed	2 / 18 (11.11%)	5 / 50 (10.00%)	
occurrences (all)	3	5	
Rhinitis allergic			
subjects affected / exposed	1 / 18 (5.56%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Rhinorrhoea			
subjects affected / exposed	0 / 18 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	4	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	1 / 18 (5.56%)	2 / 50 (4.00%)	
occurrences (all)	1	2	
Eczema			

subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	5 / 50 (10.00%) 5	
Infections and infestations			
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Candida nappy rash			
subjects affected / exposed	1 / 18 (5.56%)	3 / 50 (6.00%)	
occurrences (all)	1	3	
Conjunctivitis			
subjects affected / exposed	1 / 18 (5.56%)	2 / 50 (4.00%)	
occurrences (all)	2	2	
Conjunctivitis bacterial			
subjects affected / exposed	3 / 18 (16.67%)	4 / 50 (8.00%)	
occurrences (all)	4	4	
Coronavirus infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Ear infection			
subjects affected / exposed	1 / 18 (5.56%)	3 / 50 (6.00%)	
occurrences (all)	2	6	
Gastroenteritis			
subjects affected / exposed	0 / 18 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	4	
Bronchiolitis			
subjects affected / exposed	1 / 18 (5.56%)	6 / 50 (12.00%)	
occurrences (all)	1	7	
Viral upper respiratory tract infection			
subjects affected / exposed	4 / 18 (22.22%)	9 / 50 (18.00%)	
occurrences (all)	12	23	
Upper respiratory tract infection			
subjects affected / exposed	7 / 18 (38.89%)	16 / 50 (32.00%)	
occurrences (all)	12	39	
Rhinovirus infection			

subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	3	0	
Rhinitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 18 (11.11%)	7 / 50 (14.00%)	
occurrences (all)	2	7	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Pneumonia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Otosalpingitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Otitis media			
subjects affected / exposed	3 / 18 (16.67%)	12 / 50 (24.00%)	
occurrences (all)	9	17	
Influenza			
subjects affected / exposed	2 / 18 (11.11%)	2 / 50 (4.00%)	
occurrences (all)	2	2	
Hand-foot-and-mouth disease			
subjects affected / exposed	2 / 18 (11.11%)	4 / 50 (8.00%)	
occurrences (all)	2	4	
Gastroenteritis viral			
subjects affected / exposed	2 / 18 (11.11%)	3 / 50 (6.00%)	
occurrences (all)	3	3	
Otitis media acute			
subjects affected / exposed	4 / 18 (22.22%)	9 / 50 (18.00%)	
occurrences (all)	10	14	
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	1 / 18 (5.56%)	0 / 50 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
18 September 2023	Enrollment was paused on 18-Sep-2023 since an updated formulation was available under EUA. Enrollment was eventually discontinued in May 2024 based on interim immunogenicity results from Part 1, and neither dose level could be advanced for further evaluation. Accordingly Part 2 of the study was not initiated. Enrollment discontinuation was not related to any safety concerns.	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Based on immunogenicity results from Part 1, Part 2 was not conducted. Results should be interpreted with caution due to the small sample size of Part 1 Arm 2.

Notes: