Clinical trial results:
A Phase 2/3, Three-Part, Open-Label, Dose-Escalation, Age De-escalation and Randomized, Observer-Blind, Placebo-Controlled Expansion Study to Evaluate the Safety, Tolerability, Reactogenicity, and Effectiveness of mRNA-1273 SARS-CoV-2 Vaccine in Healthy Children 6 Months to Less Than 12 Years of Age

Summary

EudraCT number	2021-000281-15
Trial protocol	Outside EU/EEA
Global end of trial date	15 March 2024

Results information

Result version number	v1
This version publication date	30 September 2024
First version publication date	30 September 2024

Trial information

Trial identification

Sponsor protocol code	mRNA-1273-P204

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04796896
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ModernaTX, Inc.
Sponsor organisation address	325 Binney Street, Cambridge, United States, 02142
Public contact	Moderna 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)	Yes
EMA paediatric investigation plan number(s)	EMEA-005791-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	17 May 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2024
Global end of trial reached?	Yes
Global end of trial date	15 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary goal for this study is to evaluate up to 3 dose levels of mRNA-1273 vaccine given to healthy children as intramuscular (IM) injections in 2 doses (in Parts 1 and 2) and 3 doses (in Part 3), and a third dose or an optional booster dose (BD) (in Parts 1 and 2).

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	15 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 11529
Country: Number of subjects enrolled	Canada: 413
Worldwide total number of subjects	11942
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)	2837
Children (2-11 years)	9105
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:

The study was conducted in 3 parts: Part 1 (open-label; dose-escalation and age de-escalation), Part 2 (placebo-controlled), and Part 3 (open-label; lower dose regimen). A comparison to the mRNA-1273-P301 (NCT04470427) study's efficacy data was performed on a sub-group of mRNA-1273-P301 study participants aged 18-25 (N=296).

Period 1

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

Blinding implementation details:

Part 1 and Part 3 were open label. Part 2 was conducted in an observer-blind manner.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1 (6-11 Years): mRNA-1273 50 µg

Arm description:

Participants received 2 doses of 50 micrograms (µg) mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 1 (6-11 Years): mRNA-1273 100 µg

Arm description:

Participants received 2 doses of 100 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 1 (2-5 Years): mRNA-1273 25 µg

Arm description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental

Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 1 (2-5 Years): mRNA-1273 50 µg

Arm description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 1 (6-23 Months): mRNA-1273 25 µg

Arm description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 2 (6-11 Years): Placebo

Arm description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 50 µg of mRNA-1273 after the availability of a coronavirus disease 2019 (COVID-19) vaccine under Emergency Use Authorization (EUA).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate, Sterile concentrate
Routes of administration	Intramuscular use, Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1273 was administered per schedule specified in the arm description.

Arm title	Part 2 (6-11 Years): mRNA-1273 50 µg

Arm description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental

Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 2 (2-5 Years): Placebo

Arm description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1273 was administered per schedule specified in the arm description.

Arm title	Part 2 (2-5 Years): mRNA-1273 25 µg

Arm description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 2 (6-23 Months): Placebo

Arm description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1273 was administered per schedule specified in the arm description.

Arm title	Part 2 (6-23 Months): mRNA-1273 25 µg

Arm description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Arm type	Experimental

Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg

Arm description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1, and Day 29).

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Number of subjects in period 1	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg
Started	380	371	75
Received First Injection	380	371	75
Received Second Injection	379	371	75
Received First Injection in Open-label	0 [1]	0 [2]	0 [3]
Completed	307	316	55
Not completed	73	55	20
Adverse event, serious fatal	-	-	-
Physician decision	1	-	-
Consent withdrawn by subject	36	31	11
Other Than Specified	6	5	3
Adverse event, non-fatal	1	-	-
Protocol Deviation	-	-	-
Received Emergency Use Authorization (EUA) Vaccine	5	4	-
Lost to follow-up	24	15	6
Missing	-	-	-

Number of subjects in period 1	Part 1 (2-5 Years): mRNA-1273 50 µg	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo
Started	149	150	1004
Received First Injection	149	150	997
Received Second Injection	149	150	974

Received First Injection in Open-label	0 [4]	0 [5]	702
Completed	131	105	556
Not completed	18	45	448
Adverse event, serious fatal	-	-	-
Physician decision	-	-	3
Consent withdrawn by subject	8	16	162
Other Than Specified	2	6	31
Adverse event, non-fatal	-	-	1
Protocol Deviation	1	1	2
Received Emergency Use Authorization (EUA) Vaccine	3	1	194
Lost to follow-up	4	21	55
Missing	-	-	-

Number of subjects in period 1	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg
Started	3011	1008	3040
Received First Injection	3005	1007	3031
Received Second Injection	2995	984	3007
Received First Injection in Open-label	0 [6]	640	0 [7]
Completed	2329	515	2086
Not completed	682	493	954
Adverse event, serious fatal	-	-	1
Physician decision	18	1	7
Consent withdrawn by subject	299	149	303
Other Than Specified	86	66	388
Adverse event, non-fatal	1	-	1
Protocol Deviation	2	2	2
Received Emergency Use Authorization (EUA) Vaccine	37	222	29
Lost to follow-up	237	52	221
Missing	2	1	2

Number of subjects in period 1	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg
Started	669	1995	90
Received First Injection	667	1993	90
Received Second Injection	649	1979	84
Received First Injection in Open-label	444	0 [8]	0 [9]
Completed	366	1387	51
Not completed	303	608	39
Adverse event, serious fatal	-	-	-
Physician decision	-	5	-
Consent withdrawn by subject	94	192	16

Other Than Specified	48	258	4
Adverse event, non-fatal	1	1	-
Protocol Deviation	1	-	-
Received Emergency Use Authorization (EUA) Vaccine	115	9	1
Lost to follow-up	43	142	18
Missing	1	1	-

Notes:

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

[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: The number of participants in this milestone is consistent with study data.

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

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

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

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

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

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

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

Period 2

Period 2 title	Booster Dose (BD) Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

Part 1 was open label. Part 2 was conducted in an observer-blind manner.

Arms

Are arms mutually exclusive?	Yes

Arm title	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on Booster Dose (BD)-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273 was administered per dose and schedule specified in the arm description.	
Arm title	Part 1 (6-11 Years): PS mRNA-1273 100 µg - BD 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273 was administered per dose and schedule specified in the arm description.	
Arm title	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg
Arm description:	
Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273 was administered per dose and schedule specified in the arm description.	
Arm title	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg
Arm description:	
Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273 was administered per dose and schedule specified in the arm description.	
Arm title	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 10 µg
Arm description:	
Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.	
Arm type	Experimental

Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 25 µg

Arm description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 25 µg

Arm description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 2 (6 Months-5 Yrs): PS PBO - mRNA-1273 25 µg - BD 25 µg

Arm description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 2 (6 Months-5 Years): PS mRNA-1273 25 µg - BD 25 µg

Arm description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:
mRNA-1273 was administered per dose and schedule specified in the arm description.

Arm title	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 10 µg
Arm description:	
Participants received a single dose of 10 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273.214 was administered per dose and schedule specified in the arm description.	

Arm title	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 10 µg
Arm description:	
Participants received a single dose of 10 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273.214 was administered per dose and schedule specified in the arm description.	

Arm title	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273.214 was administered per dose and schedule specified in the arm description.	

Arm title	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273.214 was administered per dose and schedule specified in the arm description.	

Arm title	Part 2(6-11 Yrs): PS Placebo - mRNA-1273 50 µg - BD 1273 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Arm type	Placebo
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate, Sterile concentrate
Routes of administration	Intramuscular use, Intramuscular use
Dosage and administration details:	
mRNA-1273 was administered per dose and schedule specified in the arm description.	
Arm title	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273 was administered per dose and schedule specified in the arm description.	
Arm title	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg - BD 1273.214 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Arm type	Placebo
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1273.214 was administered per dose and schedule specified in the arm description.	
Arm title	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273.214 25 µg
Arm description:	
Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1273.214
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate, Sterile concentrate
Routes of administration	Intramuscular use, Intramuscular use
Dosage and administration details:	
mRNA-1273.214 was administered per dose and schedule specified in the arm description.	
Arm title	Part 3 (6-11 Years): BD mRNA-1273 25 µg
Arm description:	
Participants received a third dose of 25 µg mRNA-1273 by IM injection on Day 149.	
Arm type	Experimental

Investigational medicinal product name	mRNA-1273
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Sterile concentrate
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273 was administered per dose and schedule specified in the arm description.

Number of subjects in period 2[10]	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 1 (6-11 Years): PS mRNA-1273 100 µg - BD 25 µg	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg
Started	229	247	122
Received Booster Injection	229	247	122
Completed	201	227	90
Not completed	28	20	32
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	15	11	9
Physician decision	-	-	-
Other Than Specified	-	3	4
Received Another COVID-19 Vaccine Under EUA	2	1	1
Lost to follow-up	11	5	18

Number of subjects in period 2[10]	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 25 µg
Started	31	59	9
Received Booster Injection	31	59	9
Completed	24	55	9
Not completed	7	4	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	4	3	-
Physician decision	-	-	-
Other Than Specified	1	1	-
Received Another COVID-19 Vaccine Under EUA	-	-	-
Lost to follow-up	2	-	-

Number of subjects in period 2[10]	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 2 (6 Months-5 Yrs): PS PBO - mRNA-1273 25 µg - BD 25 µg	Part 2 (6 Months-5 Years): PS mRNA-1273 25 µg - BD 25 µg
Started	38	5	37
Received Booster Injection	38	5	37
Completed	36	5	30
Not completed	2	0	7

Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	-	4
Physician decision	-	-	-
Other Than Specified	-	-	-
Received Another COVID-19 Vaccine Under EUA	-	-	-
Lost to follow-up	-	-	3

Number of subjects in period 2[10]	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 10 µg	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 10 µg	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 25 µg
Started	505	2261	8
Received Booster Injection	505	2261	8
Completed	460	2073	7
Not completed	45	188	1
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	24	84	-
Physician decision	-	-	-
Other Than Specified	4	24	-
Received Another COVID-19 Vaccine Under EUA	-	1	-
Lost to follow-up	17	78	1

Number of subjects in period 2[10]	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 25 µg	Part 2(6-11 Yrs): PS Placebo - mRNA-1273 50 µg - BD 1273 25 µg	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg
Started	20	411	1879
Received Booster Injection	20	411	1879
Completed	18	351	1626
Not completed	2	60	253
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	27	107
Physician decision	-	-	3
Other Than Specified	-	5	24
Received Another COVID-19 Vaccine Under EUA	-	5	20
Lost to follow-up	2	23	99

Number of subjects in period 2[10]	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg - BD 1273.214 25 µg	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273.214 25 µg	Part 3 (6-11 Years): BD mRNA-1273 25 µg
Started	58	123	70
Received Booster Injection	58	123	70
Completed	55	115	50
Not completed	3	8	20
Adverse event, serious fatal	-	-	-

Consent withdrawn by subject	2	3	9
Physician decision	-	-	-
Other Than Specified	1	1	4
Received Another COVID-19 Vaccine Under EUA	-	-	-
Lost to follow-up	-	4	7

Notes:

[10] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: The number of participants in this period is consistent with study data.

Baseline characteristics

Reporting groups	
Reporting group title	Part 1 (6-11 Years): mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 micrograms (µg) mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (6-11 Years): mRNA-1273 100 µg
Reporting group description:	
Participants received 2 doses of 100 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (2-5 Years): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (2-5 Years): mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (6-23 Months): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 2 (6-11 Years): Placebo
Reporting group description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 50 µg of mRNA-1273 after the availability of a coronavirus disease 2019 (COVID-19) vaccine under Emergency Use Authorization (EUA).	
Reporting group title	Part 2 (6-11 Years): mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 2 (2-5 Years): Placebo
Reporting group description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.	
Reporting group title	Part 2 (2-5 Years): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 2 (6-23 Months): Placebo
Reporting group description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.	
Reporting group title	Part 2 (6-23 Months): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1, and Day 29).	

Reporting group values	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg
Number of subjects	380	371	75
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months)	0	0	0
Children (2 - 11 years)	380	371	75
Adults (between 18 and 64 years)	0	0	0
Gender Categorical Units: Subjects			
Female	185	199	39
Male	195	172	36
Race Units: Subjects			
White	266	284	54
Black or African American	34	13	3
Asian	28	25	8
American Indian or Alaska Native	0	2	0
Native Hawaiian or Other Pacific Islander	1	0	0
Other	3	10	7
Multiple	39	31	3
Not Reported	9	4	0
Unknown	0	2	0
Ethnicity Units: Subjects			
Hispanic or Latino	72	69	24
Not Hispanic or Latino	304	296	51
Not Reported	3	3	0
Unknown	1	3	0

Reporting group values	Part 1 (2-5 Years): mRNA-1273 50 µg	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo
Number of subjects	149	150	1004
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months)	0	150	0
Children (2 - 11 years)	149	0	1004
Adults (between 18 and 64 years)	0	0	0
Gender Categorical Units: Subjects			
Female	69	67	516
Male	80	83	488
Race Units: Subjects			
White	128	124	676
Black or African American	7	3	94
Asian	3	7	100

American Indian or Alaska Native	0	1	3
Native Hawaiian or Other Pacific Islander	0	0	0
Other	1	3	22
Multiple	10	11	98
Not Reported	0	0	10
Unknown	0	1	1
Ethnicity Units: Subjects			
Hispanic or Latino	17	15	183
Not Hispanic or Latino	129	133	811
Not Reported	3	1	5
Unknown	0	1	5

Reporting group values	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg
Number of subjects	3011	1008	3040
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months)	0	11	18
Children (2 - 11 years)	3011	997	3022
Adults (between 18 and 64 years)	0	0	0
Gender Categorical Units: Subjects			
Female	1456	498	1490
Male	1555	510	1550
Race Units: Subjects			
White	1960	793	2307
Black or African American	310	38	142
Asian	297	51	191
American Indian or Alaska Native	15	3	11
Native Hawaiian or Other Pacific Islander	4	3	5
Other	62	16	43
Multiple	330	100	324
Not Reported	23	4	13
Unknown	10	0	4
Ethnicity Units: Subjects			
Hispanic or Latino	562	142	429
Not Hispanic or Latino	2421	857	2593
Not Reported	21	8	13
Unknown	7	1	5

Reporting group values	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg
Number of subjects	669	1995	90
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months)	669	1989	0

Children (2 - 11 years)	0	6	90
Adults (between 18 and 64 years)	0	0	0

Gender Categorical Units: Subjects			
Female	341	981	34
Male	328	1014	56
Race Units: Subjects			
White	527	1568	48
Black or African American	18	62	37
Asian	38	94	2
American Indian or Alaska Native	0	7	2
Native Hawaiian or Other Pacific Islander	0	0	0
Other	7	33	0
Multiple	76	215	0
Not Reported	2	11	1
Unknown	1	5	0
Ethnicity Units: Subjects			
Hispanic or Latino	94	257	29
Not Hispanic or Latino	568	1719	58
Not Reported	6	17	1
Unknown	1	2	2

Reporting group values	Total		
Number of subjects	11942		
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months)	2837		
Children (2 - 11 years)	9105		
Adults (between 18 and 64 years)	0		
Gender Categorical Units: Subjects			
Female	5875		
Male	6067		
Race Units: Subjects			
White	8735		
Black or African American	761		
Asian	844		
American Indian or Alaska Native	44		
Native Hawaiian or Other Pacific Islander	13		
Other	207		
Multiple	1237		
Not Reported	77		
Unknown	24		
Ethnicity Units: Subjects			

Hispanic or Latino	1893		
Not Hispanic or Latino	9940		
Not Reported	81		
Unknown	28		

Subject analysis sets

Subject analysis set title	Part 1 (6-11 Years): mRNA-1273 50 µg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Subject analysis set title	Part 1 (6-11 Years): mRNA-1273 100 µg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of 100 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Subject analysis set title	Part 1 (2-5 Years): mRNA-1273 25 µg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Subject analysis set title	Part 1 (2-5 Years): mRNA-1273 50 µg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Subject analysis set title	Part 1 (6-23 Months): mRNA-1273 25 µg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Subject analysis set title	Part 2 (6-11 Years): Placebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 50 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.	
Subject analysis set title	Part 2 (6-11 Years): mRNA-1273 50 µg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Subject analysis set title	Part 2 (2-5 Years): Placebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.	
Subject analysis set title	Part 2 (2-5 Years): mRNA-1273 25 µg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Subject analysis set title	Part 2 (6-23 Months): Placebo

Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Subject analysis set title	Part 2 (6-23 Months): mRNA-1273 25 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 3 (6-11 Years): mRNA-1273 25 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 3 doses of 25 µg mRNA-1273 by IM injection on Days 1, 29, and 149.

Subject analysis set title	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants (young adults; 18-25 years of age) received 100 µg mRNA-1273 on a 2 injection schedule in Study mRNA-1273-P301 (P301).

Subject analysis set title	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg (Crossover)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a placebo in the blinded phase and then crossover vaccination with 50 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Subject analysis set title	Part 2 (2-5 Years): PS PBO - mRNA-1273 25 µg (Crossover)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a placebo in the blinded phase and then crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA. Adverse Events were collected from the first cross-over dose until the first booster dose.

Subject analysis set title	Part 2 (6-23 Months): PBO - mRNA-1273 25 µg (Crossover)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a placebo in the blinded phase and then crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA. Adverse Events were collected from the first cross-over dose until the first booster dose.

Subject analysis set title	BD Phase Part 1 (6 Month-5 Yrs): PS mRNA-1273 25 µg - BD 10 µg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.

Subject analysis set title	BD Part 1 and 2 (6-11 Yrs): PS mRNA-1273 50 µg - BD 1273 25 µg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

Reporting group values	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg
Number of subjects	380	371	69
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months) Children (2 - 11 years) Adults (between 18 and 64 years)			

Gender Categorical Units: Subjects			
Female Male			
Race Units: Subjects			
White Black or African American Asian American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Multiple Not Reported Unknown			
Ethnicity Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Not Reported Unknown			

Reporting group values	Part 1 (2-5 Years): mRNA-1273 50 µg	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo
Number of subjects	155	150	995
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months) Children (2 - 11 years) Adults (between 18 and 64 years)			
Gender Categorical Units: Subjects			
Female Male			
Race Units: Subjects			
White Black or African American Asian American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Multiple Not Reported Unknown			
Ethnicity Units: Subjects			
Hispanic or Latino Not Hispanic or Latino			

Not Reported Unknown			

Reporting group values	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg
Number of subjects	3007	1007	3031
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months) Children (2 - 11 years) Adults (between 18 and 64 years)			
Gender Categorical Units: Subjects			
Female Male			
Race Units: Subjects			
White Black or African American Asian American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Multiple Not Reported Unknown			
Ethnicity Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Not Reported Unknown			

Reporting group values	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg	Part 3 (6-11 Years): mRNA-1273 25 µg
Number of subjects	666	1994	90
Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months) Children (2 - 11 years) Adults (between 18 and 64 years)			
Gender Categorical Units: Subjects			
Female Male			
Race Units: Subjects			
White Black or African American			

Asian			
American Indian or Alaska Native			
Native Hawaiian or Other Pacific Islander			
Other			
Multiple			
Not Reported			
Unknown			
Ethnicity			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Not Reported			
Unknown			

Reporting group values	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg (Crossover)	Part 2 (2-5 Years): PS PBO - mRNA-1273 25 µg (Crossover)
Number of subjects	296	701	640
Age Categorical			
Units: Subjects			
Infants and toddlers (28 days - 23 months)	0		
Children (2 - 11 years)	0		
Adults (between 18 and 64 years)	296		
Gender Categorical			
Units: Subjects			
Female	153		
Male	143		
Race			
Units: Subjects			
White	207		
Black or African American	29		
Asian	30		
American Indian or Alaska Native	3		
Native Hawaiian or Other Pacific Islander	2		
Other	8		
Multiple	14		
Not Reported	3		
Unknown	0		
Ethnicity			
Units: Subjects			
Hispanic or Latino	78		
Not Hispanic or Latino	216		
Not Reported	0		
Unknown	2		

Reporting group values	Part 2 (6-23 Months): PBO - mRNA-1273 25 µg (Crossover)	BD Phase Part 1 (6 Month-5 Yrs): PS mRNA-1273 25 µg - BD 10 µg	BD Part 1 and 2 (6-11 Yrs): PS mRNA-1273 50 µg - BD 1273 25 µg
Number of subjects	444	103	189

Age Categorical Units: Subjects			
Infants and toddlers (28 days - 23 months) Children (2 - 11 years) Adults (between 18 and 64 years)			
Gender Categorical Units: Subjects			
Female Male			
Race Units: Subjects			
White Black or African American Asian American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Multiple Not Reported Unknown			
Ethnicity Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Not Reported Unknown			

End points

End points reporting groups

Reporting group title	Part 1 (6-11 Years): mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 micrograms (µg) mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (6-11 Years): mRNA-1273 100 µg
Reporting group description:	
Participants received 2 doses of 100 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (2-5 Years): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (2-5 Years): mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 1 (6-23 Months): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 2 (6-11 Years): Placebo
Reporting group description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 50 µg of mRNA-1273 after the availability of a coronavirus disease 2019 (COVID-19) vaccine under Emergency Use Authorization (EUA).	
Reporting group title	Part 2 (6-11 Years): mRNA-1273 50 µg
Reporting group description:	
Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 2 (2-5 Years): Placebo
Reporting group description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.	
Reporting group title	Part 2 (2-5 Years): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 2 (6-23 Months): Placebo
Reporting group description:	
Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.	
Reporting group title	Part 2 (6-23 Months): mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).	
Reporting group title	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg
Reporting group description:	
Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1, and Day 29).	

Reporting group title	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on Booster Dose (BD)-Day 1.	
Reporting group title	Part 1 (6-11 Years): PS mRNA-1273 100 µg - BD 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg
Reporting group description:	
Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg
Reporting group description:	
Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 10 µg
Reporting group description:	
Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 2 (6 Months-5 Yrs): PS PBO - mRNA-1273 25 µg - BD 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 2 (6 Months-5 Years): PS mRNA-1273 25 µg - BD 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 10 µg
Reporting group description:	
Participants received a single dose of 10 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Reporting group title	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 10 µg
Reporting group description:	
Participants received a single dose of 10 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Reporting group title	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Reporting group title	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.	
Reporting group title	Part 2(6-11 Yrs): PS Placebo - mRNA-1273 50 µg - BD 1273 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg
Reporting group description:	
Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.	
Reporting group title	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg - BD 1273.214 25 µg

Reporting group description:

Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.

Reporting group title	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273.214 25 µg

Reporting group description:

Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.

Reporting group title	Part 3 (6-11 Years): BD mRNA-1273 25 µg

Reporting group description:

Participants received a third dose of 25 µg mRNA-1273 by IM injection on Day 149.

Subject analysis set title	Part 1 (6-11 Years): mRNA-1273 50 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 1 (6-11 Years): mRNA-1273 100 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 100 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 1 (2-5 Years): mRNA-1273 25 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 1 (2-5 Years): mRNA-1273 50 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 1 (6-23 Months): mRNA-1273 25 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 2 (6-11 Years): Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 50 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Subject analysis set title	Part 2 (6-11 Years): mRNA-1273 50 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 2 (2-5 Years): Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Subject analysis set title	Part 2 (2-5 Years): mRNA-1273 25 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1

and Day 29).

Subject analysis set title	Part 2 (6-23 Months): Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Subject analysis set title	Part 2 (6-23 Months): mRNA-1273 25 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Subject analysis set title	Part 3 (6-11 Years): mRNA-1273 25 µg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 3 doses of 25 µg mRNA-1273 by IM injection on Days 1, 29, and 149.

Subject analysis set title	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants (young adults; 18-25 years of age) received 100 µg mRNA-1273 on a 2 injection schedule in Study mRNA-1273-P301 (P301).

Subject analysis set title	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg (Crossover)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a placebo in the blinded phase and then crossover vaccination with 50 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Subject analysis set title	Part 2 (2-5 Years): PS PBO - mRNA-1273 25 µg (Crossover)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a placebo in the blinded phase and then crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA. Adverse Events were collected from the first cross-over dose until the first booster dose.

Subject analysis set title	Part 2 (6-23 Months): PBO - mRNA-1273 25 µg (Crossover)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a placebo in the blinded phase and then crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA. Adverse Events were collected from the first cross-over dose until the first booster dose.

Subject analysis set title	BD Phase Part 1 (6 Month-5 Yrs): PS mRNA-1273 25 µg - BD 10 µg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.

Subject analysis set title	BD Part 1 and 2 (6-11 Yrs): PS mRNA-1273 50 µg - BD 1273 25 µg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

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

End point title	Number of Participants With Solicited Local and Systemic Adverse Reactions (ARs)[1]

End point description:

Solicited ARs were collected in an electronic diary (eDiary). Local ARs: injection site pain, erythema (redness), swelling/induration (hardness); and axillary (underarm) swelling or tenderness ipsilateral to

the side of injection. Systemic ARs: fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Note, not all solicited ARs were considered adverse events (AEs). Investigator reviewed whether the solicited AR was also to be recorded as an AE. A Summary of serious AEs (SAEs) and nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Solicited Safety Set: all participants in Safety Set (Safety Set of Part 1 and Part 3 included all dosed participants and of Part 2 included all randomized participants who received any study injection) who contributed any solicited AR data, that is, had at least 1 post-baseline solicited safety assessment. Data for this endpoint was not collected for the treatment groups mRNA-1273.214.

End point type	Primary

End point timeframe:

7 days post-vaccination

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Data for this endpoint was reported for the specified arms only.

End point values	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 1 (6-11 Years): PS mRNA-1273 100 µg - BD 25 µg	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	228	247	122	31
Units: participants	216	221	93	24

End point values	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 25 µg	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 2 (6 Months-5 Yrs): PS PBO - mRNA-1273 25 µg - BD 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	8	38	5
Units: participants	46	7	36	4

End point values	Part 2 (6 Months-5 Years): PS mRNA-1273 25 µg - BD 25 µg	Part 2(6-11 Yrs): PS Placebo - mRNA-1273 50 µg - BD 1273 25 µg	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg	Part 3 (6-11 Years): BD mRNA-1273 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	405	1853	56
Units: participants	12	358	1726	30

End point values	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg	Part 1 (2-5 Years): mRNA-1273 50 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	380	371	69	153
Units: participants	374	367	62	147

End point values	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	150	994	3005	998
Units: participants	141	823	2983	797

End point values	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg	Part 3 (6-11 Years): mRNA-1273 25 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3014	664	1991	90
Units: participants	2800	596	1889	66

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited AEs

End point title	Number of Participants With Unsolicited AEs[2]

End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. Any abnormal laboratory test result (hematology, clinical chemistry, or prothrombin time [PT]/partial thromboplastin time [PTT]) or other safety assessment (for example, electrocardiogram, radiological scan, vital sign measurement), including one that worsened from baseline and was considered clinically significant in the medical and scientific judgment of the Investigator was recorded as an AE. A summary of SAEs and all nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section and presented by each dose group separately. Safety Set of Part 1 and Part 3 included all dosed participants and of Part 2 included all randomized participants who received any study injection.

End point type	Primary

End point timeframe:

Up to 28 days post-vaccination

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: Data for this endpoint was reported for the specified arms only.

End point values	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 1 (6-11 Years): PS mRNA-1273 100 µg - BD 25 µg	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	229	247	122	31
Units: participants	38	20	24	8

End point values	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 25 µg	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 2 (6 Months-5 Yrs): PS PBO - mRNA-1273 25 µg - BD 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	9	38	5
Units: participants	4	1	8	1

End point values	Part 2 (6 Months-5 Years): PS mRNA-1273 25 µg - BD 25 µg	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 10 µg	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 10 µg	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	505	2261	8
Units: participants	5	57	282	0

End point values	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 25 µg	Part 2(6-11 Yrs): PS Placebo - mRNA-1273 50 µg - BD 1273 25 µg	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg - BD 1273.214 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	411	1879	58
Units: participants	0	33	196	4

End point values	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273.214 25 µg	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	123	380	371	69
Units: participants	7	106	92	15

End point values	Part 1 (2-5 Years): mRNA-1273 50 µg	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo	Part 2 (6-11 Years): mRNA-1273 50 µg

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	155	150	995	3007
Units: participants	51	75	207	785

End point values	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1007	3031	666	1994
Units: participants	325	1087	283	883

End point values	Part 3 (6-11 Years): mRNA-1273 25 µg			
Subject group type	Subject analysis set			
Number of subjects analysed	90			
Units: participants	17			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events (SAEs), AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs Leading to Discontinuation From Study

End point title	Number of Participants With Serious Adverse Events (SAEs), AEs of Special Interest (AESIs), Medically Attended AEs (MAAEs), and AEs Leading to Discontinuation From Study[3]

End point description:

An SAE was defined as any AE that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in disability, was a congenital anomaly/birth defect, or was an important medical event. AESIs included thrombocytopenia, new onset of or worsening of protocol specified neurologic diseases, anaphylaxis, multisystem inflammatory syndrome in children (MIS-C) and myocarditis and/or pericarditis. An MAAE is an AE that led to an unscheduled visit to a healthcare practitioner. This included visits to a study site for unscheduled assessments and visits to healthcare practitioners external to the study site. A summary of SAEs and all nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section and presented by each dose group separately. Safety Set of Part 1 and Part 3 included all dosed participants and of Part 2 included all randomized participants who received any study injection.

End point type	Primary

End point timeframe:

Throughout the study period (up to 24 months)

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: Data for this endpoint was reported for the specified arms only.

End point values	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 1 (6-11 Years): PS mRNA-1273 100 µg - BD 25 µg	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	229	247	122	31
Units: participants				
SAEs	1	1	1	0
AESIs	1	0	2	0
MAAEs	85	71	59	16
AEs Leading to Discontinuation	0	0	0	0

End point values	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 25 µg	Part 1 (2-5 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 2 (6 Months-5 Yrs): PS PBO - mRNA-1273 25 µg - BD 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	9	38	5
Units: participants				
SAEs	0	0	0	1
AESIs	0	0	0	0
MAAEs	23	4	17	3
AEs Leading to Discontinuation	0	0	0	0

End point values	Part 2 (6 Months-5 Years): PS mRNA-1273 25 µg - BD 25 µg	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 10 µg	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 10 µg	Part 2(6 M-5 Yr): PS PBO - mRNA-1273 25 µg - BD 1273.214 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	505	2261	8
Units: participants				
SAEs	0	7	16	0
AESIs	1	2	0	0
MAAEs	10	182	901	1
AEs Leading to Discontinuation	0	0	1	0

End point values	Part 2(6 Months-5 Yrs): PS mRNA-1273 25 µg - BD 1273.214 25 µg	Part 2(6-11 Yrs): PS Placebo - mRNA-1273 50 µg - BD 1273 25 µg	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg - BD 1273.214 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	411	1879	58
Units: participants				

SAEs	0	3	7	0
AESIs	0	2	9	0
MAAEs	3	137	616	16
AEs Leading to Discontinuation	0	0	0	0

End point values	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273.214 25 µg	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	123	380	371	69
Units: participants				
SAEs	0	5	3	0
AESIs	0	5	7	0
MAAEs	34	175	169	32
AEs Leading to Discontinuation	0	1	0	0

End point values	Part 1 (2-5 Years): mRNA-1273 50 µg	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo	Part 2 (6-11 Years): mRNA-1273 50 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	155	150	995	3007
Units: participants				
SAEs	0	3	1	22
AESIs	1	2	2	19
MAAEs	80	105	155	1095
AEs Leading to Discontinuation	0	0	0	0

End point values	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1007	3031	666	1994
Units: participants				
SAEs	3	32	6	45
AESIs	7	13	2	13
MAAEs	411	1687	340	1237
AEs Leading to Discontinuation	0	1	0	1

End point values	Part 3 (6-11 Years): mRNA-	Part 2(6-11 Yrs): PS PBO -	Part 2 (2-5 Years): PS PBO	Part 2 (6-23 Months): PBO -

	1273 25 µg	mRNA-1273 50 µg (Crossover)	- mRNA-1273 25 µg (Crossover)	mRNA-1273 25 µg (Crossover)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	90	701	640	444
Units: participants				
SAEs	1	3	8	4
AESIs	0	3	1	1
MAAEs	22	221	204	171
AEs Leading to Discontinuation	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean (GM) Value of Serum Pseudovirus Neutralizing Antibody ID50 Titers From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Trial (Study P301)

End point title	Geometric Mean (GM) Value of Serum Pseudovirus Neutralizing Antibody ID50 Titers From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Trial (Study P301)[4]

End point description:

Antibody values reported as below lower limit of quantification (LLOQ) were replaced by 0.5*LLOQ and values greater than upper limit of quantification (ULOQ) were replaced by ULOQ if actual values were not available. LLOQ was 18.5 arbitrary units (AU)/milliliter (mL) and ULOQ was 45118 AU/mL for ID50 titer. Per-Protocol (PP) Immunogenicity Subset: all enrolled participants who received at least 1 injection of study drug, had baseline SARS-CoV-2 status, had baseline and at least 1 post-injection antibody assessment for analysis endpoint, complied with immunogenicity window based on 2nd injection timing; had negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline, not receiving highly active antiretroviral therapy (HAART) for participants with HIV; and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 57 P204/Day 57 P301

Notes:

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

End point values	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg	Part 1 (2-5 Years): mRNA-1273 50 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	201	56	51	68
Units: titer				
geometric mean (confidence interval 95%)				
ID50	1669.1 (1504.5 to 1851.6)	1890.2 (1603.8 to 2227.7)	1012.5 (848.2 to 1208.6)	1845.9 (1600.5 to 2128.9)

End point values	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): mRNA-1273 50 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	97	309	294	
Units: titer				
geometric mean (confidence interval 95%)				
ID50	1782.6 (1542.0 to 2060.7)	1618.3 (1460.0 to 1793.9)	1321.9 (1196.5 to 1460.5)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2 (6-11 Years): mRNA-1273 50 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	603
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	1.224
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.061
upper limit	1.413

Primary: GM Concentration of Serum Pseudovirus Neutralizing Antibody VAC62 From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Endpoint Efficacy Trial (Study P301)

End point title	GM Concentration of Serum Pseudovirus Neutralizing Antibody VAC62 From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Endpoint Efficacy Trial (Study P301)[5]

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ and values greater than the ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PP Immunogenicity Subset: all enrolled participants who received at least 1 injection of study drug, had baseline severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) status, had baseline and at least 1 post-injection antibody assessment for analysis endpoint, complied with immunogenicity window based on 2nd injection timing; had negative reverse transcriptase polymerase chain reaction (RT-PCR) test for SARS-CoV-2 and negative serology test based on binding antibody (bAb) specific to SARS-CoV-2 nucleocapsid protein at baseline, not receiving HAART in participants with human immunodeficiency virus (HIV); and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 57 P204/Day 57 P301

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: Data for this endpoint was reported for the specified arms only.

End point values	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): mRNA-1273 25 µg	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	289	268	61	294
Units: AU/mL				
geometric mean (confidence interval 95%)	1394.1 (1267.7 to 1533.1)	1759.8 (1606.7 to 1927.4)	4368.6 (3339.6 to 5714.6)	1400.4 (1272.7 to 1541.0)

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Part 2 (6-23 Months): mRNA-1273 25 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	562
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	1.257
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.101
upper limit	1.434

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2 (2-5 Years): mRNA-1273 25 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	583
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	0.995
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.139

Primary: Seroresponse rate (SRR) For Serum Pseudovirus Neutralizing Antibody ID50 From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Trial (Study P301)

End point title	Seroresponse rate (SRR) For Serum Pseudovirus Neutralizing Antibody ID50 From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Trial (Study P301)[6]

End point description:

Percentage of participants with seroresponse for pseudovirus neutralizing antibody ID50 are reported. Seroresponse was defined as a change from below the LLOQ to equal above 4 * LLOQ, or at least a 4-fold rise if baseline is equal to or above the LLOQ. LLOQ was 18.5 AU/mL and ULOQ was 45118 AU/mL for ID50 titer. PP Immunogenicity Subset: all enrolled participants who received at least 1 injection of study drug, had baseline SARS-CoV-2 status, had baseline and at least 1 post-injection antibody assessment for analysis endpoint, complied with immunogenicity window based on 2nd injection timing; had negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline, not receiving HAART in participants with HIV; and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 57 P204/Day 57 P301

Notes:

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

End point values	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg	Part 1 (2-5 Years): mRNA-1273 50 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	201	56	50	68
Units: percentage of participants				
number (confidence interval 95%)				
ID50	99.5 (97.3 to 99.9)	100 (93.6 to 100.0)	100 (92.9 to 100)	100 (94.7 to 100.0)

End point values	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): mRNA-1273 50 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	96	307	294	
Units: percentage of participants				
number (confidence interval 95%)				
ID50	100 (96.2 to 100.0)	99.0 (97.2 to 99.8)	99.3 (97.6 to 99.9)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2 (6-11 Years): mRNA-1273 50 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	601
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	percentage difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	1.6

Primary: SRR For Serum Pseudovirus Neutralizing Antibody VAC62 From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Endpoint Efficacy Trial (Study P301)

End point title	SRR For Serum Pseudovirus Neutralizing Antibody VAC62 From Study P204 Vaccine Recipients at Day 57 Compared With Those From Young Adult (18 to 25 Years of Age) Vaccine Recipients (Day 57) in the Clinical Endpoint Efficacy Trial (Study P301)[7]

End point description:

Percentage of participants with seroresponse for Pseudovirus Neutralizing Antibody VAC62 are reported. Seroresponse was defined as a change from below the LLOQ to equal above 4 * LLOQ, or at least a 4-fold rise if baseline is equal to or above the LLOQ. LLOQ was 10 and ULOQ AU/mL was 111433 AU/mL. PP Immunogenicity Subset: all enrolled participants who received at least 1 injection of study drug, had baseline SARS-CoV-2 status, had baseline and at least 1 post-injection antibody assessment for analysis endpoint, complied with immunogenicity window based on 2nd injection timing; had negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline, not receiving HAART in participants with HIV; and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 57 P204/Day 57 P301

Notes:

[7] - 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: Data for this endpoint was reported for the specified arms only.

End point values	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): mRNA-1273 25 µg	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	284	264	61	294
Units: percentage of participants				
number (confidence interval 95%)	98.9 (96.9 to 99.8)	100 (98.6 to 100.0)	88.5 (77.8 to 95.3)	99.3 (97.6 to 99.9)

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Part 2 (6-23 Months): mRNA-1273 25 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	558
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	percentage difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	2.4

Statistical analysis title	Statistical Analysis 1
Comparison groups	Part 2 (2-5 Years): mRNA-1273 25 µg v Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg
Number of subjects included in analysis	578
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	percentage difference
Point estimate	-0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	1.5

Primary: GM Concentration of Post-booster Dose Serum Pseudovirus Neutralizing Antibody VAC62 in Study P204 Compared With Post-primary Series (Post-Dose 2) in Young Adult (18 to 25 Years of Age) Vaccine Recipients in Clinical Endpoint Efficacy Trial (Study P301)

End point title	GM Concentration of Post-booster Dose Serum Pseudovirus Neutralizing Antibody VAC62 in Study P204 Compared With Post-primary Series (Post-Dose 2) in Young Adult (18 to 25 Years of Age) Vaccine Recipients in Clinical Endpoint Efficacy Trial (Study P301)

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ and values greater than the ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PP Immunogenicity Subset (Booster Dose Analysis): all enrolled participants who

received 2 doses of planned doses of mRNA-1273 vaccination in Part 1 open-label phase or Part 2 blinded phase per schedule, received booster dose in Booster Dose Analysis, not receiving HAART in participants with HIV, had a negative SARS-CoV-2 status at baseline (pre-dose 1 of mRNA-1273), had BD-Day 29 Ab assessment for the analysis endpoint, no major protocol deviations that impacted key or critical data, and had not received off-study COVID-19 vaccination prior to BD-Day 29 visit. 'Overall number of participants analyzed' = Pre-booster SARS-CoV-2 negative participants evaluable for this endpoint.

End point type	Primary
End point timeframe:	
BD-Day 29 P204/Day 57 P301	

End point values	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg	BD Phase Part 1 (6 Month-5 Yrs): PS mRNA-1273 25 µg - BD 10 µg	BD Part 1 and 2 (6-11 Yrs): PS mRNA-1273 50 µg - BD 1273 25 µg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	294	76	137	
Units: AU/mL				
geometric mean (confidence interval 95%)	1400.4 (1272.7 to 1541.0)	5457.2 (4525.7 to 6580.3)	5575.9 (5026.8 to 6184.9)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg v BD Part 1 and 2 (6-11 Yrs): PS mRNA-1273 50 µg - BD 1273 25 µg
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	3.982
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.459
upper limit	4.583

Statistical analysis title	Statistical Analysis 1
Comparison groups	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg v BD Phase Part 1 (6 Month-5 Yrs): PS mRNA-1273 25 µg - BD 10 µg

Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	GMR
Point estimate	3.897
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.158
upper limit	4.808

Primary: GM Concentration of Post-third Dose (Part 3) Serum Pseudovirus Neutralizing Antibody VAC62 in Study P204 Compared With Post-primary Series (Post-Dose 2) in Young Adult (18 to 25 Years) Vaccine Recipients in Clinical Endpoint Efficacy Trial (Study P301)

End point title	GM Concentration of Post-third Dose (Part 3) Serum Pseudovirus Neutralizing Antibody VAC62 in Study P204 Compared With Post-primary Series (Post-Dose 2) in Young Adult (18 to 25 Years) Vaccine Recipients in Clinical Endpoint Efficacy Trial (Study P301)[8]

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ and values greater than the ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PP Immunogenicity Subset (Third Dose Analysis): all enrolled participants who received first 2 doses of planned doses of mRNA-1273 vaccination in Part 3 open-label phase per schedule, received third dose in Third Dose Analysis, not receiving HAART in participants with HIV, had BD-Day 29 antibody assessment for the analysis endpoint, had no major protocol deviations that impacted key or critical data, and had not received off-study COVID-19 vaccination prior to BD-Day 29 visit. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Third Dose-Day 29 P204/Day 57 P301

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Data for this endpoint was reported for the specified arms only.

End point values	Part 3 (6-11 Years): BD mRNA-1273 25 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	52	294		
Units: AU/mL				
geometric mean (confidence interval 95%)	4616.6 (3669.4 to 5808.3)	1400.4 (1272.7 to 1541.0)		

Statistical analyses

No statistical analyses for this end point

Primary: SRR for Post-booster Dose Serum Pseudovirus Neutralizing Antibody VAC62 From Baseline (Pre-Dose 1) Compared With Post-primary Series (Post-Dose 2) From Baseline (Pre-Dose 1) in Young Adult (18 to 25 Years) Vaccine Recipients in Clinical Trial (Study P301)

End point title	SRR for Post-booster Dose Serum Pseudovirus Neutralizing Antibody VAC62 From Baseline (Pre-Dose 1) Compared With Post-primary Series (Post-Dose 2) From Baseline (Pre-Dose 1) in Young Adult (18 to 25 Years) Vaccine Recipients in Clinical Trial (Study P301)

End point description:

Percentage of participants with seroresponse for Pseudovirus Neutralizing Antibody VAC62 are reported. Seroresponse was defined as a change from below the LLOQ to equal above 4 * LLOQ, or at least a 4-fold rise if baseline is equal to or above the LLOQ. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PP Immunogenicity Subset (Booster Dose Analysis): all enrolled participants who received 2 doses of planned doses of mRNA-1273 vaccination in Part 1 open-label phase or Part 2 blinded phase per schedule, received booster dose in Booster Dose Analysis, not receiving HAART in participants with HIV, had a negative SARS-CoV-2 status at baseline (pre-dose 1 of mRNA-1273), had BD-Day 29 Ab assessment for the analysis endpoint, no major protocol deviations that impacted key or critical data, and had not received off-study COVID-19 vaccination prior to BD-Day 29 visit. 'Overall number of participants analyzed' = Pre-booster SARS-CoV-2 negative participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

BD-Day 29 P204/Day 57 P301

End point values	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg	BD Phase Part 1 (6 Month-5 Yrs): PS mRNA-1273 25 µg - BD 10 µg	BD Part 1 and 2 (6-11 Yrs): PS mRNA-1273 50 µg - BD 1273 25 µg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	294	72	129	
Units: percentage of participants				
number (confidence interval 95%)	99.3 (97.6 to 99.9)	100 (95.0 to 100.0)	100 (97.2 to 100.0)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg v BD Part 1 and 2 (6-11 Yrs): PS mRNA-1273 50 µg - BD 1273 25 µg
Number of subjects included in analysis	423
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	percentage difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	2.4

Statistical analysis title	Statistical Analysis 1
Comparison groups	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg v BD Phase Part 1 (6 Month-5 Yrs): PS mRNA-1273 25 µg - BD 10 µg
Number of subjects included in analysis	366
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	percentage difference
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	2.4

Primary: SRR for Post-third Dose (Part 3) Serum Pseudovirus Neutralizing Antibody VAC62 From Baseline (Pre-Dose 1) Compared With Post-primary Series (Post-Dose 2) From Baseline (Pre-Dose 1) in Young Adult (18 to 25 Years) Vaccine Recipients in Study P301

End point title	SRR for Post-third Dose (Part 3) Serum Pseudovirus Neutralizing Antibody VAC62 From Baseline (Pre-Dose 1) Compared With Post-primary Series (Post-Dose 2) From Baseline (Pre-Dose 1) in Young Adult (18 to 25 Years) Vaccine Recipients in Study P301[9]

End point description:

Percentage of participants with seroresponse for Pseudovirus Neutralizing Antibody VAC62 are reported. Seroresponse was defined as a change from below the LLOQ to equal above 4 * LLOQ, or at least a 4-fold rise if baseline is equal to or above the LLOQ. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PP Immunogenicity Subset (Third Dose Analysis): all enrolled participants who received first 2 doses of planned doses of mRNA-1273 vaccination in Part 3 open-label phase per schedule, received third dose in Third Dose Analysis, not receiving HAART in participants with HIV were not receiving HAART, had BD-Day 29 antibody assessment for the analysis endpoint, had no major protocol deviations that impacted key or critical data, and had not received off-study COVID-19 vaccination prior to BD-Day 29 visit. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Third Dose-Day 29 P204/Day 57 P301

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Data for this endpoint was reported for the specified arms only.

End point values	Part 3 (6-11 Years): BD mRNA-1273 25 µg	Study mRNA-1273-P301 (NCT04470427) mRNA-1273 100 µg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	50	294		
Units: percentage of participants				
number (confidence interval 95%)	90.0 (78.2 to 96.7)	99.3 (97.6 to 99.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: GM Level of Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) S Protein-specific Binding Antibody (bAb), as Measured by MesoScale Discovery (MSD) Electrochemiluminescence (ECL) Multiplex Assay on Days 1 and 57

End point title	GM Level of Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) S Protein-specific Binding Antibody (bAb), as Measured by MesoScale Discovery (MSD) Electrochemiluminescence (ECL) Multiplex Assay on Days 1 and 57[10]

End point description:

GM level of SARSCOV2S2P immunoglobulin G (IgG) antibody VAC123/VAC72, as measured by ECL multiplex assay specific to SARS-CoV-2 spike protein is reported. Antibody values reported as <LLOQ were replaced by 0.5*LLOQ and values >ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 23 AU/mL and ULOQ was 14000000 AU/mL for VAC72. LLOQ was 69 AU/mL and ULOQ was 14400000 AU/mL for VAC123. PP Immunogenicity Subset: all enrolled participants who received at least 1 dose of IP, had baseline SARS-CoV-2 status, had baseline and at least 1 post-injection antibody assessment, complied with immunogenicity window based on 2nd injection timing; had negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 protein at baseline, not receiving HAART in participants with HIV; and had no major protocol deviations. Overall number of participants analyzed= participants evaluable for this endpoint. n = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Day 1, Day 57 (1 month after Dose 2)

Notes:

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

End point values	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg	Part 1 (2-5 Years): mRNA-1273 50 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	200	56	50	68
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline (Day 1) (n=200,56,50,68,96,294,304,285)	35.6 (31.0 to 40.8)	49.1 (33.9 to 71.1)	15.8 (13.5 to 18.5)	33.7 (26.2 to 43.4)
Day 57 (n=200,56,50, 61,95,308,301,280)	325784.0 (302917.7 to 350376.4)	457349.2 (402424.0 to 519770.8)	261952.0 (227935.8 to 301044.7)	417419.8 (359399.2 to 484807.0)

End point values	Part 1 (6-23 Months): mRNA-1273 25	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): mRNA-1273 25

	µg			µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96	308	304	285
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline (Day 1) (n=200,56,50,68,96,294,304,285)	14.6 (12.8 to 16.7)	32.6 (28.5 to 37.3)	24.5 (21.7 to 27.5)	22.0 (19.1 to 25.3)
Day 57 (n=200,56,50, 61,95,308,301,280)	297561.7 (234740.9 to 377194.3)	293118.9 (261748.3 to 328249.4)	235059.2 (198610.2 to 278197.3)	293955.4 (256077.7 to 337435.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: GM Level of SARS-CoV-2 S Protein-specific bAb, as Measured by MSD ECL Multiplex Assay on Baseline (Pre-dose 1), Day 57, Day 209, BD-Day 1, and BD-Day 29

End point title	Part 1 and Part 2: GM Level of SARS-CoV-2 S Protein-specific bAb, as Measured by MSD ECL Multiplex Assay on Baseline (Pre-dose 1), Day 57, Day 209, BD-Day 1, and BD-Day 29

End point description:

GM level of SARSCOV2S2P IgG antibody VAC123/VAC72 is reported. Antibody values reported as <LLOQ were replaced by 0.5*LLOQ and values >ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 23 and ULOQ was 14000000 AU/mL for VAC72. LLOQ was 69 and ULOQ was 14400000 AU/mL for VAC123. PP Immunogenicity Subset (Booster Dose Analysis): all enrolled participants who received 2 doses of planned doses of mRNA-1273 in Part 1 open-label phase or Part 2 blinded phase per schedule, received booster dose in Booster Dose Analysis, , not receiving HAART in participants with HIV, had a negative SARS-CoV-2 status at baseline, had BD-Day 29 antibody assessment for the analysis endpoint, no major protocol deviations that impacted key or critical data, and had not receive off-study COVID-19 vaccination prior to BD-Day 29 visit. Number analyzed = participants evaluable for this endpoint. n= participants evaluable at specified timepoint. '0.99 and 99999' signifies data not available.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose 1), Day 57, Day 209, BD-Day 1 (Pre-booster), BD-Day 29 (1 month after booster dose)

End point values	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	84	19	114
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline (n=72,80,13,91)	50.0 (42.7 to 58.6)	37.5 (34.3 to 40.9)	34.5 (0.99 to 99999)	51.9 (44.6 to 60.3)
Day 57 (n=55,56,12,16)	302128.3 (266991.2 to 341889.7)	279427.6 (242953.8 to 321377.2)	241874.9 (180565.7 to 324001.0)	336189.6 (257789.9 to 438432.5)

Day 209 (n=45,69,19,111)	74516.9 (63553.5 to 87371.5)	66516.5 (59365.2 to 74529.2)	71427.5 (50801.5 to 100427.9)	85360.1 (71680.4 to 101650.5)
BD-Day 1 (n=75,77,19,114)	66677.7 (52382.4 to 84874.2)	68322.4 (53860.8 to 86667.0)	50621.5 (34112.1 to 75121.2)	86416.4 (72836.0 to 102528.9)
BD-Day 29 (n=75,84,19,113)	633999.7 (561311.4 to 716101.0)	675348.1 (584405.3 to 780443.0)	536478.9 (403508.2 to 713268.2)	520973.0 (469812.4 to 577704.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Part 3: GM Level of SARS-CoV-2 S Protein-specific bAb, as Measured by MSD ECL Multiplex Assay on Baseline (Pre-dose 1), Day 57, Third Dose-Day 1, Third Dose-Day 29, Third Dose-Day 181

End point title	Part 3: GM Level of SARS-CoV-2 S Protein-specific bAb, as Measured by MSD ECL Multiplex Assay on Baseline (Pre-dose 1), Day 57, Third Dose-Day 1, Third Dose-Day 29, Third Dose-Day 181

End point description:

GM level of SARSCOV2S2P IgG antibody against B.1.1.529 strain is reported. Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ and values greater than the ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 102 and ULOQ was 1180000 AU/mL for VAC123. PP Immunogenicity Subset (Third Dose Analysis): all enrolled participants who received first 2 doses of planned doses of mRNA-1273 vaccination in Part 3 open-label phase per schedule, received third dose in Third Dose Analysis, participants with HIV were not receiving HAART, had BD-Day 29 antibody assessment for the analysis endpoint, had no major protocol deviations that impact key or critical data, and had not receive off-study COVID-19 vaccination prior to BD-Day 29 visit. 'Overall number of participants analyzed = participants evaluable for this endpoint. n = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose 1), Day 57, Third Dose-Day 1, Third Dose-Day 29, Third Dose-Day 181

End point values	Part 3 (6-11 Years): BD mRNA-1273 25 µg			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline (Pre-dose 1) (n = 50)	4659.5 (2918.7 to 7438.5)			
Day 57 (n = 50)	141758.0 (118762.4 to 169206.2)			
Third Dose-Day 1 (n = 49)	48176.2 (38955.2 to 59580.0)			

Third Dose-Day 29 (n = 52)	93436.4 (77735.5 to 112308.5)			
Third Dose-Day 181 (n = 46)	40271.7 (32950.9 to 49219.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: GM Value of SARS-CoV-2-specific Neutralizing Antibody ID50 Titers on Day 1 and Day 57

End point title	GM Value of SARS-CoV-2-specific Neutralizing Antibody ID50 Titers on Day 1 and Day 57[11]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ and values greater than ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 18.5 AU/mL and ULOQ was 45118 AU/mL for ID50 titer. PP Immunogenicity Subset: all enrolled participants who received at least 1 injection of study drug, had baseline SARS-CoV-2 status, had baseline and at least 1 post-injection antibody assessment for analysis endpoint, complied with immunogenicity window based on 2nd injection timing; had negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline, not receiving HAART in participants with HIV; and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint. n = participants evaluable at specified timepoint. 0.999 and 99999 signifies data not evaluable due to below limit of quantification.

End point type	Secondary

End point timeframe:

Day 1 and Day 57 (1 month after Dose 2)

Notes:

[11] - 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: Data for this endpoint was reported for the specified arms only.

End point values	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (2-5 Years): mRNA-1273 25 µg	Part 1 (2-5 Years): mRNA-1273 50 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	201	56	51	68
Units: titer				
geometric mean (confidence interval 95%)				
Day 1 (n=201,56,50,68,97,308)	9.3 (9.2 to 9.5)	9.6 (8.9 to 10.3)	9.3 (0.999 to 99999)	9.3 (0.999 to 99999)
Day 57 (n=201,56,51,68,97,309)	1669.1 (1504.5 to 1851.6)	1890.2 (1603.8 to 2227.7)	1012.5 (848.2 to 1208.6)	1845.9 (1600.5 to 2128.9)

End point values	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): mRNA-1273 50 µg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	309		
Units: titer				
geometric mean (confidence interval 95%)				
Day 1 (n=201,56,50,68,97,308)	9.6 (9.3 to 9.9)	9.3 (0.999 to 99999)		
Day 57 (n=201,56,51,68,97,309)	1782.6 (1542.0 to 2060.7)	1618.3 (1460.0 to 1793.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: GM Concentration of SARS-CoV-2-specific Neutralizing Antibody VAC62 on Day 1 and Day 57

End point title	GM Concentration of SARS-CoV-2-specific Neutralizing Antibody VAC62 on Day 1 and Day 57[12]

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ and values greater than the ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. Data are reported per Baseline SARS-CoV-2 status: Negative and Positive. PP Immunogenicity Subset: all enrolled participants who received at least 1 injection of study drug, had baseline SARS-CoV-2 status, had baseline and at least 1 post-injection antibody assessment for analysis endpoint, complied with immunogenicity window based on 2nd injection timing; had negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline, not receiving HAART in participants with HIV; and had no major protocol deviations that impacted key or critical data. 'Overall number of participants analyzed' = participants evaluable for this endpoint. n = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Day 1 and Day 57 (1 month after Dose 2)

Notes:

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

End point values	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): mRNA-1273 25 µg	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	315	311	57	
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline SARS-CoV-2 (Negative): Day 1(n=315,311,4)	7.9 (7.5 to 8.4)	8.0 (7.5 to 8.5)	21.5 (2.6 to 175.1)	
Baseline SARS-CoV-2 (Positive): Day 1 (n=28,19,57)	175.3 (130.4 to 235.6)	199.9 (109.2 to 365.9)	177.5 (111.2 to 283.3)	
Baseline SARS-CoV-2(Negative): Day 57(n=298,278,4)	1398.1 (1271.9 to 1536.8)	1760.8 (1609.7 to 1926.0)	2140.6 (728.7 to 6288.7)	

Baseline SARS-CoV-2 (Positive): Day 57(n=23,15,57)	7430.0 (5188.4 to 10640.1)	10411.6 (6712.1 to 16150.1)	4592.9 (3470.7 to 6077.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: GM Concentration of Post-booster SARS-CoV-2-specific Neutralizing Antibody VAC62 on Baseline, Day 57, Day 209, BD-Day 1, and BD-Day 29

End point title	GM Concentration of Post-booster SARS-CoV-2-specific Neutralizing Antibody VAC62 on Baseline, Day 57, Day 209, BD-Day 1, and BD-Day 29

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ and values greater than the ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PP Immunogenicity Subset (Booster Dose Analysis): all enrolled participants who received 2 doses of planned doses of mRNA-1273 vaccination in Part 1 open-label phase or Part 2 blinded phase per schedule, received booster dose in Booster Dose Analysis, not receiving HAART in participants with HIV, had a negative SARS-CoV-2 status at baseline (pre-dose 1 of mRNA-1273), had BD-Day 29 Ab assessment for the analysis endpoint, no major protocol deviations that impacted key or critical data, and had not received off-study COVID-19 vaccination prior to BD-Day 29 visit. 'Overall number of participants analyzed' = participants evaluable for this endpoint. n = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline (Pre-Dose 1), Day 57 (1 month after Dose 2), Day 209 (6 months after Dose 2), BD-Day 1 (Pre-booster), and BD-Day 29 (1 month after booster dose or third dose)

End point values	Part 1 (6-11 Years): PS mRNA-1273 50 µg - BD 25 µg	Part 1 (6-23 Months): PS mRNA-1273 25 µg - BD 10 µg	Part 1 (2-5 Years): PS mRNA-1273 25 µg - BD 10 µg	Part 2 (6-11 Years): PS mRNA-1273 50 µg - BD 1273 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	84	19	114
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline (n=81,16,111,70)	9.3 (8.5 to 10.3)	9.0 (8.2 to 9.9)	12.8 (10.0 to 16.3)	7.8 (7.1 to 8.6)
Day 57 (n=56,18,18,55)	1503.3 (1292.3 to 1748.7)	1557.1 (1294.2 to 1873.5)	1275.0 (983.0 to 1653.8)	1718.7 (1316.5 to 2243.7)
Day 209 (n=68,18,110,45)	530.3 (432.5 to 650.2)	448.6 (376.9 to 533.8)	544.5 (343.1 to 864.0)	790.7 (633.8 to 986.4)
BD-Day 1 (n=75,18,113,75)	627.9 (467.8 to 842.8)	558.0 (408.5 to 762.2)	447.2 (270.0 to 740.7)	795.5 (640.8 to 987.5)
BD-Day 29 (n=84,19,114,75)	6991.6 (6091.2 to 8025.0)	6474.7 (5406.0 to 7754.8)	5778.7 (4039.7 to 8266.4)	5805.4 (5122.4 to 6579.4)

Statistical analyses

No statistical analyses for this end point

Secondary: GM Concentration of Post-third Dose (Part 3) SARS-CoV-2-specific Neutralizing Antibody VAC62 on Baseline, Day 57, Third Dose-Day 1, Third Dose-Day 29, and Third Dose-Day 181

End point title	GM Concentration of Post-third Dose (Part 3) SARS-CoV-2-specific Neutralizing Antibody VAC62 on Baseline, Day 57, Third Dose-Day 1, Third Dose-Day 29, and Third Dose-Day 181

End point description:

Antibody values reported as below the LLOQ were replaced by 0.5*LLOQ and values greater than the ULOQ were replaced by ULOQ if actual values were not available. LLOQ was 10 AU/mL and ULOQ was 111433 AU/mL. PP Immunogenicity Subset (Third Dose Analysis): all enrolled participants who received first 2 doses of planned doses of mRNA-1273 vaccination in Part 3 open-label phase per schedule, received third dose in Third Dose Analysis, not receiving HAART in participants with HIV, had BD-Day 29 antibody assessment for the analysis endpoint, had no major protocol deviations that impacted key or critical data, and had not received off-study COVID-19 vaccination prior to BD-Day 29 visit. 'Overall number of participants analyzed' = participants evaluable for this endpoint. n = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline (Pre-Dose 1), Day 57 (1 month after Dose 2), Third Dose-Day 1 (at least 3 months or 6 months after Dose 2), Third Dose-Day 29 (1 month after third dose), and Third Dose-Day 181 (6 months after third dose)

End point values	Part 3 (6-11 Years): BD mRNA-1273 25 µg			
Subject group type	Reporting group			
Number of subjects analysed	52			
Units: AU/mL				
geometric mean (confidence interval 95%)				
Baseline (n=50)	120.0 (71.9 to 200.3)			
Day 57 (n=50)	3775.0 (2767.5 to 5149.3)			
Third Dose-Day 1 (n=49)	1839.1 (1279.8 to 2643.0)			
Third Dose-Day 29 (n=52)	4616.6 (3669.4 to 5808.3)			
Third Dose-Day 181 (n=46)	1432.5 (1038.6 to 1975.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of Participants With SARS-CoV-2 infection Including Symptomatic and Asymptomatic Infection (by Serology and/or RT-PCR)

End point title	Part 2: Number of Participants With SARS-CoV-2 infection Including Symptomatic and Asymptomatic Infection (by Serology and/or RT-PCR)[13]

End point description:

SARS-CoV-2 infection was defined in participants with negative SARS-CoV-2 at baseline: bAb level against SARS-CoV-2 nucleocapsid protein negative at Day 1, that became positive (as measured by Roche Elecsys) postbaseline; OR positive RT-PCR postbaseline. A summary of SAEs and all nonserious AEs ("Other") regardless of causality, is located in the Reported "Adverse Events" section. PP Set for Efficacy included all enrolled participants who received planned doses of study drug per schedule, complied with the 2nd injection timing, had no major protocol deviations that impacted key or critical efficacy data, and had a negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

14 days after second injection

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: Data for this endpoint was reported for the specified arms only.

End point values	Part 2 (6-11 Years): Placebo	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	849	2606	854	2592
Units: participants	14	13	178	330

End point values	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	563	1686		
Units: participants	94	198		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of Participants With Asymptomatic SARS-CoV-2 infection, Measured by RT-PCR and/or bAb Levels Against SARS-CoV-2 Nucleocapsid Protein (by Roche Elecsys)

End point title	Part 2: Number of Participants With Asymptomatic SARS-CoV-2 infection, Measured by RT-PCR and/or bAb Levels Against SARS-CoV-2 Nucleocapsid Protein (by Roche Elecsys)[14]

End point description:

Asymptomatic SARS-CoV-2 infection was identified by absence of symptoms and infections as detected by RT-PCR or serology tests: Absence of COVID-19 symptoms AND at least 1 from following: bAb level against SARS-CoV-2 nucleocapsid protein negative at Day 1 that became positive post-baseline, OR positive RT-PCR test post-baseline. A summary of SAEs and all nonserious AEs ("Other") regardless of causality, is located in the Reported "Adverse Events" section. PP Set for Efficacy included all enrolled participants who received planned doses of study drug per schedule, complied with the 2nd injection timing, had no major protocol deviations that impacted key or critical efficacy data, and had a negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

14 days after second injection

Notes:

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

End point values	Part 2 (6-11 Years): Placebo	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	849	2606	854	2592
Units: participants	10	10	55	124

End point values	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	563	1686		
Units: participants	21	70		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of Participants With Occurrence of COVID-19 (Per US Centers for Disease Control and Prevention [CDC] Case Definition of COVID-19)

End point title	Part 2: Number of Participants With Occurrence of COVID-19 (Per US Centers for Disease Control and Prevention [CDC] Case Definition of COVID-19)[15]

End point description:

A COVID-19 case was identified as a positive post-baseline RT-PCR test result together with at least 1 of following systemic symptoms: fever (≥ 38 degrees Celsius [°C]/≥ 100.4 degree Fahrenheit [°F]) or chills, fatigue, headache, myalgia, nasal congestion or rhinorrhea, new loss of taste or smell, sore throat, abdominal pain, diarrhoea, nausea/vomiting, poor appetite/poor feeding; or at least 1 of following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing. A summary of SAEs and all nonserious AEs ("Other") regardless of causality, is located in the Reported "Adverse Events" section. PP Set for Efficacy included all enrolled participants who received planned doses of study drug per schedule, complied with the 2nd injection timing, had no major protocol deviations that impacted key or critical efficacy data, and had a negative RT-PCR test for SARS-CoV-2 and negative serology test based on bAb specific to SARS-CoV-2 nucleocapsid protein at baseline.

End point type	Secondary

End point timeframe:

14 days after second injection

Notes:

[15] - 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: Data for this endpoint was reported for the specified arms only.

End point values	Part 2 (6-11 Years): Placebo	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (2-5 Years): mRNA-1273 25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	849	2606	854	2592
Units: participants	4	3	125	207

End point values	Part 2 (6-23 Months): Placebo	Part 2 (6-23 Months): mRNA-1273 25 µg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	563	1686		
Units: participants	73	130		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Throughout the study period (up to 24 months)

Adverse event reporting additional description:

Safety Set of Part 1 and Part 3 included all dosed participants and of Part 2 included all randomized participants who received any study injection.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Part 1 (6-11 Years): mRNA-1273 100 µg

Reporting group description:

Participants received 2 doses of 100 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	Part 1 (6-11 Years): mRNA-1273 50 µg

Reporting group description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	Part 1 (2-5 Years): mRNA-1273 25 µg

Reporting group description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	Part 1 (2-5 Years): mRNA-1273 50 µg

Reporting group description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	Part 1 (6-23 Months): mRNA-1273 25 µg

Reporting group description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	Part 2 (6-11 Years): Placebo

Reporting group description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 50 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Reporting group title	Part 2 (6-11 Years): mRNA-1273 50 µg

Reporting group description:

Participants received 2 doses of 50 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	Part 2 (2-5 Years): Placebo

Reporting group description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Reporting group title	Part 2 (6-23 Months): Placebo

Reporting group description:

Participants received 2 doses of matching placebo by IM injection approximately 28 days apart (Day 1 and Day 29). Participants were offered crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Reporting group title	Part 2 (2-5 Years): mRNA-1273 25 µg

Reporting group description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	Part 2 (6-23 Months): mRNA-1273 25 µg

Reporting group description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1 and Day 29).

Reporting group title	6-11 Yrs: BD mRNA-1273.214 25 µg

Reporting group description:

Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.

Reporting group title	6-11 Years: BD mRNA-1273 25 µg

Reporting group description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

Reporting group title	Part 3 (6-11 Years): BD mRNA-1273 25 µg

Reporting group description:

Participants received a third dose of 25 µg mRNA-1273 by IM injection on Day 149.

Reporting group title	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg

Reporting group description:

Participants received 2 doses of 25 µg mRNA-1273 by IM injection approximately 28 days apart (Day 1, and Day 29).

Reporting group title	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg (Crossover)

Reporting group description:

Participants received a placebo in the blinded phase and then crossover vaccination with 50 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA.

Reporting group title	Part 2 (2-5 Years): PS PBO - mRNA-1273 25 µg (Crossover)

Reporting group description:

Participants received a placebo in the blinded phase and then crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA. Adverse Events were collected from the first cross-over dose until the first booster dose.

Reporting group title	Part 2 (6-23 Months): PBO - mRNA-1273 25 µg (Crossover)

Reporting group description:

Participants received a placebo in the blinded phase and then crossover vaccination with 25 µg of mRNA-1273 after the availability of a COVID-19 vaccine under EUA. Adverse Events were collected from the first cross-over dose until the first booster dose.

Reporting group title	6 Months-5 Yrs: BD mRNA-1273 25 µg

Reporting group description:

Participants received a single dose of 25 µg mRNA-1273 by IM injection on BD-Day 1.

Reporting group title	6 Months-5 Yrs: BD mRNA-1273 10 µg

Reporting group description:

Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.

Reporting group title	6 Months-5 Yrs: BD mRNA-1273.214 10 µg

Reporting group description:

Participants received a single dose of 10 µg mRNA-1273 by IM injection on BD-Day 1.

Reporting group title	6 Months-5 Yrs: BD mRNA-1273.214 25 µg

Reporting group description:

Participants received a single dose of 25 µg mRNA-1273.214 by IM injection on BD-Day 1.

Serious adverse events	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (2-5 Years): mRNA-1273 25 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 371 (0.81%)	5 / 380 (1.32%)	0 / 69 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Reproductive system and breast disorders			
Adnexal torsion			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Acute respiratory failure			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Bronchial hyperreactivity			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Asthma			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Bronchospasm			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Hypoxia			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Wheezing			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Bronchiectasis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Oppositional defiant disorder			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Suicidal ideation			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Anxiety			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Aggression			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Mental status changes			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body ingestion			
subjects affected / exposed	0 / 371 (0.00%)	1 / 380 (0.26%)	0 / 69 (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
Epiphyseal fracture			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Foreign body in respiratory tract			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Greenstick fracture			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Humerus fracture			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Skull fracture			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Tibia fracture			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Torus fracture			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Radius fracture			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Ulna fracture			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Scrotal haematoma			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Congenital, familial and genetic disorders			
Congenital hydronephrosis			
subjects affected / exposed	0 / 371 (0.00%)	1 / 380 (0.26%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 371 (0.27%)	0 / 380 (0.00%)	0 / 69 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Petit mal epilepsy			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Seizure			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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 rolandic epilepsy			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Partial seizures			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Bone marrow failure			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Febrile neutropenia			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Lymphadenitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Neutropenia			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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			
Optic disc drusen			
subjects affected / exposed	0 / 371 (0.00%)	1 / 380 (0.26%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 371 (0.27%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 371 (0.27%)	0 / 380 (0.00%)	0 / 69 (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
Pancreatitis acute			
subjects affected / exposed	1 / 371 (0.27%)	0 / 380 (0.00%)	0 / 69 (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

Abdominal discomfort			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Gastritis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Ileus			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Vomiting			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Intussusception			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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 intestinal obstruction			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Hepatitis acute			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Skin and subcutaneous tissue disorders			

Dermatomyositis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Erythema multiforme			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Arthritis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	1 / 371 (0.27%)	0 / 380 (0.00%)	0 / 69 (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
Rhinovirus infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 371 (0.00%)	2 / 380 (0.53%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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

Abscess			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Bronchiolitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Cellulitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Cellulitis orbital			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Croup infectious			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Escherichia sepsis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Meningitis aseptic			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Pneumonia			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Pneumonia bacterial			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Pneumonia viral			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Pyelonephritis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Subperiosteal abscess			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Tonsillitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Urosepsis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Meningitis enteroviral			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Influenza			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Pneumonia pseudomonal			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Sinusitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Streptococcal infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Tracheitis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Type 1 diabetes mellitus			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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
Hypophagia			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (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 1 (2-5 Years): mRNA-1273 50 µg	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 155 (0.00%)	3 / 150 (2.00%)	1 / 995 (0.10%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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			
Anaphylactic reaction			

subjects affected / exposed	0 / 155 (0.00%)	1 / 150 (0.67%)	0 / 995 (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
Reproductive system and breast disorders			
Adnexal torsion			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Acute respiratory failure			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Bronchial hyperreactivity			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Asthma			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Bronchospasm			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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

Hypoxia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Wheezing			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Bronchiectasis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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

Oppositional defiant disorder			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Suicidal ideation			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Anxiety			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Aggression			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Mental status changes			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body ingestion			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Epiphyseal fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Foreign body in respiratory tract			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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

Greenstick fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Humerus fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Skull fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Tibia fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Torus fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Radius fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Ulna fracture			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Scrotal haematoma			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Congenital, familial and genetic disorders			

Congenital hydronephrosis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 155 (0.00%)	1 / 150 (0.67%)	0 / 995 (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
Epilepsy			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Petit mal epilepsy			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Seizure			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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 rolandic epilepsy			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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

Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Partial seizures			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Febrile neutropenia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Lymphadenitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Neutropenia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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			
Optic disc drusen			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Constipation			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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 acute			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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 discomfort			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Gastritis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Ileus			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Vomiting			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Intussusception			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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 intestinal obstruction			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Hepatitis acute			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Erythema multiforme			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Arthritis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Rhinovirus infection			
subjects affected / exposed	0 / 155 (0.00%)	1 / 150 (0.67%)	0 / 995 (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
Appendicitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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 wall abscess			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Abscess			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Bronchiolitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Cellulitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Cellulitis orbital			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Croup infectious			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Escherichia sepsis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Meningitis aseptic			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Pneumonia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Pneumonia bacterial			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Pneumonia viral			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Pyelonephritis			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Subperiosteal abscess			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Tonsillitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Urosepsis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Meningitis enteroviral			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Influenza			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Pneumonia pseudomonal			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Sinusitis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Streptococcal infection			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Tracheitis			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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
Hypophagia			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (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 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (6-23 Months): Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 3007 (0.73%)	3 / 1007 (0.30%)	7 / 666 (1.05%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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			
Pyrexia			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3007 (0.00%)	1 / 1007 (0.10%)	0 / 666 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Reproductive system and breast disorders			
Adnexal torsion			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Acute respiratory failure			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	2 / 666 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Asthma			
subjects affected / exposed	1 / 3007 (0.03%)	1 / 1007 (0.10%)	0 / 666 (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
Bronchospasm			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Hypoxia			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	1 / 666 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Wheezing			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Bronchiectasis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Oppositional defiant disorder			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Suicidal ideation			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Aggression			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Mental status changes			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body ingestion			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Epiphyseal fracture			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Foreign body in respiratory tract			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Greenstick fracture			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Humerus fracture			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Skull fracture			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Tibia fracture			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Torus fracture			

subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Radius fracture			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Ulna fracture			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Scrotal haematoma			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Congenital, familial and genetic disorders			
Congenital hydronephrosis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Petit mal epilepsy			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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 rolandic epilepsy			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Partial seizures			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Febrile neutropenia			

subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Lymphadenitis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Neutropenia			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Eye disorders			
Optic disc drusen			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Constipation			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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 acute			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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 discomfort			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Gastritis			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Ileus			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Vomiting			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Intussusception			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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 intestinal obstruction			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Hepatitis acute			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Erythema multiforme			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Rhinovirus infection			
subjects affected / exposed	0 / 3007 (0.00%)	1 / 1007 (0.10%)	1 / 666 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	4 / 3007 (0.13%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	0 / 3007 (0.00%)	1 / 1007 (0.10%)	0 / 666 (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
Abscess			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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

Bronchiolitis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	4 / 666 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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 orbital			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Croup infectious			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	1 / 666 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Escherichia sepsis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Meningitis aseptic			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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 / 3007 (0.07%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Pneumonia viral			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Pyelonephritis			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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 syncytial virus bronchiolitis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Subperiosteal abscess			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Tonsillitis			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Urosepsis			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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
Meningitis enteroviral			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Influenza			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Pneumonia pseudomonal			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Sinusitis			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Streptococcal infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Tracheitis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 3007 (0.03%)	0 / 1007 (0.00%)	0 / 666 (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 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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
Hypophagia			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (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 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): mRNA-1273 25 µg	6-11 Yrs: BD mRNA-1273.214 25 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 3031 (1.06%)	45 / 1994 (2.26%)	0 / 184 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	1 / 3031 (0.03%)	1 / 1994 (0.05%)	0 / 184 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 3031 (0.03%)	1 / 1994 (0.05%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Reproductive system and breast disorders			

Adnexal torsion			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 3031 (0.07%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 3031 (0.00%)	2 / 1994 (0.10%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	2 / 3031 (0.07%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 3031 (0.03%)	3 / 1994 (0.15%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Dyspnoea			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Hypoxia			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory distress			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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 failure			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Status asthmaticus			
subjects affected / exposed	0 / 3031 (0.00%)	2 / 1994 (0.10%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Bronchiectasis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Oppositional defiant disorder			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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

Suicidal ideation			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Anxiety			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Aggression			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Mental status changes			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body ingestion			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Epiphyseal fracture			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Foreign body in respiratory tract			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Greenstick fracture			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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

Humerus fracture			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Skull fracture			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Tibia fracture			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Torus fracture			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Radius fracture			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Ulna fracture			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Scrotal haematoma			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Congenital, familial and genetic disorders			
Congenital hydronephrosis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 3031 (0.00%)	3 / 1994 (0.15%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Petit mal epilepsy			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Seizure			
subjects affected / exposed	1 / 3031 (0.03%)	1 / 1994 (0.05%)	0 / 184 (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
Benign rolandic epilepsy			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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

Partial seizures			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Febrile neutropenia			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Lymphadenitis			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Neutropenia			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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			
Optic disc drusen			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Constipation			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Pancreatitis acute			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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 discomfort			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Gastritis			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Ileus			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Vomiting			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Intussusception			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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 intestinal obstruction			

subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Hepatitis acute			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Erythema multiforme			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Arthritis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			

subjects affected / exposed	1 / 3031 (0.03%)	2 / 1994 (0.10%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	2 / 3031 (0.07%)	3 / 1994 (0.15%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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 wall abscess			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Abscess			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Bronchiolitis			
subjects affected / exposed	1 / 3031 (0.03%)	8 / 1994 (0.40%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Cellulitis orbital			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Croup infectious			

subjects affected / exposed	2 / 3031 (0.07%)	2 / 1994 (0.10%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Escherichia sepsis			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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 salmonella			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 3031 (0.00%)	2 / 1994 (0.10%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Mastoiditis			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Meningitis aseptic			

subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Metapneumovirus infection			
subjects affected / exposed	2 / 3031 (0.07%)	2 / 1994 (0.10%)	0 / 184 (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
Otitis media acute			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Pneumonia			
subjects affected / exposed	0 / 3031 (0.00%)	3 / 1994 (0.15%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	2 / 3031 (0.07%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	2 / 3031 (0.07%)	1 / 1994 (0.05%)	0 / 184 (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
Pyelonephritis			

subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	2 / 3031 (0.07%)	2 / 1994 (0.10%)	0 / 184 (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
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 3031 (0.07%)	3 / 1994 (0.15%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Subperiosteal abscess			
subjects affected / exposed	1 / 3031 (0.03%)	0 / 1994 (0.00%)	0 / 184 (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
Tonsillitis			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Urinary tract infection			
subjects affected / exposed	1 / 3031 (0.03%)	1 / 1994 (0.05%)	0 / 184 (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
Urosepsis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Meningitis enteroviral			

subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Influenza			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Pneumonia pseudomonal			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Sinusitis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Streptococcal infection			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Tracheitis			

subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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			
Diabetic ketoacidosis			
subjects affected / exposed	1 / 3031 (0.03%)	1 / 1994 (0.05%)	0 / 184 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 3031 (0.00%)	1 / 1994 (0.05%)	0 / 184 (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
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 3031 (0.03%)	1 / 1994 (0.05%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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
Hypophagia			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (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	6-11 Years: BD mRNA-1273 25 µg	Part 3 (6-11 Years): BD mRNA-1273 25 µg	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 2766 (0.43%)	0 / 70 (0.00%)	1 / 90 (1.11%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events			
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Reproductive system and breast disorders			
Adnexal torsion			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Acute respiratory failure			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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

Bronchial hyperreactivity			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Asthma			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Bronchospasm			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Hypoxia			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Wheezing			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Bronchiectasis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Oppositional defiant disorder			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Suicidal ideation			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Aggression			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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
Mental status changes			

subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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			
Foreign body ingestion			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Epiphyseal fracture			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Foreign body in respiratory tract			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Greenstick fracture			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Humerus fracture			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Skull fracture			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Tibia fracture			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Torus fracture			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Radius fracture			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Ulna fracture			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Scrotal haematoma			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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			
Congenital hydronephrosis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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

Epilepsy			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Petit mal epilepsy			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Seizure			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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
Benign rolandic epilepsy			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Partial seizures			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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
Status epilepticus			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Febrile neutropenia			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Lymphadenitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Neutropenia			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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			
Optic disc drusen			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 2766 (0.07%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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 acute			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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 discomfort			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Gastritis			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Ileus			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Vomiting			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Intussusception			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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 intestinal obstruction			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Hepatitis acute			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Erythema multiforme			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Arthritis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Rhinovirus infection			
subjects affected / exposed	2 / 2766 (0.07%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 2766 (0.07%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Abscess			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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

Bronchiolitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Cellulitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Cellulitis orbital			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Croup infectious			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Escherichia sepsis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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 salmonella			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Meningitis aseptic			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Pneumonia			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Pneumonia bacterial			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Pneumonia viral			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Pyelonephritis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Subperiosteal abscess			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Tonsillitis			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Urosepsis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Meningitis enteroviral			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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
Influenza			
subjects affected / exposed	2 / 2766 (0.07%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal abscess			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Pneumonia pseudomonal			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Sinusitis			

subjects affected / exposed	1 / 2766 (0.04%)	0 / 70 (0.00%)	0 / 90 (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
Staphylococcal abscess			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Streptococcal infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Tracheitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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
Hypophagia			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (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(6-11 Yrs): PS PBO - mRNA-1273 50 µg (Crossover)	Part 2 (2-5 Years): PS PBO - mRNA-1273 25 µg (Crossover)	Part 2 (6-23 Months): PBO - mRNA-1273 25 µg (Crossover)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 701 (0.43%)	8 / 640 (1.25%)	4 / 444 (0.90%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Reproductive system and breast disorders			

Adnexal torsion			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Acute respiratory failure			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	1 / 444 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Asthma			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Bronchospasm			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Hypoxia			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory distress			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	0 / 444 (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
Wheezing			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Bronchiectasis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Oppositional defiant disorder			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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

Suicidal ideation			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Anxiety			
subjects affected / exposed	1 / 701 (0.14%)	0 / 640 (0.00%)	0 / 444 (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
Aggression			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Mental status changes			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body ingestion			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Epiphyseal fracture			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Foreign body in respiratory tract			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Greenstick fracture			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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

Humerus fracture			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Skull fracture			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Tibia fracture			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Torus fracture			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Radius fracture			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	0 / 444 (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
Ulna fracture			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	0 / 444 (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
Scrotal haematoma			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Congenital, familial and genetic disorders			
Congenital hydronephrosis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	0 / 444 (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
Epilepsy			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Petit mal epilepsy			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Seizure			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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 rolandic epilepsy			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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

Partial seizures			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Febrile neutropenia			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Lymphadenitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Neutropenia			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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			
Optic disc drusen			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Constipation			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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 acute			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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 discomfort			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Gastritis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Ileus			
subjects affected / exposed	1 / 701 (0.14%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	0 / 444 (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
Intussusception			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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 intestinal obstruction			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Hepatitis acute			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Erythema multiforme			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Arthritis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	1 / 444 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Rhinovirus infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 701 (0.14%)	0 / 640 (0.00%)	0 / 444 (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
Abdominal wall abscess			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Abscess			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Bronchiolitis			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	1 / 444 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Cellulitis orbital			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Croup infectious			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Epstein-Barr virus infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Escherichia sepsis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Meningitis aseptic			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Pneumonia			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Pneumonia viral			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Pyelonephritis			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 701 (0.00%)	2 / 640 (0.31%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Subperiosteal abscess			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Tonsillitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Urosepsis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Meningitis enteroviral			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	1 / 444 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Influenza			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Pneumonia pseudomonal			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Sinusitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Streptococcal infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Tracheitis			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (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
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 701 (0.00%)	2 / 640 (0.31%)	0 / 444 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 701 (0.00%)	1 / 640 (0.16%)	0 / 444 (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

Serious adverse events	6 Months-5 Yrs: BD mRNA-1273 25 µg	6 Months-5 Yrs: BD mRNA-1273 10 µg	6 Months-5 Yrs: BD mRNA-1273.214 10 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 89 (1.12%)	1 / 212 (0.47%)	23 / 2771 (0.83%)
number of deaths (all causes)	0	0	1
number of deaths resulting from	0	0	1

adverse events			
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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			
Anaphylactic reaction			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Reproductive system and breast disorders			
Adnexal torsion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Acute respiratory failure			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchial hyperreactivity			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Asthma			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Hypoxia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Wheezing			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Bronchiectasis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Oppositional defiant disorder			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Suicidal ideation			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Anxiety			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Aggression			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Mental status changes			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Foreign body ingestion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Epiphyseal fracture			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Foreign body in respiratory tract			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Greenstick fracture			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Humerus fracture			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Skull fracture			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
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	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Torus fracture			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Radius fracture			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Ulna fracture			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Scrotal haematoma			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Congenital, familial and genetic disorders			
Congenital hydronephrosis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Petit mal epilepsy			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Seizure			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
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 rolandic epilepsy			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Febrile neutropenia			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Lymphadenitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Neutropenia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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			
Optic disc drusen			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Constipation			
subjects affected / exposed	1 / 89 (1.12%)	0 / 212 (0.00%)	0 / 2771 (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
Pancreatitis acute			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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 discomfort			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Gastritis			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Ileus			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Vomiting			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Intussusception			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Hepatitis acute			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Erythema multiforme			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Arthritis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Rhinovirus infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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 wall abscess			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Abscess			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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

Bronchiolitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	2 / 2771 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Cellulitis orbital			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Croup infectious			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Escherichia sepsis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Meningitis aseptic			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	2 / 2771 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Pneumonia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	5 / 2771 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Pneumonia viral			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Pyelonephritis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	2 / 2771 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Subperiosteal abscess			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Tonsillitis			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Urosepsis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Meningitis enteroviral			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Influenza			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 89 (0.00%)	1 / 212 (0.47%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 89 (0.00%)	1 / 212 (0.47%)	0 / 2771 (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
Tracheitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	1 / 2771 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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
Hypophagia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (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	6 Months-5 Yrs: BD mRNA-1273.214 25 µg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			

Adnexal torsion				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute respiratory distress syndrome				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial hyperreactivity				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Respiratory distress				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Status asthmaticus				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wheezing				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiectasis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory symptom				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Disruptive mood dysregulation disorder				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oppositional defiant disorder				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Suicidal ideation				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aggression				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Foreign body ingestion				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epiphyseal fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foreign body in respiratory tract				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Greenstick fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Humerus fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Torus fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulna fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scrotal haematoma				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Congenital hydronephrosis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Petit mal epilepsy			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign rolandic epilepsy			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Partial seizures			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Status epilepticus			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Optic disc drusen			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal discomfort				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intussusception				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				

subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erythema multiforme			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Adenovirus infection			

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal wall abscess				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiolitis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis orbital				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Croup infectious				

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epstein-Barr virus infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis salmonella				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infectious pleural effusion				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mastoiditis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis aseptic				

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metapneumovirus infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media acute				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subperiosteal abscess				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis enteroviral				

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal viral infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngeal abscess				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia pseudomonal				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal abscess				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheitis				

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Diabetic ketoacidosis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Type 1 diabetes mellitus				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypophagia				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Part 1 (6-11 Years): mRNA-1273 100 µg	Part 1 (6-11 Years): mRNA-1273 50 µg	Part 1 (2-5 Years): mRNA-1273 25 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	134 / 371 (36.12%)	145 / 380 (38.16%)	30 / 69 (43.48%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	10 / 371 (2.70%)	10 / 380 (2.63%)	0 / 69 (0.00%)
occurrences (all)	11	10	0
Pyrexia			
subjects affected / exposed	21 / 371 (5.66%)	17 / 380 (4.47%)	2 / 69 (2.90%)
occurrences (all)	26	17	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	7 / 371 (1.89%)	6 / 380 (1.58%)	2 / 69 (2.90%)
occurrences (all)	7	6	2
Teething			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	6 / 371 (1.62%)	11 / 380 (2.89%)	1 / 69 (1.45%)
occurrences (all)	6	11	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	34 / 371 (9.16%)	23 / 380 (6.05%)	8 / 69 (11.59%)
occurrences (all)	40	25	9
Nasal congestion			
subjects affected / exposed	34 / 371 (9.16%)	27 / 380 (7.11%)	5 / 69 (7.25%)
occurrences (all)	45	28	6
Rhinorrhoea			
subjects affected / exposed	26 / 371 (7.01%)	12 / 380 (3.16%)	6 / 69 (8.70%)
occurrences (all)	31	12	6
Oropharyngeal pain			
subjects affected / exposed	24 / 371 (6.47%)	20 / 380 (5.26%)	2 / 69 (2.90%)
occurrences (all)	32	20	2
Psychiatric disorders			
Attention deficit hyperactivity disorder			

subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Croup infectious			
subjects affected / exposed	5 / 371 (1.35%)	2 / 380 (0.53%)	1 / 69 (1.45%)
occurrences (all)	5	2	1
Ear infection			
subjects affected / exposed	9 / 371 (2.43%)	1 / 380 (0.26%)	4 / 69 (5.80%)
occurrences (all)	9	1	4
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	1 / 69 (1.45%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	3 / 371 (0.81%)	0 / 380 (0.00%)	1 / 69 (1.45%)
occurrences (all)	3	0	1
Otitis media			
subjects affected / exposed	1 / 371 (0.27%)	5 / 380 (1.32%)	3 / 69 (4.35%)
occurrences (all)	2	5	3
Respiratory tract infection viral			
subjects affected / exposed	0 / 371 (0.00%)	25 / 380 (6.58%)	0 / 69 (0.00%)
occurrences (all)	0	31	0
Sinusitis			
subjects affected / exposed	8 / 371 (2.16%)	4 / 380 (1.05%)	2 / 69 (2.90%)
occurrences (all)	8	4	2
Upper respiratory tract infection			
subjects affected / exposed	50 / 371 (13.48%)	56 / 380 (14.74%)	9 / 69 (13.04%)
occurrences (all)	75	87	11
Viral upper respiratory tract infection			
subjects affected / exposed	12 / 371 (3.23%)	11 / 380 (2.89%)	4 / 69 (5.80%)
occurrences (all)	15	14	4
Pharyngitis streptococcal			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 371 (0.00%)	0 / 380 (0.00%)	0 / 69 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1 (2-5 Years): mRNA-1273 50 µg	Part 1 (6-23 Months): mRNA-1273 25 µg	Part 2 (6-11 Years): Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	78 / 155 (50.32%)	111 / 150 (74.00%)	100 / 995 (10.05%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 155 (0.65%)	9 / 150 (6.00%)	0 / 995 (0.00%)
occurrences (all)	1	11	0
Pyrexia			
subjects affected / exposed	23 / 155 (14.84%)	40 / 150 (26.67%)	10 / 995 (1.01%)
occurrences (all)	29	58	11
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 155 (2.58%)	9 / 150 (6.00%)	0 / 995 (0.00%)
occurrences (all)	4	12	0
Teething			
subjects affected / exposed	0 / 155 (0.00%)	15 / 150 (10.00%)	0 / 995 (0.00%)
occurrences (all)	0	17	0
Vomiting			
subjects affected / exposed	6 / 155 (3.87%)	12 / 150 (8.00%)	0 / 995 (0.00%)
occurrences (all)	6	12	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	12 / 155 (7.74%)	27 / 150 (18.00%)	26 / 995 (2.61%)
occurrences (all)	14	42	30
Nasal congestion			
subjects affected / exposed	5 / 155 (3.23%)	18 / 150 (12.00%)	0 / 995 (0.00%)
occurrences (all)	5	27	0
Rhinorrhoea			
subjects affected / exposed	13 / 155 (8.39%)	34 / 150 (22.67%)	28 / 995 (2.81%)
occurrences (all)	16	53	30
Oropharyngeal pain			
subjects affected / exposed	4 / 155 (2.58%)	1 / 150 (0.67%)	0 / 995 (0.00%)
occurrences (all)	4	1	0
Psychiatric disorders			

Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Croup infectious			
subjects affected / exposed	2 / 155 (1.29%)	10 / 150 (6.67%)	2 / 995 (0.20%)
occurrences (all)	2	10	2
Ear infection			
subjects affected / exposed	3 / 155 (1.94%)	19 / 150 (12.67%)	3 / 995 (0.30%)
occurrences (all)	6	25	3
Hand-foot-and-mouth disease			
subjects affected / exposed	3 / 155 (1.94%)	14 / 150 (9.33%)	0 / 995 (0.00%)
occurrences (all)	3	14	0
Otitis media acute			
subjects affected / exposed	2 / 155 (1.29%)	15 / 150 (10.00%)	1 / 995 (0.10%)
occurrences (all)	2	29	1
Otitis media			
subjects affected / exposed	7 / 155 (4.52%)	24 / 150 (16.00%)	2 / 995 (0.20%)
occurrences (all)	9	38	2
Respiratory tract infection viral			
subjects affected / exposed	5 / 155 (3.23%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences (all)	7	0	0
Sinusitis			
subjects affected / exposed	4 / 155 (2.58%)	8 / 150 (5.33%)	0 / 995 (0.00%)
occurrences (all)	4	8	0
Upper respiratory tract infection			
subjects affected / exposed	45 / 155 (29.03%)	37 / 150 (24.67%)	47 / 995 (4.72%)
occurrences (all)	81	70	49
Viral upper respiratory tract infection			
subjects affected / exposed	12 / 155 (7.74%)	9 / 150 (6.00%)	0 / 995 (0.00%)
occurrences (all)	13	14	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed	0 / 155 (0.00%)	0 / 150 (0.00%)	0 / 995 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2 (6-11 Years): mRNA-1273 50 µg	Part 2 (2-5 Years): Placebo	Part 2 (6-23 Months): Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	573 / 3007 (19.06%)	356 / 1007 (35.35%)	317 / 666 (47.60%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	83 / 3007 (2.76%)	49 / 1007 (4.87%)	57 / 666 (8.56%)
occurrences (all)	89	58	70
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	1 / 3007 (0.03%)	7 / 1007 (0.70%)	39 / 666 (5.86%)
occurrences (all)	1	7	43
Vomiting			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	136 / 3007 (4.52%)	69 / 1007 (6.85%)	43 / 666 (6.46%)
occurrences (all)	148	90	54
Nasal congestion			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	107 / 3007 (3.56%)	70 / 1007 (6.95%)	53 / 666 (7.96%)
occurrences (all)	125	87	70
Oropharyngeal pain			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Croup infectious			
subjects affected / exposed	17 / 3007 (0.57%)	16 / 1007 (1.59%)	15 / 666 (2.25%)
occurrences (all)	18	19	16
Ear infection			
subjects affected / exposed	22 / 3007 (0.73%)	47 / 1007 (4.67%)	64 / 666 (9.61%)
occurrences (all)	22	64	95
Hand-foot-and-mouth disease			
subjects affected / exposed	8 / 3007 (0.27%)	10 / 1007 (0.99%)	22 / 666 (3.30%)
occurrences (all)	8	10	22
Otitis media acute			
subjects affected / exposed	12 / 3007 (0.40%)	16 / 1007 (1.59%)	18 / 666 (2.70%)
occurrences (all)	12	19	24
Otitis media			
subjects affected / exposed	31 / 3007 (1.03%)	42 / 1007 (4.17%)	54 / 666 (8.11%)
occurrences (all)	35	52	73
Respiratory tract infection viral			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	284 / 3007 (9.44%)	190 / 1007 (18.87%)	146 / 666 (21.92%)
occurrences (all)	370	262	218
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			

subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3007 (0.00%)	0 / 1007 (0.00%)	0 / 666 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2 (2-5 Years): mRNA-1273 25 µg	Part 2 (6-23 Months): mRNA-1273 25 µg	6-11 Yrs: BD mRNA-1273.214 25 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1341 / 3031 (44.24%)	1095 / 1994 (54.91%)	28 / 184 (15.22%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	222 / 3031 (7.32%)	194 / 1994 (9.73%)	0 / 184 (0.00%)
occurrences (all)	269	224	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	9 / 3031 (0.30%)	109 / 1994 (5.47%)	0 / 184 (0.00%)
occurrences (all)	9	131	0
Vomiting			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	262 / 3031 (8.64%)	130 / 1994 (6.52%)	0 / 184 (0.00%)
occurrences (all)	351	161	0
Nasal congestion			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	250 / 3031 (8.25%)	173 / 1994 (8.68%)	0 / 184 (0.00%)
occurrences (all)	310	222	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	1 / 184 (0.54%)
occurrences (all)	0	0	1
Infections and infestations			
Croup infectious			
subjects affected / exposed	96 / 3031 (3.17%)	104 / 1994 (5.22%)	0 / 184 (0.00%)
occurrences (all)	107	124	0
Ear infection			
subjects affected / exposed	237 / 3031 (7.82%)	249 / 1994 (12.49%)	2 / 184 (1.09%)
occurrences (all)	291	353	2
Hand-foot-and-mouth disease			
subjects affected / exposed	60 / 3031 (1.98%)	114 / 1994 (5.72%)	0 / 184 (0.00%)
occurrences (all)	63	122	0
Otitis media acute			
subjects affected / exposed	84 / 3031 (2.77%)	113 / 1994 (5.67%)	0 / 184 (0.00%)
occurrences (all)	103	154	0
Otitis media			
subjects affected / exposed	231 / 3031 (7.62%)	258 / 1994 (12.94%)	1 / 184 (0.54%)
occurrences (all)	280	385	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	630 / 3031 (20.79%)	512 / 1994 (25.68%)	2 / 184 (1.09%)
occurrences (all)	926	805	2
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	10 / 184 (5.43%)
occurrences (all)	0	0	12
Influenza			
subjects affected / exposed	0 / 3031 (0.00%)	0 / 1994 (0.00%)	18 / 184 (9.78%)
occurrences (all)	0	0	18

Non-serious adverse events	6-11 Years: BD mRNA-1273 25 µg	Part 3 (6-11 Years): BD mRNA-1273 25 µg	Part 3 (6-11 Years): Primary Series mRNA-1273 25 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	468 / 2766 (16.92%)	4 / 70 (5.71%)	9 / 90 (10.00%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			

subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	44 / 2766 (1.59%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	44	0	0
Infections and infestations			
Croup infectious			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	37 / 2766 (1.34%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	38	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	46 / 2766 (1.66%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	48	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	164 / 2766 (5.93%)	4 / 70 (5.71%)	9 / 90 (10.00%)
occurrences (all)	205	8	11
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2766 (0.00%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	134 / 2766 (4.84%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	151	0	0
Influenza			
subjects affected / exposed	132 / 2766 (4.77%)	0 / 70 (0.00%)	0 / 90 (0.00%)
occurrences (all)	135	0	0

Non-serious adverse events	Part 2(6-11 Yrs): PS PBO - mRNA-1273 50 µg (Crossover)	Part 2 (2-5 Years): PS PBO - mRNA-1273 25 µg (Crossover)	Part 2 (6-23 Months): PBO - mRNA-1273 25 µg (Crossover)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	64 / 701 (9.13%)	58 / 640 (9.06%)	62 / 444 (13.96%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Croup infectious			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	5 / 701 (0.71%)	23 / 640 (3.59%)	38 / 444 (8.56%)
occurrences (all)	5	28	45
Respiratory tract infection viral			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	59 / 701 (8.42%)	39 / 640 (6.09%)	31 / 444 (6.98%)
occurrences (all)	64	46	46
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 701 (0.00%)	0 / 640 (0.00%)	0 / 444 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	6 Months-5 Yrs: BD mRNA-1273 25 µg	6 Months-5 Yrs: BD mRNA-1273 10 µg	6 Months-5 Yrs: BD mRNA-1273.214 10 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 89 (22.47%)	56 / 212 (26.42%)	655 / 2771 (23.64%)
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	3 / 89 (3.37%)	1 / 212 (0.47%)	10 / 2771 (0.36%)
occurrences (all)	3	1	10
Infections and infestations			
Croup infectious			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	3 / 89 (3.37%)	10 / 212 (4.72%)	141 / 2771 (5.09%)
occurrences (all)	4	13	163
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	5 / 89 (5.62%)	16 / 212 (7.55%)	225 / 2771 (8.12%)
occurrences (all)	5	22	258
Respiratory tract infection viral			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	6 / 89 (6.74%)	24 / 212 (11.32%)	132 / 2771 (4.76%)
occurrences (all)	6	35	142
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 89 (0.00%)	0 / 212 (0.00%)	0 / 2771 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	5 / 89 (5.62%)	12 / 212 (5.66%)	190 / 2771 (6.86%)
occurrences (all)	5	17	215
Influenza			
subjects affected / exposed	3 / 89 (3.37%)	6 / 212 (2.83%)	102 / 2771 (3.68%)
occurrences (all)	3	7	106

Non-serious adverse events	6 Months-5 Yrs: BD mRNA-1273.214 25 µg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 28 (14.29%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Teething			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Infections and infestations			
Croup infectious			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Otitis media acute			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	2		
Respiratory tract infection viral			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		

Sinusitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pharyngitis streptococcal			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	2		
Influenza			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 April 2021	- To allow a Data Safety Monitoring Board (DSMB) safety review when approximately 375 children have received mRNA-1273 in each age group, before expanding enrollment to each full age cohort in Part 2.
17 June 2021	- To add an optional blood collection on Day 57 for participants in the expansion part of Arm 1 and Arm 2 to gather additional data on immunogenicity. - To integrate the decision in Part 1 to not evaluate the 100 µg dose in participants less than 2 years by removing Arm 7 (6 to 23 months, 100 µg dose) from this age group. - To maintain dose ranging in the 2 to 5 years age group by allowing Arm 7 enrollment of participants in this age group to evaluate the 25 µg dose.
23 July 2021	- To add a case definition for myocarditis and pericarditis as well as guidance for reporting and assessing suspected cases for this study, given the recent emergence of a temporal association between mRNA vaccine administration and signs and symptoms of myocarditis/pericarditis. - To increase, the sample size for each age group in Part 2 (blinded part) to allow for a 95% probability to detect a rare AE occurring at a rate of 1 in 1000.
25 August 2021	- To introduce an additional blood draw within 4 days after the second dose for participants in Cohort D (phlebotomy cohort) in Part 2 in each age group (optional if already enrolled). The samples were stored for potential future analysis per a request from the Food and Drug Administration (FDA).
29 September 2021	- To simplify the process for potential crossover vaccination given the increased sample size of the study and to ensure retention in the study for safety follow-up. - To align with the Cardiac Event Adjudication Committee (CEAC) charter, and to clarify the DSMB safety data review process for the younger age groups (2 to 5 years; 6 to 23 months) to match the process in the older age group (6 to 11 years) and allow DSMB review of Part 1 (Open-label Phase) data before start of Part 2 (Blinded Phase) for the younger age groups.
07 January 2022	- To add an additional part to the study (Part 3) aimed at studying the safety, tolerability, reactogenicity, and immunogenicity of a lower dose level and regimen for 6 to 11-year-old children. - Addition of an Open-label Study Arm 14 for this age group with a sample size of approximately 300 participants who will receive two doses of 25 µg one month apart followed by a booster at least 3 months after the second dose.
18 February 2022	- To introduce an optional booster dose of mRNA-1273 for all participants in Part 1 (all age groups) and for the 6 to 11 years age group in Part 2 of the study. - Dosage levels are determined by age at booster dose: 25 µg for 6 to 11 years, 10 µg for 6 months to 5 years, regardless of primary series dosage level. - Interval of the booster dose is at least 6 months after Dose 2 of the primary series. - Safety follow-up is 12 months after the booster dose.
23 May 2022	- To unblind recipients receiving placebo who are under 6 years of age 6 months following their second vaccine dose so that they could be provided the option of receiving the crossover vaccine.
04 August 2022	- To provide an optional booster dose with mRNA-1273.214, a bivalent (Omicron containing) adaptation of the original COVID-19 vaccine (mRNA-1273) used in this study, at least 3 months after Dose 2 to all participants who had not received a booster dose after their primary series with mRNA-1273. - To remove COVID-19 surveillance for all parts of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported