Clinical trial results:
A Phase 1, Randomized, Observer-Blind, Placebo-Controlled, Dose Escalation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus (RSV), in Healthy Younger Adults Aged 18 to 49 Years, Women of Child-Bearing Potential Aged 18 to 40 Years, Healthy Older Adults Aged 65 to 79 Years, Japanese Older Adults Aged 60 Years, and RSV-Seropositive Children Aged 12 to 59 Months

Summary

EudraCT number	2024-000122-18
Trial protocol	Outside EU/EEA
Global end of trial date	18 July 2024

Results information

Result version number	v1 (current)
This version publication date	18 May 2025
First version publication date	18 May 2025

Trial information

Trial identification

Sponsor protocol code	mRNA-1345-P101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04528719
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-003309-PIP01-22
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	18 July 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 July 2024
Global end of trial reached?	Yes
Global end of trial date	18 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study were to evaluate the tolerability and reactogenicity of a single injection of up to 5 dose levels of mRNA-1345 in younger adults, women of child-bearing potential, and older adults including Japanese older adults; of 3 injections of the middle dose level of mRNA-1345 given 56 days apart in younger adults; of a booster injection of mRNA-1345 given approximately 12 and 24 months after the primary injection in older adults; and of 3 injections of 1 of 2 dose levels of mRNA-1345 given 56 days apart in children who were RSV-seropositive.

Protection of trial subjects:

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki, Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, applicable International Organization for Standardization (ISO) 14155 medical device guidelines, and other applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2020
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: 651
Worldwide total number of subjects	651
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)	7

Children (2-11 years)	39
Adolescents (12-17 years)	0
Adults (18-64 years)	288
From 65 to 84 years	317
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study included 4 Younger Adult Cohorts, 5 Older Adult Cohorts, 1 Japanese Older Adult Cohort, 2 Pediatric Cohorts, and 3 Women of Child-Bearing Potential (WOCBP) Cohorts.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)

Arm description:

Participants received a single injection of Dose A of mRNA-1345 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)

Arm description:

Participants received a single injection of Dose B of mRNA-1345 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose B of mRNA-1345 per day on Day 1, Day 57, and Day 113.

Arm type	Experimental

Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)

Arm description:

Participants received a single injection of Dose C of mRNA-1345 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Single Injection Placebo in Younger Adults (18 to 49 Years)

Arm description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Three Injection Placebo in Younger Adults (18 to 49 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose D of mRNA-1345 per day on Day 1, Day 57, and Day 113.

Arm type	Experimental

Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose G of mRNA-1345 per day on Day 1, Day 57, and Day 113.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Three Injection Placebo in Children (12 to 59 Months)

Arm description:

Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose A of mRNA-1345 on Day 1, a booster injection of Dose A of mRNA-1345 approximately 12 months later and a second booster injection of Dose A of mRNA-1345 approximately 24 months after Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose B of mRNA-1345 on Day 1, a booster injection of Dose B of mRNA-1345 approximately 12 months later and a second booster injection of Dose B of mRNA-1345 approximately 24 months after Day 1.

Arm type	Experimental

Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose C of mRNA-1345 on Day 1, a booster injection of Dose C of mRNA-1345 approximately 12 months later and a second booster injection of Dose C of mRNA-1345 approximately 24 months after Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose E of mRNA-1345 on Day 1, a booster injection of Dose E of mRNA-1345 approximately 12 months later and a second booster injection of Dose E of mRNA-1345 approximately 24 months after Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of Dose F of mRNA-1345 on Day 1, a booster injection of Dose F of mRNA-1345 approximately 12 months later and a second booster injection of Dose F of mRNA-1345 approximately 24 months after Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Two Injection Placebo in Older Adults (65 to 79 Years)

Arm description:

Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1 and approximately 12 months later. Participants received second booster injection of Dose A of mRNA-1345 approximately 24 months after Day 1.

Arm type	Placebo

Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)

Arm description:

Participants received a single injection of Dose F of mRNA-1345 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)

Arm description:

Participants received a single injection of Dose E of mRNA-1345 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)

Arm description:

Participants received a single injection of Dose A of mRNA-1345 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Single Injection Placebo in WOCBP (18 to 40 Years)

Arm description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults

Arm description:

Participants received a single injection of Dose B of mRNA-1345 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per dose and schedule specified in the arm description.

Arm title	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)

Arm description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Number of subjects in period 1	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Started	20	20	20
Safety Set	19	20	20
Completed	18	19	15
Not completed	2	1	5
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	1	4
Physician decision	-	-	-
Other Than Specified	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	1	-	1
Protocol deviation	-	-	-

Number of subjects in period 1	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)	Single Injection Placebo in Younger Adults (18 to 49 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)
Started	20	15	5
Safety Set	20	15	5
Completed	19	14	3
Not completed	1	1	2
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	1
Physician decision	-	-	-
Other Than Specified	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	1	-	1
Protocol deviation	-	-	-

Number of subjects in period 1	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)
Started	16	15	15
Safety Set	15	15	15
Completed	11	11	9
Not completed	5	4	6
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	2
Physician decision	-	-	-
Other Than Specified	2	-	1
Adverse event, non-fatal	-	-	-
Lost to follow-up	3	4	2
Protocol deviation	-	-	1

Number of subjects in period 1	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)
Started	48	48	48
Safety Set	47	48	48
Completed	36	31	30
Not completed	12	17	18
Adverse event, serious fatal	-	1	1
Consent withdrawn by subject	8	3	12
Physician decision	1	1	-
Other Than Specified	1	2	2
Adverse event, non-fatal	-	-	-
Lost to follow-up	2	10	3

Protocol deviation	-	-	-

Number of subjects in period 1	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)
Started	48	48	60
Safety Set	48	48	59
Completed	40	40	44
Not completed	8	8	16
Adverse event, serious fatal	1	1	-
Consent withdrawn by subject	3	4	5
Physician decision	-	-	-
Other Than Specified	1	-	1
Adverse event, non-fatal	-	1	-
Lost to follow-up	3	1	10
Protocol deviation	-	1	-

Number of subjects in period 1	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)
Started	50	50	50
Safety Set	50	49	49
Completed	45	44	42
Not completed	5	6	8
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	4	5
Physician decision	-	-	-
Other Than Specified	1	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	3	2	3
Protocol deviation	-	-	-

Number of subjects in period 1	Single Injection Placebo in WOCBP (18 to 40 Years)	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)
Started	30	20	5
Safety Set	30	20	5
Completed	26	20	5
Not completed	4	0	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	-	-
Physician decision	-	-	-
Other Than Specified	-	-	-
Adverse event, non-fatal	-	-	-

Lost to follow-up	2	-	-
Protocol deviation	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of Dose A of mRNA-1345 on Day 1.	
Reporting group title	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of Dose B of mRNA-1345 on Day 1.	
Reporting group title	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose B of mRNA-1345 per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of Dose C of mRNA-1345 on Day 1.	
Reporting group title	Single Injection Placebo in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of mRNA-1345 matching-placebo on Day 1.	
Reporting group title	Three Injection Placebo in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose D of mRNA-1345 per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose G of mRNA-1345 per day on Day 1, Day 57, and Day 113.	
Reporting group title	Three Injection Placebo in Children (12 to 59 Months)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose A of mRNA-1345 on Day 1, a booster injection of Dose A of mRNA-1345 approximately 12 months later and a second booster injection of Dose A of mRNA-1345 approximately 24 months after Day 1.	
Reporting group title	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose B of mRNA-1345 on Day 1, a booster injection of Dose B of mRNA-1345 approximately 12 months later and a second booster injection of Dose B of mRNA-1345 approximately 24 months after Day 1.	
Reporting group title	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose C of mRNA-1345 on Day 1, a booster injection of Dose C of mRNA-1345 approximately 12 months later and a second booster injection of Dose C of mRNA-1345 approximately 24 months after Day 1.	
Reporting group title	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)

Reporting group description:

Participants received a total of 3 injections: 1 injection of Dose E of mRNA-1345 on Day 1, a booster injection of Dose E of mRNA-1345 approximately 12 months later and a second booster injection of Dose E of mRNA-1345 approximately 24 months after Day 1.

Reporting group title	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)

Reporting group description:

Participants received a total of 3 injections: 1 injection of Dose F of mRNA-1345 on Day 1, a booster injection of Dose F of mRNA-1345 approximately 12 months later and a second booster injection of Dose F of mRNA-1345 approximately 24 months after Day 1.

Reporting group title	Two Injection Placebo in Older Adults (65 to 79 Years)

Reporting group description:

Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1 and approximately 12 months later. Participants received second booster injection of Dose A of mRNA-1345 approximately 24 months after Day 1.

Reporting group title	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose F of mRNA-1345 on Day 1.

Reporting group title	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose E of mRNA-1345 on Day 1.

Reporting group title	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose A of mRNA-1345 on Day 1.

Reporting group title	Single Injection Placebo in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Reporting group title	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults

Reporting group description:

Participants received a single injection of Dose B of mRNA-1345 on Day 1.

Reporting group title	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)

Reporting group description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Reporting group values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Number of subjects	20	20	20
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	36.1	33.4	32.0
standard deviation	± 7.50	± 7.56	± 9.55
Gender categorical Units: Subjects			
Female	10	11	16
Male	10	9	4
Race Units: Subjects			
White	14	16	16
Black or African American	6	4	4

Asian	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	0	0	0
Other	0	0	0
Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	20	19	20
Not Reported	0	0	0

Reporting group values	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)	Single Injection Placebo in Younger Adults (18 to 49 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)
Number of subjects	20	15	5
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	31.8	37.5	24.8
standard deviation	± 4.81	± 6.64	± 4.09
Gender categorical Units: Subjects			
Female	6	12	3
Male	14	3	2
Race Units: Subjects			
White	18	11	3
Black or African American	0	4	2
Asian	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	2	0	0
Other	0	0	0
Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	20	14	5
Not Reported	0	0	0

Reporting group values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)
Number of subjects	16	15	15
Age categorical Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	3.6	3.2	3.2
standard deviation	± 1.08	± 1.01	± 1.17
Gender categorical			
Units: Subjects			
Female	11	7	6
Male	5	8	9
Race			
Units: Subjects			
White	11	10	8
Black or African American	1	3	6
Asian	0	1	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	1	1	1
Other	3	0	0
Not Reported	0	0	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	2	0	2
Not Hispanic or Latino	14	15	13
Not Reported	0	0	0

Reporting group values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)
Number of subjects	48	48	48
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	70.1	70.2	69.9
standard deviation	± 3.81	± 3.88	± 3.94
Gender categorical			
Units: Subjects			
Female	25	25	28
Male	23	23	20
Race			
Units: Subjects			
White	45	42	46
Black or African American	1	6	1
Asian	1	0	0
American Indian or Alaska Native	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	1	0	0
Other	0	0	0
Not Reported	0	0	0
Ethnicity			

Units: Subjects			
Hispanic or Latino	3	0	4
Not Hispanic or Latino	45	48	44
Not Reported	0	0	0

Reporting group values	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)
Number of subjects	48	48	60
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	70.7	69.9	69.9
standard deviation	± 3.71	± 3.23	± 3.71
Gender categorical			
Units: Subjects			
Female	26	29	33
Male	22	19	27
Race			
Units: Subjects			
White	43	44	50
Black or African American	2	4	7
Asian	2	0	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	1
Multiple	0	0	0
Other	1	0	1
Not Reported	0	0	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	2	2	4
Not Hispanic or Latino	46	44	56
Not Reported	0	2	0

Reporting group values	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)
Number of subjects	50	50	50
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	29.6	30.3	31.3
standard deviation	± 6.64	± 5.77	± 6.24
Gender categorical			
Units: Subjects			
Female	50	50	50
Male	0	0	0

Race Units: Subjects			
White	45	37	43
Black or African American	5	8	3
Asian	0	2	4
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	0	3	0
Other	0	0	0
Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	6	1	4
Not Hispanic or Latino	44	49	46
Not Reported	0	0	0

Reporting group values	Single Injection Placebo in WOCBP (18 to 40 Years)	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)
Number of subjects	30	20	5
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	29.7	68.6	65.4
standard deviation	± 6.29	± 6.89	± 4.28
Gender categorical Units: Subjects			
Female	30	10	2
Male	0	10	3
Race Units: Subjects			
White	27	0	0
Black or African American	1	0	0
Asian	0	20	5
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	1	0	0
Multiple	0	0	0
Other	0	0	0
Not Reported	1	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	0	0
Not Hispanic or Latino	26	20	5
Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	651		

Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- 		
Gender categorical Units: Subjects			
Female	440		
Male	211		
Race Units: Subjects			
White	529		
Black or African American	68		
Asian	36		
American Indian or Alaska Native	1		
Native Hawaiian or Other Pacific Islander	2		
Multiple	9		
Other	5		
Not Reported	1		
Ethnicity Units: Subjects			
Hispanic or Latino	36		
Not Hispanic or Latino	613		
Not Reported	2		

End points

End points reporting groups

Reporting group title	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of Dose A of mRNA-1345 on Day 1.	
Reporting group title	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of Dose B of mRNA-1345 on Day 1.	
Reporting group title	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose B of mRNA-1345 per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of Dose C of mRNA-1345 on Day 1.	
Reporting group title	Single Injection Placebo in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a single injection of mRNA-1345 matching-placebo on Day 1.	
Reporting group title	Three Injection Placebo in Younger Adults (18 to 49 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose D of mRNA-1345 per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose G of mRNA-1345 per day on Day 1, Day 57, and Day 113.	
Reporting group title	Three Injection Placebo in Children (12 to 59 Months)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.	
Reporting group title	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose A of mRNA-1345 on Day 1, a booster injection of Dose A of mRNA-1345 approximately 12 months later and a second booster injection of Dose A of mRNA-1345 approximately 24 months after Day 1.	
Reporting group title	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose B of mRNA-1345 on Day 1, a booster injection of Dose B of mRNA-1345 approximately 12 months later and a second booster injection of Dose B of mRNA-1345 approximately 24 months after Day 1.	
Reporting group title	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)
Reporting group description:	
Participants received a total of 3 injections: 1 injection of Dose C of mRNA-1345 on Day 1, a booster injection of Dose C of mRNA-1345 approximately 12 months later and a second booster injection of Dose C of mRNA-1345 approximately 24 months after Day 1.	
Reporting group title	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)

Reporting group description:

Participants received a total of 3 injections: 1 injection of Dose E of mRNA-1345 on Day 1, a booster injection of Dose E of mRNA-1345 approximately 12 months later and a second booster injection of Dose E of mRNA-1345 approximately 24 months after Day 1.

Reporting group title	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)

Reporting group description:

Participants received a total of 3 injections: 1 injection of Dose F of mRNA-1345 on Day 1, a booster injection of Dose F of mRNA-1345 approximately 12 months later and a second booster injection of Dose F of mRNA-1345 approximately 24 months after Day 1.

Reporting group title	Two Injection Placebo in Older Adults (65 to 79 Years)

Reporting group description:

Participants received a total of 3 injections: 1 injection of mRNA-1345 matching-placebo per day on Day 1 and approximately 12 months later. Participants received second booster injection of Dose A of mRNA-1345 approximately 24 months after Day 1.

Reporting group title	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose F of mRNA-1345 on Day 1.

Reporting group title	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose E of mRNA-1345 on Day 1.

Reporting group title	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose A of mRNA-1345 on Day 1.

Reporting group title	Single Injection Placebo in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Reporting group title	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults

Reporting group description:

Participants received a single injection of Dose B of mRNA-1345 on Day 1.

Reporting group title	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)

Reporting group description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Subject analysis set title	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a single injection of Dose B of mRNA-1345 on Day 1.

Subject analysis set title	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Subject analysis set title	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a single injection of Dose F of mRNA-1345 on Day 1.

Subject analysis set title	Two Injection Placebo in Older Adults (After 1st Dose)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 1.

Subject analysis set title	Cohort 7: mRNA-1345 Dose A in Older Adults (After 1st Dose)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose A of mRNA-1345 on Day 1.

Subject analysis set title	Cohort 8: mRNA-1345 Dose B in Older Adults (After 1st Dose)

Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose B of mRNA-1345 on Day 1.	
Subject analysis set title	Cohort 9: mRNA-1345 Dose C in Older Adults (After 1st Dose)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose C of mRNA-1345 on Day 1.	
Subject analysis set title	Cohort 10: mRNA-1345 Dose E in Older Adults (After 1st Dose)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose E of mRNA-1345 on Day 1.	
Subject analysis set title	Cohort 11: mRNA-1345 Dose F in Older Adults (After 1st Dose)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose F of mRNA-1345 on Day 1.	
Subject analysis set title	Two Injection Placebo in Older Adults (After Month 12)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of mRNA-1345 matching-placebo approximately 12 months later.	
Subject analysis set title	Cohort 7: mRNA-1345 Dose A in Older Adults (After Month 12)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose A of mRNA-1345 approximately 12 months later.	
Subject analysis set title	Cohort 8: mRNA-1345 Dose B in Older Adults (After Month 12)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose B of mRNA-1345 approximately 12 months later.	
Subject analysis set title	Cohort 9: mRNA-1345 Dose C in Older Adults (After Month 12)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose C of mRNA-1345 approximately 12 months later.	
Subject analysis set title	Cohort 10: mRNA-1345 Dose E in Older Adults (After Month 12)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose E of mRNA-1345 approximately 12 months later.	
Subject analysis set title	Cohort 11: mRNA-1345 Dose F in Older Adults (After Month 12)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose F of mRNA-1345 approximately 12 months later.	
Subject analysis set title	Older Adult Cohorts: After Month 24: mRNA-1345 Dose A
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received second booster injection of Dose A of mRNA-1345 at Month 24.	
Subject analysis set title	Cohort 3: mRNA-1345 Dose B in Younger Adults (After 1st Dose)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 1 injection of Dose B of mRNA-1345 on Day 1.	
Subject analysis set title	Cohort 3: mRNA-1345 Dose B in Young Adults (After 2nd Dose)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose B of mRNA-1345 on Day 57.

Subject analysis set title	Cohort 3: mRNA-1345 Dose B in Young Adults (After 3rd Dose)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose B of mRNA-1345 on Day 113.

Subject analysis set title	Three Injection Placebo in Young Adults (After 1st Dose)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 1.

Subject analysis set title	Three Injection Placebo in Younger Adults (After 2nd Dose)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 57.

Subject analysis set title	Three Injection Placebo in Younger Adults (After 3rd Dose)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 113.

Subject analysis set title	mRNA-1345 Dose A in Older Adults (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose A of mRNA-1345 on Day 1.

Subject analysis set title	mRNA-1345 Dose B in Older Adults (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose B of mRNA-1345 on Day 1.

Subject analysis set title	mRNA-1345 Dose C in Older Adults (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose C of mRNA-1345 on Day 1.

Subject analysis set title	mRNA-1345 Dose E in Older Adults (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose E of mRNA-1345 on Day 1.

Subject analysis set title	mRNA-1345 Dose F in Older Adults (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose F of mRNA-1345 on Day 1.

Subject analysis set title	Two Injection Placebo in Older Adults (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 1.

Subject analysis set title	mRNA-1345 Dose A in Older Adults (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose A of mRNA-1345 approximately 12 months later.

Subject analysis set title	mRNA-1345 Dose B in Older Adults (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose B of mRNA-1345 approximately 12 months later.

Subject analysis set title	mRNA-1345 Dose C in Older Adults (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose C of mRNA-1345 approximately 12 months later.

Subject analysis set title	mRNA-1345 Dose E in Older Adults (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose E of mRNA-1345 approximately 12 months later.

Subject analysis set title	mRNA-1345 Dose F in Older Adults (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose F of mRNA-1345 approximately 12 months later.

Subject analysis set title	Two Injection Placebo in Older Adults (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo approximately 12 months later.

Subject analysis set title	mRNA-1345 Dose A/Dose A in Older Adults (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received second booster injection of Dose A of mRNA-1345 at Month 24.

Subject analysis set title	mRNA-1345 Dose B/Dose A in Older Adults (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received second booster injection of Dose A of mRNA-1345 at Month 24.

Subject analysis set title	mRNA-1345 Dose C/Dose A in Older Adults (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received second booster injection of Dose A of mRNA-1345 at Month 24.

Subject analysis set title	mRNA-1345 Dose E/Dose A in Older Adults (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received second booster injection of Dose A of mRNA-1345 at Month 24.

Subject analysis set title	mRNA-1345 Dose F/Dose A in Older Adults (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received second booster injection of Dose A of mRNA-1345 at Month 24.

Subject analysis set title	2-Injection Placebo/Dose A in Old Adults (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received second booster injection of Dose A of mRNA-1345 at Month 24.

Subject analysis set title	mRNA-1345 Dose D in Children (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose D of mRNA-1345 on Day 1.

Subject analysis set title	mRNA-1345 Dose G in Children (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose G of mRNA-1345 on Day 1.

Subject analysis set title	Three Injection Placebo in Children (After 1st Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 1.

Subject analysis set title	mRNA-1345 Dose D in Children (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose D of mRNA-1345 on Day 57.

Subject analysis set title	mRNA-1345 Dose G in Children (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose G of mRNA-1345 on Day 57.

Subject analysis set title	Three Injection Placebo in Children (After 2nd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 57.

Subject analysis set title	mRNA-1345 Dose D in Children (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose D of mRNA-1345 on Day 113.

Subject analysis set title	mRNA-1345 Dose G in Children (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of Dose G of mRNA-1345 on Day 113.

Subject analysis set title	Three Injection Placebo in Children (After 3rd Injection)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 113.

Primary: Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) in Young Adult Cohorts

End point title	Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) in Young Adult Cohorts[1][2]

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 included all randomized participants who received any study injection and contributed any solicited AR data (that is, had at least 1 postbaseline solicited safety [eDiary] assessment). Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

7 days after injection

Notes:

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

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)	Single Injection Placebo in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	20	20	15
Units: participants	15	18	20	6

End point values	Cohort 3: mRNA-1345 Dose B in Younger Adults (After 1st Dose)	Cohort 3: mRNA-1345 Dose B in Young Adults (After 2nd Dose)	Cohort 3: mRNA-1345 Dose B in Young Adults (After 3rd Dose)	Three Injection Placebo in Young Adults (After 1st Dose)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	16	14	5
Units: participants	20	14	12	2

End point values	Three Injection Placebo in Younger Adults (After 2nd Dose)	Three Injection Placebo in Younger Adults (After 3rd Dose)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	3		
Units: participants	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Solicited Local and Systemic ARs in WOCBP Cohorts and Japanese Adult Cohorts

End point title	Number of Participants with Solicited Local and Systemic ARs in WOCBP Cohorts and Japanese Adult Cohorts[3][4]

End point description:

Solicited ARs were collected in an 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 AEs. Investigator reviewed whether the solicited AR was also to be recorded as an AE. A Summary of SAEs and nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Solicited Safety Set included all randomized participants who received any study injection and contributed any solicited AR data (that is, had at least 1 postbaseline solicited safety [eDiary] assessment). Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

7 days after injection

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: The endpoint is descriptive in nature.

[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: The endpoint is descriptive in nature.

End point values	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	49	48	30	21
Units: participants	46	44	11	20

End point values	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	51		
Units: participants	3	48		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Solicited Local and Systemic ARs in Older Adult Cohorts

End point title	Number of Participants with Solicited Local and Systemic ARs in Older Adult Cohorts[5]

End point description:

Solicited ARs were collected in an 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 AEs. Investigator reviewed whether the solicited AR was also to be recorded as an AE. A Summary of SAEs and nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Solicited Safety Set included all randomized participants who received any study injection and contributed any solicited AR data (that is, had at least 1 postbaseline solicited safety [eDiary] assessment). Participants were included in the treatment arm corresponding to the study drug they actually received. Number analyzed = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

7 days after each injection

Notes:

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

End point values	mRNA-1345 Dose A in Older Adults (After 1st Injection)	mRNA-1345 Dose B in Older Adults (After 1st Injection)	mRNA-1345 Dose C in Older Adults (After 1st Injection)	mRNA-1345 Dose E in Older Adults (After 1st Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47	47	47	44
Units: participants	34	42	42	35

End point values	mRNA-1345 Dose F in Older Adults (After 1st Injection)	Two Injection Placebo in Older Adults (After 1st Injection)	mRNA-1345 Dose A in Older Adults (After 2nd Injection)	mRNA-1345 Dose B in Older Adults (After 2nd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46	55	21	18
Units: participants	31	25	7	8

End point values	mRNA-1345 Dose C in Older Adults (After 2nd Injection)	mRNA-1345 Dose E in Older Adults (After 2nd Injection)	mRNA-1345 Dose F in Older Adults (After 2nd Injection)	Two Injection Placebo in Older Adults (After 2nd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	20	19	51
Units: participants	3	10	7	14

End point values	mRNA-1345 Dose A/Dose A in Older Adults (After 3rd Injection)	mRNA-1345 Dose B/Dose A in Older Adults (After 3rd Injection)	mRNA-1345 Dose C/Dose A in Older Adults (After 3rd Injection)	mRNA-1345 Dose E/Dose A in Older Adults (After 3rd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	7	3	10
Units: participants	8	7	2	9

End point values	mRNA-1345 Dose F/Dose A in Older Adults (After 3rd Injection)	2-Injection Placebo/Dose A in Old Adults (After 3rd Injection)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	22		
Units: participants	11	15		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Solicited Local and Systemic ARs in Children Cohorts

End point title	Number of Participants with Solicited Local and Systemic ARs in Children Cohorts[6]

End point description:

Solicited ARs were collected in an 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 AEs. Investigator reviewed whether the solicited AR was also to be recorded as an AE. A Summary of SAEs and nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Solicited Safety Set included all randomized participants who received any study injection and contributed any solicited AR data (that is, had at least 1 postbaseline solicited safety [eDiary] assessment). Participants were included in the treatment arm corresponding to the study drug they actually received. Number analyzed = participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

7 days after each injection

Notes:

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

End point values	mRNA-1345 Dose D in Children (After 1st Injection)	mRNA-1345 Dose G in Children (After 1st Injection)	Three Injection Placebo in Children (After 1st Injection)	mRNA-1345 Dose D in Children (After 2nd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	15	14	15	8
Units: participants	8	7	7	5

End point values	mRNA-1345 Dose G in Children (After 2nd Injection)	Three Injection Placebo in Children (After 2nd Injection)	mRNA-1345 Dose D in Children (After 3rd Injection)	mRNA-1345 Dose G in Children (After 3rd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	11	9	11
Units: participants	9	7	6	5

End point values	Three Injection Placebo in Children (After 3rd Injection)			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: participants	5			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Unsolicited AEs in Younger Adult Cohorts

End point title	Number of Participants with Unsolicited AEs in Younger Adult Cohorts[7][8]

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. Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to 28 days after each injection

Notes:

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

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)	Single Injection Placebo in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	20	20	15
Units: participants	2	2	15	5

End point values	Cohort 3: mRNA-1345 Dose B in Younger Adults (After 1st Dose)	Cohort 3: mRNA-1345 Dose B in Young Adults (After 2nd Dose)	Cohort 3: mRNA-1345 Dose B in Young Adults (After 3rd Dose)	Three Injection Placebo in Young Adults (After 1st Dose)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	16	15	5
Units: participants	6	1	3	0

End point values	Three Injection Placebo in Younger Adults (After 2nd Dose)	Three Injection Placebo in Younger Adults (After 3rd Dose)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	3		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Unsolicited AE in WOCBP Cohorts and Japanese Adult Cohorts

End point title	Number of Participants with Unsolicited AE in WOCBP Cohorts and Japanese Adult Cohorts[9][10]

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 PT/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. Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to 28 days after each injection

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: The endpoint is descriptive in nature.

[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: The endpoint is descriptive in nature.

End point values	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	49	48	30	21
Units: participants	12	5	4	1

End point values	Single Injection Placebo in	Cohort 12: mRNA-1345		

	Japanese Older Adults (≥ 60 Years)	Dose F in WOCBP (18 to 40 Years)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	51		
Units: participants	2	11		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Unsolicited AEs in Older Adult Cohorts

End point title	Number of Participants with Unsolicited AEs in Older Adult Cohorts[11][12]

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 PT/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. Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to 28 days after each injection

Notes:

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

[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: The endpoint is descriptive in nature.

End point values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	48	48	48
Units: participants	19	15	19	19

End point values	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	59		
Units: participants	21	14		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with SAEs or Medically Attended AEs (MAAEs) in Younger Adult Cohorts

End point title	Number of Participants with SAEs or Medically Attended AEs (MAAEs) in Younger Adult Cohorts[13][14]

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. 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. Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to Day 1095 (End of Study)

Notes:

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

[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: The endpoint is descriptive in nature.

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)	Single Injection Placebo in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	20	20	15
Units: participants				
SAEs	0	0	0	0
MAAEs	0	0	9	4

End point values	Cohort 3: mRNA-1345 Dose B in Younger Adults (After 1st Dose)	Cohort 3: mRNA-1345 Dose B in Young Adults (After 2nd Dose)	Cohort 3: mRNA-1345 Dose B in Young Adults (After 3rd Dose)	Three Injection Placebo in Young Adults (After 1st Dose)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	16	15	5

Units: participants				
SAEs	0	0	0	0
MAAEs	2	1	2	0

End point values	Three Injection Placebo in Younger Adults (After 2nd Dose)	Three Injection Placebo in Younger Adults (After 3rd Dose)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	3		
Units: participants				
SAEs	0	0		
MAAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Unsolicited AEs in Children Cohorts

End point title	Number of Participants with Unsolicited AEs in Children

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 PT/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. Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to 28 days after each injection

Notes:

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

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	15	15	
Units: participants	4	6	7	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with SAEs or MAAEs in WOCBP Cohorts and Japanese Adult Cohorts

End point title	Number of Participants with SAEs or MAAEs in WOCBP Cohorts and Japanese Adult Cohorts[17][18]

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. 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. Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to Day 1095 (End of Study)

Notes:

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

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

End point values	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	48	49	30	21
Units: participants				
SAEs	0	0	0	0
MAAEs	11	17	10	1

End point values	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	51		
Units: participants				

SAEs	0	1		
MAAEs	1	15		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with SAEs or MAAEs in Older Adult Cohorts

End point title	Number of Participants with SAEs or MAAEs in Older Adult Cohorts[19]

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. 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. Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to Day 1095 (End of Study)

Notes:

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

End point values	mRNA-1345 Dose A in Older Adults (After 1st Injection)	mRNA-1345 Dose B in Older Adults (After 1st Injection)	mRNA-1345 Dose C in Older Adults (After 1st Injection)	mRNA-1345 Dose E in Older Adults (After 1st Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47	48	48	48
Units: participants				
SAEs	4	0	1	3
MAAEs	8	4	7	6

End point values	mRNA-1345 Dose F in Older Adults (After 1st Injection)	Two Injection Placebo in Older Adults (After 1st Injection)	mRNA-1345 Dose A in Older Adults (After 2nd Injection)	mRNA-1345 Dose B in Older Adults (After 2nd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	59	21	18
Units: participants				
SAEs	5	1	1	1
MAAEs	8	4	2	0

End point values	mRNA-1345 Dose C in Older Adults (After 2nd Injection)	mRNA-1345 Dose E in Older Adults (After 2nd Injection)	mRNA-1345 Dose F in Older Adults (After 2nd Injection)	Two Injection Placebo in Older Adults (After 2nd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	20	20	52
Units: participants				
SAEs	2	1	1	1
MAAEs	2	2	2	4

End point values	mRNA-1345 Dose A/Dose A in Older Adults (After 3rd Injection)	mRNA-1345 Dose B/Dose A in Older Adults (After 3rd Injection)	mRNA-1345 Dose C/Dose A in Older Adults (After 3rd Injection)	mRNA-1345 Dose E/Dose A in Older Adults (After 3rd Injection)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	7	3	10
Units: participants				
SAEs	0	1	0	1
MAAEs	2	0	0	1

End point values	mRNA-1345 Dose F/Dose A in Older Adults (After 3rd Injection)	2-Injection Placebo/Dose A in Old Adults (After 3rd Injection)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	22		
Units: participants				
SAEs	1	1		
MAAEs	2	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with SAEs or MAAEs in Children Cohorts

End point title	Number of Participants with SAEs or MAAEs in Children

End point description:

Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received.

End point type	Primary

End point timeframe:

Up to Day 1095 (End of Study)

Notes:

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

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	15	15	
Units: participants				
SAEs	0	0	0	
MAAEs	5	11	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer (GMT) of Serum RSV Neutralizing Antibodies (Abs) (RSV-A and RSV-B) for Young Adult Cohorts

End point title	Geometric Mean Titer (GMT) of Serum RSV Neutralizing Antibodies (Abs) (RSV-A and RSV-B) for Young Adult Cohorts[22]

End point description:

Antibody values reported as below lower limit of quantification (LLOQ) were replaced by 0.5*LLOQ. LLOQ was 11 international units (IU)/milliliter (mL) for RSV-A and 8 IU/mL for RSV-B. Per-protocol (PP) Set: Full Analysis Set (FAS) participants (all randomized participants who received any study injection, had baseline data for analyses that require baseline data, and had at least 1 postinjection assessment for analysis endpoint) who a) complied with injection schedule, b) complied with timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during period corresponding to immunogenicity analysis objective. Participants were included in the arm to which they were randomized. 'n' = participants evaluable for specified categories. '9999' represents data not collected for specified cohorts.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, 113, 141, 169, and 281

Notes:

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	19	19
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=18,19,19,19,15,4)	981.7 (688.4 to 1399.8)	750.1 (472.8 to 1190.0)	811.9 (525.6 to 1254.1)	1252.6 (767.5 to 2044.3)
RSV-A: Day 29 (n=18,19,19,19,15,4)	20140.7 (13749.6 to 29502.4)	16687.8 (11984.9 to 23236.2)	19111.9 (12383.9 to 29495.1)	22312.3 (15470.8 to 32179.3)
RSV-A: Day 57 (n=18,19,15,17,14,4)	17184.7 (11128.9 to 26535.8)	12624.2 (8407.6 to 18955.4)	11856.0 (5981.3 to 23500.7)	17390.2 (10457.9 to 28917.8)
RSV-A: Day 85 (n=18,19,13,17,13,3)	15484.6 (10242.6 to 23409.4)	8838.7 (6448.5 to 12114.9)	17802.2 (9821.8 to 32267.0)	12581.7 (8142.4 to 19441.4)
RSV-A: Day 113 (n=18,17,12,16,13,3)	13991.8 (9014.2 to 21718.1)	7034.8 (5109.9 to 9684.7)	12571.6 (6782.8 to 23300.7)	14692.4 (9907.9 to 21787.4)
RSV-A: Day 141 (n=18,19,13,16,14,3)	9561.8 (5982.5 to 15282.5)	5582.9 (4028.9 to 7736.2)	10500.2 (6144.7 to 17942.8)	14375.8 (9374.3 to 22045.8)
RSV-A: Day 169 (n=18,19,13,17,13,3)	9448.0 (6169.7 to 14468.4)	5232.8 (3684.1 to 7432.5)	13287.2 (7992.9 to 22088.2)	11516.4 (6681.9 to 19848.7)
RSV-A: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	8669.8 (5301.3 to 14178.7)	9999 (9999 to 9999)
RSV-B: Day 1 (n=18,19,19,19,15,4)	795.3 (532.8 to 1187.3)	1091.6 (560.2 to 2127.3)	842.7 (494.3 to 1436.5)	1097.4 (533.8 to 2255.8)
RSV-B: Day 29 (n=18,19,19,18,15,4)	11487.5 (7894.8 to 16715.3)	12741.6 (9388.1 to 17293.0)	13496.5 (8379.8 to 21737.4)	12901.6 (8474.9 to 19640.5)
RSV-B: Day 57 (n=18,19,15,17,14,4)	12156.5 (7773.0 to 19012.1)	14221.7 (9366.5 to 21593.6)	15341.5 (10067.7 to 23378.0)	9374.5 (5178.1 to 16971.7)
RSV-B: Day 85 (n=18,19,13,17,13,3)	8380.0 (5212.3 to 13472.9)	8996.4 (5678.6 to 14252.8)	13400.3 (8814.8 to 20371.2)	9007.3 (4360.2 to 18607.0)
RSV-B: Day 113 (n=18,17,12,16,13,3)	8255.0 (5581.9 to 12208.0)	10657.0 (6790.7 to 16724.4)	13515.1 (8581.1 to 21286.0)	8744.3 (4545.8 to 16820.5)
RSV-B: Day 141 (n=18,19,13,16,14,3)	8478.6 (5461.9 to 13161.5)	8019.8 (5289.7 to 12159.0)	14408.6 (8599.6 to 24141.7)	7313.6 (3859.4 to 13859.6)
RSV-B: Day 169 (n=18,19,13,17,13,3)	7078.4 (4563.6 to 10978.8)	5769.0 (3878.2 to 8581.6)	11801.7 (7020.9 to 19837.7)	6276.6 (3418.9 to 11522.9)
RSV-B: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	7081.8 (4123.2 to 12163.2)	819.2 (22.2 to 30249.3)

End point values	Single Injection Placebo in	Three Injection Placebo in		

	Younger Adults (18 to 49 Years)	Younger Adults (18 to 49 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	4		
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=18,19,19,19,15,4)	1581.0 (1113.2 to 2245.4)	2054.7 (1262.7 to 3343.4)		
RSV-A: Day 29 (n=18,19,19,19,15,4)	1461.0 (941.7 to 2266.6)	1988.9 (930.6 to 4251.1)		
RSV-A: Day 57 (n=18,19,15,17,14,4)	1321.8 (928.2 to 1882.3)	1564.6 (665.8 to 3676.6)		
RSV-A: Day 85 (n=18,19,13,17,13,3)	1426.1 (926.5 to 2195.2)	1400.5 (555.1 to 3533.8)		
RSV-A: Day 113 (n=18,17,12,16,13,3)	1230.2 (815.4 to 1856.0)	1940.4 (297.7 to 12646.6)		
RSV-A: Day 141 (n=18,19,13,16,14,3)	1378.9 (857.8 to 2216.6)	1909.1 (522.8 to 6970.7)		
RSV-A: Day 169 (n=18,19,13,17,13,3)	1334.8 (902.7 to 1973.7)	1345.1 (363.4 to 4978.4)		
RSV-A: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	1103.5 (776.9 to 1567.4)		
RSV-B: Day 1 (n=18,19,19,19,15,4)	1144.2 (694.9 to 1884.1)	1373.7 (448.2 to 4210.6)		
RSV-B: Day 29 (n=18,19,19,18,15,4)	1009.5 (612.3 to 1664.5)	1640.5 (294.4 to 9143.0)		
RSV-B: Day 57 (n=18,19,15,17,14,4)	1053.3 (527.6 to 2102.6)	2168.5 (411.5 to 11428.7)		
RSV-B: Day 85 (n=18,19,13,17,13,3)	939.1 (513.2 to 1718.6)	1324.8 (98.6 to 17800.2)		
RSV-B: Day 113 (n=18,17,12,16,13,3)	874.2 (447.1 to 1709.4)	1459.2 (162.8 to 13081.1)		
RSV-B: Day 141 (n=18,19,13,16,14,3)	963.4 (571.5 to 1624.0)	1478.9 (79.2 to 27622.2)		
RSV-B: Day 169 (n=18,19,13,17,13,3)	730.6 (394.3 to 1353.8)	1119.5 (66.8 to 18749.5)		
RSV-B: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for Older Adults Cohorts

End point title	GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for Older Adults Cohorts[23]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 13 IU/mL for RSV-A and 10 IU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding

to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, 169, and 365

Notes:

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

End point values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	46	47	46
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=47,46,47,46,46,58)	1204.7 (918.5 to 1580.0)	1224.9 (877.7 to 1709.4)	1879.9 (1403.5 to 2517.9)	1519.0 (1128.8 to 2044.0)
RSV-A: Day 29 (n=44,43,47,45,44,56)	13739.0 (9875.5 to 19113.8)	17053.4 (12486.8 to 23289.9)	31341.0 (24366.7 to 40311.4)	19008.4 (14470.5 to 24969.5)
RSV-A: Day 57 (n=46,39,44,42,45,58)	10967.5 (7762.9 to 15494.9)	15494.9 (8445.9 to 16648.4)	24600.2 (18782.3 to 32220.3)	15121.9 (10705.9 to 21359.5)
RSV-A: Day 85 (n=44,42,46,45,43,55)	9020.8 (6523.6 to 12474.0)	9947.3 (7262.5 to 13624.5)	17772.8 (13062.3 to 24182.0)	11372.8 (8253.5 to 15671.1)
RSV-A: Day 169 (n=43,42,44,44,44,55)	5746.9 (4133.8 to 7989.4)	4815.2 (3517.0 to 6592.4)	10674.2 (7754.6 to 14693.1)	5936.5 (4280.0 to 8234.3)
RSV-A: Day 365 (n=38,33,36,41,40,49)	3399.6 (2279.9 to 5069.2)	2525.7 (1795.9 to 3551.9)	6141.1 (4144.2 to 9100.1)	4592.4 (3343.7 to 6307.5)
RSV-B: Day 1 (n=47,46,47,46,46,58)	1135.3 (833.2 to 1547.0)	941.0 (681.6 to 1299.1)	1455.4 (1008.2 to 2100.9)	1507.7 (1055.3 to 2153.9)
RSV-B: Day 29 (n=44,43,47,45,44,56)	9432.1 (6706.2 to 13266.0)	9319.9 (6754.5 to 12859.7)	18187.1 (13207.4 to 25044.4)	10235.2 (7445.9 to 14069.5)
RSV-B: Day 57 (n=46,39,44,42,45,58)	7905.3 (5765.3 to 10839.5)	8869.0 (6455.4 to 12185.0)	15182.3 (11431.9 to 20163.0)	8004.0 (5684.9 to 11269.1)
RSV-B: Day 85 (n=44,42,46,45,43,55)	6385.1 (4652.7 to 8762.4)	6931.0 (4873.8 to 9856.6)	11985.6 (8513.6 to 16873.6)	6754.9 (4823.0 to 9460.6)
RSV-B: Day 169 (n=43,42,44,44,44,55)	5226.3 (3747.5 to 7288.8)	4313.9 (3166.9 to 5876.2)	8171.7 (6023.4 to 11086.3)	4873.5 (3518.5 to 6750.3)
RSV-B: Day 365 (n=38,33,36,41,40,49)	2586.2 (1849.1 to 3617.2)	2475.8 (1791.4 to 3421.5)	4262.6 (3088.9 to 5882.2)	2321.2 (1657.2 to 3251.1)

End point values	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	58		
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=47,46,47,46,46,58)	1329.8 (969.1 to 1824.8)	1590.7 (1141.8 to 2215.9)		
RSV-A: Day 29 (n=44,43,47,45,44,56)	13619.5 (9340.7 to 19858.3)	1827.2 (1306.1 to 2556.2)		
RSV-A: Day 57 (n=46,39,44,42,45,58)	9476.3 (6537.5 to 13736.3)	1783.9 (1257.5 to 2530.7)		
RSV-A: Day 85 (n=44,42,46,45,43,55)	7192.1 (4987.4 to 10371.4)	1761.0 (1243.8 to 2493.3)		
RSV-A: Day 169 (n=43,42,44,44,44,55)	4263.2 (3028.4 to 6001.6)	1652.6 (1186.1 to 2302.6)		
RSV-A: Day 365 (n=38,33,36,41,40,49)	3161.4 (2187.0 to 4570.0)	2035.5 (1403.1 to 2952.8)		
RSV-B: Day 1 (n=47,46,47,46,46,58)	1437.5 (1015.1 to 2035.4)	1451.0 (1053.2 to 1998.9)		
RSV-B: Day 29 (n=44,43,47,45,44,56)	8154.9 (5568.3 to 11943.0)	1580.1 (1102.0 to 2265.5)		
RSV-B: Day 57 (n=46,39,44,42,45,58)	6196.1 (4369.6 to 8786.0)	1840.8 (1332.2 to 2543.5)		
RSV-B: Day 85 (n=44,42,46,45,43,55)	5065.2 (3432.3 to 7474.8)	1874.2 (1375.7 to 2553.3)		
RSV-B: Day 169 (n=43,42,44,44,44,55)	4164.0 (2876.3 to 6028.0)	2034.3 (1484.3 to 2788.2)		
RSV-B: Day 365 (n=38,33,36,41,40,49)	2113.9 (1548.6 to 2885.6)	1673.2 (1190.9 to 2350.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for Japanese Adults Cohorts

End point title	GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for Japanese Adults Cohorts[24]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 11 IU/mL for RSV-A and 8 IU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1

postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, and 169

Notes:

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

End point values	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	4		
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=20,4)	1602.1 (1042.5 to 2462.1)	1798.9 (1125.1 to 2876.2)		
RSV-A: Day 29 (n=20,4)	17861.7 (10929.3 to 29191.4)	1476.5 (918.1 to 2374.5)		
RSV-A: Day 57 (n=20,4)	15627.7 (9983.1 to 24463.9)	1508.3 (554.5 to 4102.6)		
RSV-A: Day 85 (n=19,4)	12447.6 (7781.3 to 19912.1)	1449.6 (606.4 to 3465.0)		
RSV-A: Day 169 (n=20,4)	6658.1 (4213.0 to 10522.3)	1292.8 (810.1 to 2062.9)		
RSV-B: Day 1 (n=20,4)	1029.4 (732.8 to 1446.1)	1275.6 (368.5 to 4415.3)		
RSV-B: Day 29 (n=20,4)	6791.7 (4432.3 to 10406.8)	1033.4 (293.4 to 3640.0)		
RSV-B: Day 57 (n=20,4)	4862.2 (3312.9 to 7136.1)	1086.3 (261.0 to 4521.1)		
RSV-B: Day 85 (n=19,4)	3818.4 (2655.8 to 5490.0)	1039.1 (302.4 to 3571.0)		
RSV-B: Day 169 (n=20,4)	2751.5 (1933.2 to 3916.1)	879.9 (342.0 to 2263.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for WOCBP Cohorts

End point title	GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for WOCBP Cohorts[25]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 13 IU/mL for RSV-A and 10 IU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, 113, 141, and 169

Notes:

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

End point values	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	44	29
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=49,48,44,29)	902.8 (688.4 to 1184.1)	1111.6 (858.6 to 1439.3)	1135.1 (844.5 to 1525.8)	1358.4 (879.1 to 2099.0)
RSV-A: Day 29 (n=49,46,41,28)	8497.2 (6631.2 to 10888.3)	12362.2 (8923.0 to 17127.0)	12635.8 (9143.8 to 17461.5)	1348.6 (855.1 to 2127.1)
RSV-A: Day 57 (n=45,45,42,28)	8250.2 (6278.4 to 10841.3)	11270.7 (8269.0 to 15362.1)	12722.4 (9594.7 to 16869.7)	1940.5 (1200.9 to 3135.7)
RSV-A: Day 85 (n=43,41,37,24)	6364.7 (4855.0 to 8343.8)	10169.9 (7272.4 to 14221.8)	10568.9 (7406.5 to 15081.5)	1683.1 (996.9 to 2841.7)
RSV-A: Day 113 (n=44,43,37,25)	5231.9 (3797.5 to 7207.9)	7675.4 (5725.6 to 10289.2)	8439.8 (5882.5 to 12109.0)	1885.9 (1118.6 to 3179.5)
RSV-A: Day 141 (n=40,42,36,25)	4518.2 (3263.9 to 6254.7)	6315.6 (4534.8 to 8795.8)	7059.2 (4777.3 to 10431.2)	1519.5 (943.7 to 2446.5)
RSV-A: Day 169 (n=41,43,34,23)	3731.9 (2736.9 to 5088.7)	5476.8 (3924.4 to 7643.2)	5387.8 (3720.1 to 7803.1)	1620.7 (988.3 to 2657.9)
RSV-B: Day 1 (n=49,48,44,29)	958.4 (724.4 to 1267.8)	1676.1 (1197.0 to 2346.8)	1148.9 (789.9 to 1670.9)	930.8 (597.4 to 1450.2)
RSV-B: Day 29 (n=49,46,41,28)	7236.5 (5573.6 to 9395.4)	11368.3 (8304.0 to 15563.4)	10591.9 (7302.2 to 15363.5)	903.0 (554.2 to 1471.3)
RSV-B: Day 57 (n=45,45,42,28)	5129.7 (3937.6 to 6682.7)	7873.5 (5922.9 to 10466.6)	8072.7 (6072.3 to 10732.0)	1333.1 (832.2 to 2135.7)

RSV-B: Day 85 (n=43,41,37,24)	4592.4 (3542.9 to 5952.6)	7877.3 (5767.7 to 10758.6)	6470.1 (4836.7 to 8655.1)	1536.9 (952.1 to 2481.0)
RSV-B: Day 113 (n=44,43,37,25)	3453.3 (2743.4 to 4346.9)	6448.3 (4858.8 to 8557.7)	5348.4 (3996.3 to 7158.0)	1319.7 (833.5 to 2089.6)
RSV-B: Day 141 (n=40,42,36,25)	3470.7 (2626.8 to 4585.9)	5421.0 (3977.3 to 7388.7)	4670.8 (3375.0 to 6464.2)	1317.5 (848.1 to 2046.7)
RSV-B: Day 169 (n=41,43,34,23)	3112.6 (2372.6 to 4083.4)	4959.7 (3637.6 to 6762.3)	3879.0 (2771.7 to 5428.7)	1151.9 (704.6 to 1883.3)

Statistical analyses

No statistical analyses for this end point

Secondary: GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for Children Cohorts

End point title	GMT of Serum RSV Neutralizing Abs (RSV-A and RSV-B) for Children Cohorts[26]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 13 IU/mL for RSV-A and 10 IU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 85, and 141

Notes:

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	13	11	
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=14,13,11)	240.1 (96.4 to 597.8)	602.1 (185.8 to 1951.4)	447.2 (152.3 to 1312.9)	
RSV-A: Day 29 (n=14,12,11)	8376.1 (3354.9 to 20912.2)	11440.4 (6477.0 to 20207.1)	642.6 (236.9 to 1743.4)	
RSV-A: Day 85 (n=5,9,4)	5114.0 (1255.2 to 20835.8)	4820.1 (1823.9 to 12737.9)	145.2 (23.5 to 896.3)	

RSV-A: Day 141 (n=4,5,5)	4660.8 (1141.8 to 19025.7)	13233.4 (3136.2 to 55840.1)	735.9 (199.3 to 2716.9)	
RSV-B: Day 1 (n=14,13,11)	345.7 (152.1 to 785.9)	832.9 (312.6 to 2219.5)	394.4 (138.3 to 1124.5)	
RSV-B: Day 29 (n=14,12,11)	4931.9 (2080.0 to 11693.7)	5940.3 (3446.4 to 10238.9)	490.2 (178.2 to 1348.1)	
RSV-B: Day 85 (n=5,9,4)	2534.8 (1213.6 to 5294.1)	2622.2 (1453.8 to 4729.7)	107.2 (25.2 to 455.3)	
RSV-B: Day 141 (n=4,5,5)	2899.9 (419.8 to 20031.0)	5038.4 (2241.8 to 11323.7)	957.0 (192.0 to 4770.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) of Serum Binding Abs (PreF and PostF) for Young Adult Cohorts

End point title	Geometric Mean Concentration (GMC) of Serum Binding Abs (PreF and PostF) for Young Adult Cohorts[27]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 19 arbitrary unit (AU)/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories. '9999' represents data not collected for specified cohorts.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, 113, 141, 169, and 281

Notes:

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	15	19
Units: AU/mL				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 1 (n=18,19,15,19,14,4)	7467.2 (5552.0 to 10043.2)	5812.9 (4162.1 to 8118.4)	6215.6 (4738.9 to 8152.4)	7722.4 (5034.0 to 11846.5)

PreF-bAb: Day 29 (n=18,19,15,18,14,4)	120491.6 (92412.4 to 157102.6)	125952.6 (103884.6 to 152708.3)	135260.0 (95356.2 to 191862.2)	116742.7 (89152.0 to 152872.1)
PreF-bAb: Day 57 (n=18,19,14,17,14,4)	98849.5 (75545.8 to 129341.8)	89896.9 (70717.8 to 114277.4)	98889.3 (65188.1 to 150013.4)	90612.8 (65451.1 to 125447.6)
PreF-bAb: Day 85 (n=18,19,12,17,13,3)	69574.6 (50071.5 to 96674.2)	67912.3 (51691.0 to 89224.0)	112481.0 (76987.5 to 164337.9)	70057.9 (49495.6 to 99162.5)
PreF-bAb: Day 113 (n=18,17,12,16,13,3)	61182.6 (43795.1 to 85473.2)	58058.4 (43549.8 to 77400.6)	103093.5 (66326.3 to 160241.9)	61171.5 (44176.0 to 84705.6)
PreF-bAb: Day 141 (n=18,19,13,16,14,3)	57291.0 (40876.2 to 80297.6)	48121.1 (37794.8 to 61268.8)	99738.7 (70499.4 to 141104.8)	59941.7 (46326.6 to 77558.0)
PreF-bAb: Day 169 (n=18,19,13,17,13,3)	48392.9 (34510.9 to 67858.8)	40948.1 (31357.1 to 53472.6)	83648.6 (56870.6 to 123035.3)	49499.8 (35508.9 to 69003.3)
PreF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	54418.7 (36137.6 to 81947.8)	9999 (9999 to 9999)
PostF-bAb: Day 1 (n=18,19,15,19,14,4)	7781.5 (5367.0 to 11282.3)	6372.2 (4670.2 to 8694.6)	8569.1 (5972.0 to 12295.8)	9605.3 (5951.6 to 15502.0)
PostF-bAb: Day 29 (n=18,19,15,18,14,4)	108811.5 (72461.7 to 163395.8)	112799.6 (82736.5 to 153786.4)	132127.9 (84337.9 to 206998.2)	130974.4 (97851.3 to 175309.8)
PostF-bAb: Day 57 (n=18,19,14,17,14,4)	85196.0 (58250.0 to 124606.9)	75628.1 (51928.5 to 110143.8)	94125.8 (56861.6 to 155811.0)	81923.9 (56585.6 to 118608.3)
PostF-bAb: Day 85 (n=18,19,12,17,13,3)	60967.0 (39795.8 to 93401.0)	59128.0 (40040.4 to 87314.9)	89605.4 (50873.4 to 157825.7)	61176.8 (42975.5 to 87086.9)
PostF-bAb: Day 113 (n=18,17,12,16,13,3)	53258.8 (35653.9 to 79556.5)	51435.0 (33669.1 to 78575.2)	85589.8 (48631.9 to 150634.0)	53606.8 (36326.1 to 79108.0)
PostF-bAb: Day 141 (n=18,19,13,16,14,3)	48311.1 (32332.8 to 72185.7)	41981.1 (27984.5 to 62977.9)	71562.6 (43250.9 to 118406.8)	52803.7 (35845.3 to 77785.3)
PostF-bAb: Day 169 (n=18,19,13,17,13,3)	41471.6 (27763.8 to 61947.1)	34074.2 (23529.9 to 49343.5)	63113.6 (37586.8 to 105976.6)	44688.8 (30203.3 to 66121.4)
PostF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	43784.2 (24668.6 to 77712.5)	9999 (9999 to 9999)

End point values	Single Injection Placebo in Younger Adults (18 to 49 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	4		
Units: AU/mL				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 1 (n=18,19,15,19,14,4)	7272.6 (5784.0 to 9144.5)	9290.5 (6403.5 to 13479.2)		

PreF-bAb: Day 29 (n=18,19,15,18,14,4)	7226.1 (5489.8 to 9511.7)	10307.3 (7281.3 to 14590.9)		
PreF-bAb: Day 57 (n=18,19,14,17,14,4)	7659.7 (5931.1 to 9892.2)	9097.5 (7091.1 to 11671.6)		
PreF-bAb: Day 85 (n=18,19,12,17,13,3)	7154.4 (5232.9 to 9781.4)	10664.3 (8260.2 to 13768.0)		
PreF-bAb: Day 113 (n=18,17,12,16,13,3)	6877.3 (5199.8 to 9096.0)	10317.7 (9299.1 to 11447.8)		
PreF-bAb: Day 141 (n=18,19,13,16,14,3)	7077.7 (5307.6 to 9438.1)	10026.5 (6884.4 to 14602.7)		
PreF-bAb: Day 169 (n=18,19,13,17,13,3)	6953.1 (5161.5 to 9366.6)	9958.8 (9347.1 to 10610.6)		
PreF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	8330.4 (3649.2 to 19016.7)		
PostF-bAb: Day 1 (n=18,19,15,19,14,4)	7788.2 (5463.6 to 11101.9)	7759.1 (996.6 to 60412.1)		
PostF-bAb: Day 29 (n=18,19,15,18,14,4)	8011.2 (5514.7 to 11637.9)	8495.6 (1077.7 to 66969.9)		
PostF-bAb: Day 57 (n=18,19,14,17,14,4)	7984.5 (5469.2 to 11656.5)	7997.4 (909.5 to 70318.9)		
PostF-bAb: Day 85 (n=18,19,12,17,13,3)	7318.3 (5049.8 to 10605.9)	7683.9 (166.3 to 354981.2)		
PostF-bAb: Day 113 (n=18,17,12,16,13,3)	8374.5 (5784.3 to 12124.5)	7441.6 (150.4 to 368224.0)		
PostF-bAb: Day 141 (n=18,19,13,16,14,3)	8019.4 (5567.2 to 11551.7)	7352.4 (177.1 to 305240.2)		
PostF-bAb: Day 169 (n=18,19,13,17,13,3)	8438.3 (5792.5 to 12292.6)	7024.3 (110.4 to 446737.5)		
PostF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	5859.6 (134.3 to 255601.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMC of Serum Binding Abs (PreF and PostF) for Older Adults Cohorts

End point title	GMC of Serum Binding Abs (PreF and PostF) for Older Adults Cohorts[28]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the

period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, 169, and 365

Notes:

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

End point values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	46	47	46
Units: AU/mL				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 1 (n=47,46,47,46,46,58)	7184.6 (5872.3 to 8790.1)	6960.5 (5456.3 to 8879.3)	9173.2 (7267.6 to 11578.5)	9134.1 (7414.4 to 11252.7)
PreF-bAb: Day 29 (n=44,43,47,45,44,56)	58206.6 (46911.4 to 72221.3)	80760.1 (67929.5 to 96014.0)	111145.6 (87974.7 to 140419.4)	77569.9 (62867.0 to 95711.4)
PreF-bAb: Day 57 (n=46,39,44,42,45,58)	50630.1 (41214.3 to 62197.1)	56860.8 (47987.0 to 67375.5)	85785.4 (70699.4 to 104090.5)	56901.4 (44316.0 to 73060.9)
PreF-bAb: Day 85 (n=44,42,46,45,43,55)	39390.5 (31889.7 to 48655.6)	47141.3 (40078.1 to 55449.3)	64628.3 (52007.5 to 80311.8)	48550.6 (38678.9 to 60941.8)
PreF-bAb: Day 169 (n=43,42,44,44,44,55)	27977.0 (22479.6 to 34818.8)	27948.6 (22579.4 to 34594.4)	41137.0 (33523.9 to 50479.0)	29704.2 (23626.6 to 37345.1)
PreF-bAb: Day 365 (n=38,33,36,41,40,49)	19409.7 (15017.6 to 25086.3)	19632.9 (15902.1 to 24238.9)	31346.1 (24301.8 to 40432.2)	21454.1 (17263.3 to 26662.3)
PostF-bAb: Day 1 (n=47,46,47,46,46,58)	12066.0 (9323.5 to 15615.2)	10638.2 (8135.1 to 13911.5)	10424.6 (8167.5 to 13305.5)	14206.6 (10853.0 to 18596.5)
PostF-bAb: Day 29 (n=44,43,47,45,44,56)	69105.0 (52552.2 to 90871.5)	85033.1 (66619.6 to 108535.9)	95879.2 (71829.4 to 127981.4)	84909.7 (64905.4 to 111079.5)
PostF-bAb: Day 57 (n=46,39,44,42,45,58)	57804.6 (45307.2 to 73749.2)	51619.0 (40747.4 to 65391.2)	78968.1 (61971.7 to 100626.0)	59943.4 (43861.2 to 81922.2)
PostF-bAb: Day 85 (n=44,42,46,45,43,55)	45084.0 (34300.5 to 59257.6)	48819.9 (39107.1 to 60945.1)	59983.2 (45895.2 to 78395.6)	54054.5 (40304.3 to 72495.8)
PostF-bAb: Day 169 (n=43,42,44,44,44,55)	35691.0 (27328.8 to 46611.8)	29608.9 (22904.2 to 38276.1)	39154.9 (30112.5 to 50912.6)	37080.4 (27865.2 to 49343.2)
PostF-bAb: Day 365 (n=38,33,36,41,40,49)	25144.5 (18758.7 to 33704.2)	21589.3 (16517.4 to 28218.6)	27730.5 (20151.4 to 38160.1)	26193.9 (19873.3 to 34524.7)

End point values	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	58		
Units: AU/mL				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 1 (n=47,46,47,46,46,58)	8077.0 (6430.5 to 10145.0)	7871.3 (6388.4 to 9698.5)		
PreF-bAb: Day 29 (n=44,43,47,45,44,56)	59833.7 (45903.3 to 77991.6)	8119.5 (6379.3 to 10334.4)		
PreF-bAb: Day 57 (n=46,39,44,42,45,58)	41427.1 (31766.9 to 54025.1)	8164.6 (6555.1 to 10169.3)		
PreF-bAb: Day 85 (n=44,42,46,45,43,55)	35150.3 (26811.4 to 46082.7)	8157.9 (6427.1 to 10354.9)		
PreF-bAb: Day 169 (n=43,42,44,44,44,55)	23376.4 (18019.0 to 30326.6)	8338.6 (6717.2 to 10351.4)		
PreF-bAb: Day 365 (n=38,33,36,41,40,49)	16715.1 (12878.1 to 21695.2)	9660.9 (7556.6 to 12351.2)		
PostF-bAb: Day 1 (n=47,46,47,46,46,58)	10454.3 (7820.9 to 13974.4)	11806.0 (9501.6 to 14669.2)		
PostF-bAb: Day 29 (n=44,43,47,45,44,56)	47736.3 (35493.9 to 64201.5)	12067.1 (9309.9 to 15640.8)		
PostF-bAb: Day 57 (n=46,39,44,42,45,58)	35785.6 (26916.4 to 47577.3)	12029.2 (9463.0 to 15291.4)		
PostF-bAb: Day 85 (n=44,42,46,45,43,55)	30765.7 (22703.4 to 41691.1)	12343.8 (9609.4 to 15856.1)		
PostF-bAb: Day 169 (n=43,42,44,44,44,55)	20712.5 (15371.7 to 27908.9)	12392.0 (9900.6 to 15510.5)		
PostF-bAb: Day 365 (n=38,33,36,41,40,49)	16381.1 (11727.9 to 22880.5)	13768.8 (10464.4 to 18116.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMC of Serum Binding Abs (PreF and PostF) for Japanese Adults Cohorts

End point title	GMC of Serum Binding Abs (PreF and PostF) for Japanese Adults Cohorts[29]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule,

b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, and 169

Notes:

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

End point values	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	4		
Units: AU/mL				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 1 (n=20,4)	7545.4 (5542.0 to 10273.0)	6680.8 (1973.6 to 22614.3)		
PreF-bAb: Day 29 (n=20,4)	68684.0 (53080.2 to 88874.6)	7135.5 (2085.4 to 24414.7)		
PreF-bAb: Day 57 (n=20,4)	54618.2 (41547.3 to 71801.3)	7424.1 (1926.2 to 28614.2)		
PreF-bAb: Day 85 (n=19,4)	44979.3 (33718.5 to 60000.7)	7024.4 (1766.1 to 27939.0)		
PreF-bAb: Day 169 (n=20,4)	29334.8 (22147.5 to 38854.6)	6674.7 (1804.1 to 24694.1)		
PostF-bAb: Day 1 (n=20,4)	9925.8 (6459.4 to 15252.6)	8374.0 (1665.8 to 42096.2)		
PostF-bAb: Day 29 (n=20,4)	75173.8 (55351.4 to 102095.1)	7936.5 (1775.1 to 35483.8)		
PostF-bAb: Day 57 (n=20,4)	57428.6 (42049.2 to 78433.0)	8492.2 (1601.8 to 45021.9)		
PostF-bAb: Day 85 (n=19,4)	47821.3 (33458.4 to 68349.9)	8387.1 (1575.0 to 44663.5)		
PostF-bAb: Day 169 (n=20,4)	32673.4 (23417.0 to 45588.9)	8090.6 (1394.2 to 46950.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMC of Serum Binding Abs (PreF and PostF) for WOCBP Cohorts

End point title	GMC of Serum Binding Abs (PreF and PostF) for WOCBP Cohorts[30]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 57, 85, 113, 141, and 169

Notes:

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

End point values	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	44	29
Units: AU/mL				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 1 (n=49,48,44,29)	5928.0 (4863.4 to 7225.7)	7202.1 (6057.1 to 8563.7)	7343.9 (5928.6 to 9097.1)	7304.7 (5506.0 to 9691.1)
PreF-bAb: Day 29 (n=49,46,41,28)	49988.1 (42696.9 to 58524.3)	67953.4 (57275.4 to 80622.1)	73032.9 (57716.9 to 92413.0)	7096.0 (5310.3 to 9482.3)
PreF-bAb: Day 57 (n=45,45,42,28)	38705.6 (31796.3 to 47116.3)	53448.8 (45016.1 to 63461.1)	60971.6 (49956.9 to 74414.9)	7249.7 (5279.3 to 9955.6)
PreF-bAb: Day 85 (n=43,41,37,24)	32336.5 (26872.1 to 38912.0)	44024.8 (36651.3 to 52881.8)	47681.9 (37818.8 to 60117.3)	7439.4 (5228.9 to 10584.4)
PreF-bAb: Day 113 (n=44,43,37,25)	27226.3 (22498.5 to 32947.5)	37691.8 (31871.8 to 44574.5)	39558.4 (30970.3 to 50528.0)	8630.9 (6060.7 to 12290.8)
PreF-bAb: Day 141 (n=40,42,36,24)	24463.1 (19820.3 to 30193.3)	33916.5 (28517.4 to 40337.9)	34388.8 (27339.6 to 43255.6)	8582.2 (6206.3 to 11867.8)
PreF-bAb: Day 169 (n=41,43,34,23)	22511.6 (18527.1 to 27353.0)	30274.0 (25749.3 to 35593.8)	33390.0 (26145.5 to 42641.8)	8374.0 (6075.5 to 11542.1)
PostF-bAb: Day 1 (n=49,48,44,29)	7337.1 (5793.8 to 9291.5)	8284.3 (6672.7 to 10285.2)	10108.1 (8068.3 to 12663.7)	9374.8 (6909.2 to 12720.3)
PostF-bAb: Day 29 (n=49,46,41,28)	56083.1 (44704.7 to 70357.5)	58023.9 (44840.2 to 75083.8)	79654.7 (60853.5 to 104264.7)	8807.1 (6531.0 to 11876.5)
PostF-bAb: Day 57 (n=45,45,42,28)	43453.5 (34303.0 to 55045.0)	43215.3 (33324.0 to 56042.6)	60988.0 (46949.1 to 79225.0)	9300.0 (6784.0 to 12749.0)

PostF-bAb: Day 85 (n=43,41,37,24)	34371.5 (26637.2 to 44351.6)	32642.4 (24808.7 to 42949.7)	49095.5 (36720.7 to 65640.7)	9031.4 (6213.4 to 13127.4)
PostF-bAb: Day 113 (n=44,43,37,25)	29414.6 (23233.3 to 37240.6)	31019.5 (23547.8 to 40862.1)	43359.9 (32563.0 to 57736.6)	10585.1 (7253.6 to 15446.6)
PostF-bAb: Day 141 (n=40,42,36,24)	26740.9 (20593.7 to 34722.9)	26633.4 (20241.6 to 35043.6)	37108.7 (27752.6 to 49618.8)	10775.7 (7529.3 to 15421.8)
PostF-bAb: Day 169 (n=41,43,34,23)	23089.1 (18052.3 to 29531.4)	24488.3 (18865.9 to 31786.3)	36499.6 (27296.8 to 48804.9)	9459.4 (6424.5 to 13927.9)

Statistical analyses

No statistical analyses for this end point

Secondary: GMC of Serum Binding Abs (PreF and PostF) for Children Cohorts

End point title	GMC of Serum Binding Abs (PreF and PostF) for Children Cohorts[31]

End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 1, 29, 85, and 141

Notes:

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	13	11	
Units: AU/mL				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 1 (n=14,13,11)	2917.4 (1032.3 to 8244.7)	8082.8 (3651.1 to 17893.8)	3049.5 (646.4 to 14387.0)	
PreF-bAb: Day 29 (n=14,11,11)	77346.4 (40482.2 to 147780.1)	85262.9 (58818.3 to 123596.7)	5607.0 (2180.6 to 14417.8)	
PreF-bAb: Day 85 (n=5,9,4)	52637.4 (24725.1 to 112059.9)	47425.7 (29293.9 to 76780.5)	1340.6 (188.5 to 9535.5)	

PreF-bAb: Day 141 (n=4,5,5)	56838.9 (27535.9 to 117325.1)	85960.5 (53327.1 to 138564.0)	9477.9 (2516.4 to 35699.0)	
PostF-bAb: Day 1 (n=14,13,11)	4452.1 (2103.2 to 9424.4)	14341.2 (7611.3 to 27021.9)	5101.7 (991.9 to 26240.5)	
PostF-bAb: Day 29 (n=14,11,11)	71426.3 (34951.2 to 145966.8)	121809.4 (69071.8 to 214813.1)	9566.1 (3803.8 to 24057.8)	
PostF-bAb: Day 85 (n=5,9,4)	36288.6 (12278.4 to 107250.9)	57293.0 (31394.4 to 104556.5)	1906.1 (647.6 to 5610.0)	
PostF-bAb: Day 141 (n=4,5,5)	42645.7 (8769.3 to 207389.1)	87523.8 (36792.6 to 208205.3)	7012.1 (1396.5 to 35207.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold-Rise (GMFR) of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Young Adults Cohorts

End point title	Geometric Mean Fold-Rise (GMFR) of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Young Adults Cohorts[32]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 11 AU/mL for RSV-A and 8 AU/mL for RSV-B. PP Set included FAS participants (all randomized participants who received any study injection, had baseline data for analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories. '9999' represents data not collected for specified cohorts.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, 169, and 281

Notes:

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	19	19
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=18,19,19,18,15,4)	20.52 (13.62 to 30.91)	22.25 (14.77 to 33.51)	23.54 (16.14 to 34.33)	19.96 (13.95 to 28.58)

RSV-A: Day 57 (n=18,19,15,17,14,4)	17.51 (10.98 to 27.91)	16.83 (10.09 to 28.08)	15.33 (9.24 to 25.44)	13.93 (9.80 to 19.81)
RSV-A: Day 85 (n=18,19,13,17,13,3)	15.77 (10.67 to 23.33)	11.78 (7.76 to 17.90)	21.19 (11.53 to 38.93)	9.34 (5.99 to 14.56)
RSV-A: Day 113 (n=18,17,12,16,13,3)	14.25 (9.09 to 22.34)	8.70 (5.30 to 14.27)	17.22 (10.58 to 28.02)	9.58 (6.65 to 13.82)
RSV-A: Day 141 (n=18,19,13,16,14,3)	9.74 (6.07 to 15.63)	7.44 (4.94 to 11.20)	15.56 (9.54 to 25.38)	9.22 (6.82 to 12.47)
RSV-A: Day 169 (n=18,19,13,17,13,3)	9.62 (6.27 to 14.77)	6.98 (4.64 to 10.49)	19.69 (12.79 to 30.30)	8.42 (5.91 to 12.01)
RSV-A: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	12.55 (7.96 to 19.78)	9999 (9999 to 9999)
RSV-B: Day 29 (n=18,19,19,18,15,4)	14.44 (9.57 to 21.80)	11.67 (6.72 to 20.28)	16.02 (9.92 to 25.87)	13.88 (8.06 to 23.92)
RSV-B: Day 57 (n=18,19,15,17,14,4)	15.28 (9.61 to 24.32)	13.03 (8.11 to 20.94)	19.28 (12.29 to 30.23)	8.68 (5.18 to 14.56)
RSV-B: Day 85 (n=18,19,13,17,13,3)	10.54 (6.78 to 16.36)	8.24 (5.23 to 12.97)	14.87 (8.66 to 25.54)	7.34 (4.36 to 12.36)
RSV-B: Day 113 (n=18,17,12,16,13,3)	10.38 (6.51 to 16.55)	8.52 (5.36 to 13.54)	16.54 (8.49 to 32.23)	6.38 (3.71 to 10.97)
RSV-B: Day 141 (n=18,19,13,16,14,3)	10.66 (6.45 to 17.62)	7.35 (4.52 to 11.95)	20.19 (12.20 to 33.40)	5.23 (3.34 to 8.18)
RSV-B: Day 169 (n=18,19,13,17,13,3)	8.90 (5.69 to 13.93)	5.28 (3.54 to 7.90)	16.54 (9.40 to 29.08)	5.01 (3.17 to 7.93)
RSV-B: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	10.66 (5.82 to 19.54)	9999 (9999 to 9999)

End point values	Single Injection Placebo in Younger Adults (18 to 49 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	4		
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=18,19,19,18,15,4)	0.92 (0.79 to 1.08)	0.97 (0.69 to 1.35)		
RSV-A: Day 57 (n=18,19,15,17,14,4)	0.91 (0.73 to 1.14)	0.76 (0.31 to 1.90)		
RSV-A: Day 85 (n=18,19,13,17,13,3)	0.95 (0.77 to 1.17)	0.73 (0.35 to 1.54)		
RSV-A: Day 113 (n=18,17,12,16,13,3)	0.87 (0.70 to 1.08)	1.02 (0.20 to 5.28)		
RSV-A: Day 141 (n=18,19,13,16,14,3)	0.95 (0.70 to 1.31)	1.00 (0.13 to 7.46)		
RSV-A: Day 169 (n=18,19,13,17,13,3)	0.95 (0.76 to 1.18)	0.71 (0.15 to 3.36)		
RSV-A: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.58 (0.35 to 0.95)		
RSV-B: Day 29 (n=18,19,19,18,15,4)	0.88 (0.69 to 1.13)	1.19 (0.60 to 2.38)		
RSV-B: Day 57 (n=18,19,15,17,14,4)	0.94 (0.67 to 1.33)	1.58 (0.54 to 4.61)		
RSV-B: Day 85 (n=18,19,13,17,13,3)	0.92 (0.63 to 1.35)	1.21 (0.37 to 3.90)		

RSV-B: Day 113 (n=18,17,12,16,13,3)	0.80 (0.59 to 1.08)	1.33 (0.71 to 2.48)		
RSV-B: Day 141 (n=18,19,13,16,14,3)	0.86 (0.65 to 1.13)	1.35 (0.35 to 5.23)		
RSV-B: Day 169 (n=18,19,13,17,13,3)	0.67 (0.49 to 0.92)	1.02 (0.26 to 3.97)		
RSV-B: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.75 (0.09 to 5.90)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Older Adults Cohorts

End point title	GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Older Adults Cohorts[33]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 11 AU/mL for RSV-A and 8 AU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 169, and 365

Notes:

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

End point values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	43	47	45
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=44,43,47,45,44,56)	12.03 (8.78 to 16.47)	14.14 (10.23 to 19.54)	16.67 (12.34 to 22.53)	12.17 (8.90 to 16.64)
RSV-A: Day 57 (n=46,39,44,42,45,58)	9.16 (6.73 to 12.47)	9.31 (6.65 to 13.04)	12.86 (9.62 to 17.19)	10.03 (7.18 to 14.03)
RSV-A: Day 85 (n=44,42,46,45,43,55)	7.53 (5.54 to 10.24)	7.73 (5.95 to 10.05)	9.43 (6.80 to 13.06)	7.54 (5.57 to 10.22)
RSV-A: Day 169 (n=43,42,44,44,44,55)	5.05 (3.77 to 6.67)	4.05 (2.96 to 5.54)	5.79 (4.56 to 7.35)	4.10 (3.04 to 5.54)
RSV-A: Day 365 (n=38,33,36,41,40,49)	3.06 (2.20 to 4.24)	2.66 (1.94 to 3.66)	3.19 (2.37 to 4.30)	2.96 (2.22 to 3.94)

RSV-B: Day 29 (n=44,43,47,45,44,56)	8.96 (6.79 to 11.84)	9.60 (7.31 to 12.61)	12.50 (9.10 to 17.16)	6.65 (4.86 to 8.87)
RSV-B: Day 57 (n=46,39,44,42,45,58)	7.08 (5.40 to 9.28)	8.87 (6.71 to 11.73)	9.77 (7.34 to 13.00)	5.66 (4.35 to 7.36)
RSV-B: Day 85 (n=44,42,46,45,43,55)	5.62 (4.24 to 7.45)	7.02 (5.35 to 9.20)	7.99 (6.00 to 10.64)	4.57 (3.54 to 5.90)
RSV-B: Day 169 (n=43,42,44,44,44,55)	4.38 (3.37 to 5.70)	4.60 (3.69 to 5.73)	5.50 (4.39 to 6.89)	3.20 (2.36 to 4.34)
RSV-B: Day 365 (n=38,33,36,41,40,49)	2.37 (1.87 to 3.01)	2.78 (2.10 to 3.69)	2.89 (2.28 to 3.66)	1.61 (1.25 to 2.06)

End point values	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	58		
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=44,43,47,45,44,56)	10.19 (7.17 to 14.48)	1.15 (0.99 to 1.34)		
RSV-A: Day 57 (n=46,39,44,42,45,58)	7.05 (5.14 to 9.69)	1.12 (0.95 to 1.33)		
RSV-A: Day 85 (n=44,42,46,45,43,55)	5.27 (3.82 to 7.29)	1.11 (0.98 to 1.26)		
RSV-A: Day 169 (n=43,42,44,44,44,55)	3.08 (2.33 to 4.08)	0.99 (0.86 to 1.15)		
RSV-A: Day 365 (n=38,33,36,41,40,49)	2.39 (1.84 to 3.10)	1.15 (0.96 to 3.38)		
RSV-B: Day 29 (n=44,43,47,45,44,56)	5.30 (3.74 to 7.49)	1.12 (0.98 to 1.29)		
RSV-B: Day 57 (n=46,39,44,42,45,58)	4.28 (3.21 to 5.72)	1.27 (1.12 to 1.44)		
RSV-B: Day 85 (n=44,42,46,45,43,55)	3.51 (2.58 to 4.78)	1.27 (1.12 to 1.44)		
RSV-B: Day 169 (n=43,42,44,44,44,55)	2.87 (2.24 to 3.70)	1.33 (1.14 to 1.55)		
RSV-B: Day 365 (n=38,33,36,41,40,49)	1.52 (1.23 to 1.88)	1.07 (0.89 to 1.29)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Japanese Adults Cohorts

End point title	GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Japanese Adults Cohorts [34]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-

baseline to baseline titer values. LLOQ was 11 AU/mL for RSV-A and 8 AU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, and 169

Notes:

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

End point values	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	4		
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=20,4)	11.15 (7.76 to 16.01)	0.82 (0.42 to 1.60)		
RSV-A: Day 57 (n=20,4)	9.75 (7.17 to 13.27)	0.84 (0.32 to 2.19)		
RSV-A: Day 85 (n=19,4)	7.77 (5.61 to 10.76)	0.81 (0.28 to 2.29)		
RSV-A: Day 169 (n=20,4)	4.16 (2.96 to 5.43)	0.72 (0.33 to 1.55)		
RSV-B: Day 29 (n=20,4)	6.60 (4.90 to 8.88)	0.81 (0.47 to 1.41)		
RSV-B: Day 57 (n=20,4)	4.72 (3.60 to 6.19)	0.85 (0.60 to 1.20)		
RSV-B: Day 85 (n=19,4)	3.82 (2.97 to 4.91)	0.81 (0.49 to 1.36)		
RSV-B: Day 169 (n=20,4)	2.67 (2.04 to 3.50)	0.69 (0.47 to 1.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for WOCBP Cohorts

End point title	GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for WOCBP Cohorts [35]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-

baseline to baseline titer values. LLOQ was 11 AU/mL for RSV-A and 8 AU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, and 169

Notes:

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

End point values	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	46	41	28
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=49,46,41,28)	9.41 (7.29 to 12.15)	11.22 (8.43 to 14.94)	11.60 (8.71 to 15.46)	1.05 (0.88 to 1.26)
RSV-A: Day 57 (n=45,45,42,28)	9.30 (6.99 to 12.36)	10.19 (7.80 to 13.31)	10.79 (8.53 to 13.64)	1.41 (1.11 to 1.78)
RSV-A: Day 85 (n=43,41,37,24)	7.50 (5.60 to 10.05)	10.15 (7.60 to 13.57)	8.75 (6.59 to 11.61)	1.21 (0.94 to 1.56)
RSV-A: Day 113 (n=44,43,37,25)	6.07 (4.48 to 8.22)	7.07 (5.39 to 9.27)	6.88 (5.30 to 8.94)	1.32 (0.99 to 1.75)
RSV-A: Day 141 (n=40,42,36,25)	4.75 (3.49 to 6.46)	5.84 (4.58 to 7.43)	5.70 (4.30 to 7.56)	1.02 (0.79 to 1.33)
RSV-A: Day 169 (n=41,43,34,23)	3.94 (2.94 to 5.29)	5.11 (3.86 to 6.77)	4.42 (3.60 to 5.43)	0.99 (0.81 to 1.21)
RSV-B: Day 29 (n=49,46,41,28)	7.55 (5.36 to 10.64)	6.45 (4.68 to 8.89)	9.09 (6.04 to 13.68)	0.95 (0.75 to 1.21)
RSV-B: Day 57 (n=45,45,42,28)	5.45 (3.90 to 7.62)	4.76 (3.49 to 6.49)	6.63 (4.71 to 9.34)	1.46 (1.19 to 1.80)
RSV-B: Day 85 (n=43,41,37,24)	5.65 (4.14 to 7.72)	4.56 (3.29 to 6.31)	5.88 (4.27 to 8.10)	1.47 (1.11 to 1.97)
RSV-B: Day 113 (n=44,43,37,25)	3.91 (2.83 to 5.41)	3.79 (2.78 to 5.16)	5.02 (3.80 to 6.64)	1.73 (1.20 to 2.49)
RSV-B: Day 141 (n=40,42,36,25)	3.52 (2.55 to 4.87)	3.15 (2.39 to 4.16)	3.79 (2.69 to 5.33)	1.44 (1.09 to 1.92)
RSV-B: Day 169 (n=41,43,34,23)	3.15 (2.27 to 4.36)	2.98 (2.21 to 4.02)	3.06 (2.24 to 4.17)	1.21 (0.96 to 1.52)

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Children Cohorts

End point title	GMFR of Postbaseline/Baseline RSV Neutralizing Abs (RSV-A and RSV-B) Titers for Children Cohorts[36]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 11 AU/mL for RSV-A and 8 AU/mL for RSV-B. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 85, and 141

Notes:

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	12	11	
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=14,12,11)	34.88 (13.79 to 88.22)	18.94 (5.54 to 64.71)	1.44 (0.66 to 3.15)	
RSV-A: Day 85 (n=5,9,4)	40.25 (15.23 to 106.35)	7.26 (1.75 to 30.14)	0.65 (0.21 to 2.02)	
RSV-A: Day 141 (n=4,5,5)	49.96 (9.01 to 276.88)	17.71 (1.69 to 185.65)	1.41 (0.32 to 6.12)	
RSV-B: Day 29 (n=14,12,11)	14.26 (7.05 to 28.87)	7.21 (2.36 to 22.02)	1.24 (0.55 to 2.82)	
RSV-B: Day 85 (n=5,9,4)	17.56 (5.59 to 55.13)	3.20 (0.94 to 10.89)	0.64 (0.27 to 1.52)	
RSV-B: Day 141 (n=4,5,5)	13.28 (3.35 to 52.64)	6.32 (3.30 to 12.08)	1.93 (0.35 to 52.64)	

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Young Adults Cohorts

End point title	GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Young Adults Cohorts[37]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included FAS participants (all randomized participants who received any study injection, had baseline data for analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with injection schedule, b) complied with timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories. '9999' represents data not collected for specified cohorts.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, 169, and 281

Notes:

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	15	18
Units: ratio				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 29 (n=18,19,15,18,14,4)	16.14 (11.44 to 22.76)	21.67 (15.42 to 30.45)	21.76 (16.73 to 28.30)	16.87 (12.41 to 22.94)
PreF-bAb: Day 57 (n=18,19,14,17,14,4)	13.24 (9.71 to 18.05)	15.47 (10.80 to 22.15)	16.02 (11.60 to 22.12)	11.89 (8.46 to 16.72)
PreF-bAb: Day 85 (n=18,19,12,17,13,3)	9.32 (6.40 to 13.57)	11.68 (7.93 to 17.22)	17.08 (13.05 to 22.37)	9.27 (6.85 to 12.54)
PreF-bAb: Day 113 (n=18,17,12,16,13,3)	8.19 (5.94 to 11.30)	9.67 (6.52 to 14.35)	15.27 (10.79 to 21.61)	7.46 (5.27 to 10.57)
PreF-bAb: Day 141 (n=18,19,13,16,14,3)	7.67 (5.47 to 10.75)	8.28 (6.02 to 11.38)	16.07 (12.12 to 21.30)	6.50 (4.73 to 8.95)
PreF-bAb: Day 169 (n=18,19,13,17,13,3)	6.48 (4.72 to 8.89)	7.04 (5.14 to 9.65)	13.48 (10.07 to 18.04)	5.87 (4.44 to 7.75)
PreF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	8.42 (5.87 to 12.08)	9999 (9999 to 9999)
PostF-bAb: Day 29 (n=18,19,15,18,14,4)	13.98 (8.69 to 22.49)	17.70 (11.75 to 26.66)	15.42 (10.99 to 21.64)	14.64 (10.81 to 19.83)
PostF-bAb: Day 57 (n=18,19,14,17,14,4)	10.95 (7.07 to 16.95)	11.87 (7.70 to 18.30)	10.85 (7.39 to 15.94)	9.08 (6.65 to 12.41)
PostF-bAb: Day 85 (n=18,19,12,17,13,3)	7.83 (4.79 to 12.81)	9.28 (5.93 to 14.52)	9.87 (6.48 to 15.02)	6.90 (5.08 to 9.38)
PostF-bAb: Day 113 (n=18,17,12,16,13,3)	6.84 (4.46 to 10.49)	7.56 (4.72 to 12.10)	8.96 (5.79 to 13.88)	5.60 (4.01 to 7.82)
PostF-bAb: Day 141 (n=18,19,13,16,14,3)	6.21 (4.06 to 9.49)	6.59 (4.23 to 10.26)	7.98 (5.47 to 11.63)	4.54 (3.38 to 6.11)
PostF-bAb: Day 169 (n=18,19,13,17,13,3)	5.33 (3.53 to 8.04)	5.35 (3.58 to 7.98)	7.04 (4.87 to 10.17)	4.20 (3.14 to 5.62)
PostF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	4.78 (3.25 to 7.04)	9999 (9999 to 9999)

End point values	Single Injection Placebo in Younger Adults (18 to 49 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	4		
Units: ratio				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 29 (n=18,19,15,18,14,4)	0.99 (0.88 to 1.12)	1.11 (0.86 to 1.43)		
PreF-bAb: Day 57 (n=18,19,14,17,14,4)	1.05 (0.97 to 1.14)	0.98 (0.83 to 1.16)		
PreF-bAb: Day 85 (n=18,19,12,17,13,3)	0.99 (0.89 to 1.11)	1.02 (0.80 to 1.31)		
PreF-bAb: Day 113 (n=18,17,12,16,13,3)	0.96 (0.85 to 1.08)	0.99 (0.85 to 1.15)		
PreF-bAb: Day 141 (n=18,19,13,16,14,3)	0.97 (0.86 to 1.10)	0.96 (0.63 to 1.47)		
PreF-bAb: Day 169 (n=18,19,13,17,13,3)	0.97 (0.85 to 1.11)	0.96 (0.89 to 1.03)		
PreF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.80 (0.34 to 1.90)		
PostF-bAb: Day 29 (n=18,19,15,18,14,4)	1.03 (0.94 to 1.12)	1.09 (0.96 to 1.25)		
PostF-bAb: Day 57 (n=18,19,14,17,14,4)	1.03 (0.97 to 1.09)	1.03 (0.86 to 1.24)		
PostF-bAb: Day 85 (n=18,19,12,17,13,3)	1.02 (0.95 to 1.10)	1.12 (0.94 to 1.33)		
PostF-bAb: Day 113 (n=18,17,12,16,13,3)	1.05 (0.98 to 1.13)	1.09 (0.98 to 1.20)		
PostF-bAb: Day 141 (n=18,19,13,16,14,3)	1.03 (0.95 to 1.12)	1.07 (0.90 to 1.27)		
PostF-bAb: Day 169 (n=18,19,13,17,13,3)	1.06 (0.97 to 1.16)	1.02 (0.72 to 1.46)		
PostF-bAb: Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.85 (0.40 to 1.84)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Older Adults Cohorts

End point title	GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Older Adults Cohorts[38]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least

1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 169, and 365

Notes:

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

End point values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	43	47	45
Units: ratio				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 29 (n=44,43,47,45,44,56)	8.46 (6.79 to 10.55)	11.61 (9.24 to 14.58)	12.12 (9.17 to 16.01)	8.40 (6.77 to 10.41)
PreF-bAb: Day 57 (n=46,39,44,42,45,58)	7.03 (5.75 to 8.59)	7.83 (6.32 to 9.69)	9.25 (7.20 to 11.87)	6.57 (5.26 to 8.22)
PreF-bAb: Day 85 (n=44,42,46,45,43,55)	5.44 (4.27 to 6.92)	6.54 (5.26 to 8.11)	6.96 (5.43 to 8.93)	5.40 (4.40 to 6.63)
PreF-bAb: Day 169 (n=43,42,44,44,44,55)	4.05 (3.34 to 4.90)	4.08 (3.25 to 5.14)	4.72 (3.83 to 5.81)	3.31 (2.71 to 4.06)
PreF-bAb: Day 365 (n=38,33,36,41,40,49)	2.90 (2.38 to 3.53)	3.37 (2.62 to 4.33)	3.22 (2.55 to 4.07)	2.42 (1.98 to 2.95)
PostF-bAb: Day 29 (n=44,43,47,45,44,56)	5.91 (4.63 to 7.54)	7.89 (6.20 to 10.04)	9.20 (7.08 to 11.94)	5.86 (4.54 to 7.56)
PostF-bAb: Day 57 (n=46,39,44,42,45,58)	4.85 (3.92 to 6.01)	4.99 (4.00 to 6.22)	7.40 (5.89 to 9.30)	4.12 (3.08 to 5.51)
PostF-bAb: Day 85 (n=44,42,46,45,43,55)	3.75 (2.83 to 4.97)	4.30 (3.41 to 5.41)	5.66 (4.51 to 7.12)	3.82 (3.00 to 4.87)
PostF-bAb: Day 169 (n=43,42,44,44,44,55)	3.00 (2.47 to 3.64)	2.69 (2.15 to 3.37)	3.75 (3.05 to 4.62)	2.58 (2.03 to 3.27)
PostF-bAb: Day 365 (n=38,33,36,41,40,49)	2.27 (1.86 to 2.77)	2.34 (1.87 to 2.93)	2.62 (2.17 to 3.15)	1.87 (1.47 to 2.37)

End point values	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	56		
Units: ratio				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 29 (n=44,43,47,45,44,56)	7.21 (5.61 to 9.26)	1.04 (0.92 to 1.17)		

PreF-bAb: Day 57 (n=46,39,44,42,45,58)	5.11 (4.03 to 6.48)	1.04 (0.92 to 1.16)		
PreF-bAb: Day 85 (n=44,42,46,45,43,55)	4.32 (3.42 to 5.46)	1.02 (0.91 to 1.14)		
PreF-bAb: Day 169 (n=43,42,44,44,44,55)	2.82 (2.28 to 3.48)	1.02 (0.89 to 1.16)		
PreF-bAb: Day 365 (n=38,33,36,41,40,49)	2.10 (1.73 to 2.55)	1.16 (0.96 to 1.39)		
PostF-bAb: Day 29 (n=44,43,47,45,44,56)	4.35 (3.60 to 5.25)	1.03 (0.92 to 1.17)		
PostF-bAb: Day 57 (n=46,39,44,42,45,58)	3.42 (2.85 to 4.09)	1.02 (0.92 to 1.13)		
PostF-bAb: Day 85 (n=44,42,46,45,43,55)	2.86 (2.41 to 3.40)	1.02 (0.91 to 1.14)		
PostF-bAb: Day 169 (n=43,42,44,44,44,55)	1.93 (1.66 to 2.25)	1.00 (0.89 to 1.13)		
PostF-bAb: Day 365 (n=38,33,36,41,40,49)	1.56 (1.35 to 1.81)	1.16 (0.97 to 1.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Japanese Adults Cohorts

End point title	GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Japanese Adults Cohorts[39]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, and 169

Notes:

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

End point values	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	4		
Units: ratio				
geometric mean (confidence interval 95%)				

PreF-bAb: Day 29 (n=20,4)	9.10 (6.46 to 12.83)	1.07 (0.94 to 1.21)		
PreF-bAb: Day 57 (n=20,4)	7.24 (5.26 to 9.97)	1.11 (0.96 to 1.29)		
PreF-bAb: Day 85 (n=19,4)	6.04 (4.34 to 8.41)	1.05 (0.85 to 1.30)		
PreF-bAb: Day 169 (n=20,4)	3.89 (2.87 to 5.26)	1.00 (0.85 to 1.17)		
PostF-bAb: Day 29 (n=20,4)	7.57 (4.70 to 12.21)	0.95 (0.79 to 1.14)		
PostF-bAb: Day 57 (n=20,4)	5.79 (3.80 to 8.82)	1.01 (0.88 to 1.17)		
PostF-bAb: Day 85 (n=19,4)	4.60 (3.11 to 6.80)	1.00 (0.90 to 1.11)		
PostF-bAb: Day 169 (n=20,4)	3.29 (2.36 to 4.60)	0.97 (0.78 to 1.20)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for WOCBP Cohorts

End point title	GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for WOCBP Cohorts[40]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, and 169

Notes:

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

End point values	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	46	42	28
Units: ratio				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 29 (n=49,46,41,28)	8.43 (6.86 to 10.37)	9.58 (7.74 to 11.86)	10.22 (7.80 to 13.39)	1.00 (0.88 to 1.13)

PreF-bAb: Day 57 (n=45,45,42,28)	6.65 (5.26 to 8.39)	7.45 (6.10 to 9.10)	8.09 (6.54 to 10.01)	0.99 (0.87 to 1.14)
PreF-bAb: Day 85 (n=43,41,37,24)	5.65 (4.44 to 7.18)	6.54 (5.30 to 8.08)	6.17 (4.84 to 7.87)	0.99 (0.85 to 1.16)
PreF-bAb: Day 113 (n=44,43,37,25)	4.81 (3.82 to 6.06)	5.43 (4.41 to 6.69)	5.10 (3.96 to 6.56)	1.17 (0.94 to 1.47)
PreF-bAb: Day 141 (n=40,42,36,24)	4.08 (3.23 to 5.14)	4.95 (4.17 to 5.88)	4.32 (3.53 to 5.29)	1.14 (0.92 to 1.41)
PreF-bAb: Day 169 (n=41,43,34,23)	3.83 (3.04 to 4.82)	4.43 (3.64 to 5.40)	4.05 (3.30 to 4.98)	1.02 (0.91 to 1.16)
PostF-bAb: Day 29 (n=49,46,41,28)	7.64 (6.00 to 9.74)	7.22 (5.74 to 9.09)	8.11 (6.39 to 10.29)	0.97 (0.89 to 1.07)
PostF-bAb: Day 57 (n=45,45,42,28)	5.90 (4.66 to 7.48)	5.16 (4.13 to 6.43)	5.86 (4.85 to 7.08)	0.99 (0.89 to 1.10)
PostF-bAb: Day 85 (n=43,41,37,24)	4.76 (3.74 to 6.05)	4.39 (3.46 to 5.58)	4.40 (3.52 to 5.50)	0.96 (0.85 to 1.10)
PostF-bAb: Day 113 (n=44,43,37,25)	4.19 (3.37 to 5.21)	3.94 (3.15 to 4.93)	3.93 (3.18 to 4.86)	1.13 (0.95 to 1.35)
PostF-bAb: Day 141 (n=40,42,36,24)	3.58 (2.83 to 4.53)	3.41 (2.80 to 4.15)	3.35 (2.76 to 4.08)	1.10 (0.92 to 1.32)
PostF-bAb: Day 169 (n=41,43,34,23)	3.27 (2.62 to 4.08)	3.19 (2.60 to 3.92)	3.12 (2.54 to 3.83)	1.00 (0.87 to 1.15)

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Children Cohorts

End point title	GMFR of Postbaseline/Baseline Serum Binding Abs (PreF and PostF) Titers for Children Cohorts[41]

End point description:

Antibody values reported as below LLOQ at baseline were replaced by LLOQ for GMFR comparing post-baseline to baseline titer values. LLOQ was 19 AU/mL for PreF-bAb and 16 AU/mL for PostF-bAb. PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 85, and 141

Notes:

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	11	11	
Units: ratio				
geometric mean (confidence interval 95%)				
PreF-bAb: Day 29 (n=14,11,11)	26.51 (13.37 to 52.59)	13.92 (6.90 to 28.10)	1.73 (0.56 to 5.31)	
PreF-bAb: Day 85 (n=5,9,4)	51.02 (5.41 to 481.44)	6.48 (3.02 to 13.87)	0.67 (0.48 to 0.93)	
PreF-bAb: Day 141 (n=4,5,5)	62.82 (1.54 to 2556.22)	8.32 (5.75 to 12.03)	1.74 (0.35 to 8.61)	
PostF-bAb: Day 29 (n=14,11,11)	16.04 (9.19 to 28.00)	9.28 (4.42 to 19.48)	1.76 (0.47 to 6.61)	
PostF-bAb: Day 85 (n=5,9,4)	12.13 (2.21 to 66.49)	4.68 (2.01 to 10.92)	0.68 (0.39 to 1.18)	
PostF-bAb: Day 141 (n=4,5,5)	10.62 (0.95 to 118.19)	4.47 (1.37 to 14.62)	1.01 (0.57 to 1.81)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Young Adult Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Young Adult Cohorts[42]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories. '9999' represents data not collected for specified cohorts.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, 169, and 281

Notes:

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	19	18
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: ≥2-fold Rise- Day 29 (n=18,19,19,18,15,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (82.4 to 100.0)	100.0 (81.5 to 100.0)
RSV-A: ≥4-fold Rise- Day 29 (n=18,19,19,18,15,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (82.4 to 100.0)	100.0 (81.5 to 100.0)
RSV-A: ≥2-fold Rise- Day 57 (n=18,19,15,17,14,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (78.2 to 100.0)	100.0 (80.5 to 100.0)
RSV-A: ≥4-fold Rise- Day 57 (n=18,19,15,17,14,4)	94.4 (72.7 to 99.9)	94.7 (74.0 to 99.9)	86.7 (59.5 to 98.3)	100.0 (80.5 to 100.0)
RSV-A: ≥2-fold Rise- Day 85 (n=18,19,13,17,13,3)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (75.3 to 100.0)	94.1 (71.3 to 99.9)
RSV-A: ≥4-fold Rise- Day 85 (n=18,19,13,17,13,3)	94.4 (72.7 to 99.9)	94.7 (74.0 to 99.9)	84.6 (54.6 to 98.1)	94.1 (71.3 to 99.9)
RSV-A: ≥2-fold Rise- Day 113 (n=18,17,12,16,13,3)	100.0 (81.5 to 100.0)	100.0 (80.5 to 100.0)	100.0 (73.5 to 100.0)	100.0 (79.4 to 100.0)
RSV-A: ≥4-fold Rise- Day 113 (n=18,17,12,16,13,3)	94.4 (72.7 to 99.9)	70.6 (44.0 to 89.7)	91.7 (61.5 to 99.8)	93.8 (69.8 to 99.8)
RSV-A: ≥2-fold Rise- Day 141 (n=18,19,13,16,14,3)	94.4 (72.7 to 99.9)	94.7 (74.0 to 99.9)	100.0 (75.3 to 100.0)	100.0 (79.4 to 100.0)
RSV-A: ≥4-fold Rise- Day 141 (n=18,19,13,16,14,3)	77.8 (52.4 to 93.6)	73.7 (48.8 to 90.9)	92.3 (64.0 to 99.8)	93.8 (69.8 to 99.8)
RSV-A: ≥2-fold Rise- Day 169 (n=18,19,13,17,13,3)	100.0 (81.5 to 100.0)	94.7 (74.0 to 99.9)	100.0 (75.3 to 100.0)	100.0 (80.5 to 100.0)
RSV-A: ≥4-fold Rise- Day 169 (n=18,19,13,17,13,3)	83.3 (58.6 to 96.4)	73.7 (48.8 to 90.9)	100.0 (75.3 to 100.0)	82.4 (56.6 to 96.2)
RSV-A: ≥2-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	100.0 (73.5 to 100.0)	9999 (9999 to 9999)
RSV-A: ≥4-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	91.7 (61.5 to 99.8)	9999 (9999 to 9999)
RSV-B: ≥2-fold Rise- Day 29 (n=18,19,19,18,15,4)	100.0 (81.5 to 100.0)	94.7 (74.0 to 99.9)	100.0 (82.4 to 100.0)	100.0 (81.5 to 100.0)
RSV-B: ≥4-fold Rise- Day 29 (n=18,19,19,18,15,4)	94.4 (72.7 to 99.9)	89.5 (66.9 to 98.7)	89.5 (66.9 to 98.7)	94.4 (72.7 to 99.9)
RSV-B: ≥2-fold Rise- Day 57 (n=18,19,15,17,14,4)	100.0 (81.5 to 100.0)	94.7 (74.0 to 99.9)	100.0 (78.2 to 100.0)	94.1 (71.3 to 99.9)
RSV-B: ≥4-fold Rise- Day 57 (n=18,19,15,17,14,4)	94.4 (72.7 to 99.9)	89.5 (72.7 to 99.9)	100.0 (78.2 to 100.0)	76.5 (50.1 to 93.2)
RSV-B: ≥2-fold Rise- Day 85 (n=18,19,13,17,13,3)	100.0 (81.5 to 100.0)	94.7 (74.0 to 99.9)	100.0 (75.3 to 100.0)	94.1 (71.3 to 99.9)
RSV-B: ≥4-fold Rise- Day 85 (n=18,19,13,17,13,3)	88.9 (65.3 to 98.6)	78.9 (54.4 to 93.9)	92.3 (64.0 to 99.8)	76.5 (50.1 to 93.2)
RSV-B: ≥2-fold Rise- Day 113 (n=18,17,12,16,13,3)	94.4 (72.7 to 99.9)	94.1 (71.3 to 99.9)	100.0 (73.5 to 100.0)	93.8 (69.8 to 99.8)
RSV-B: ≥4-fold Rise- Day 113 (n=18,17,12,16,13,3)	88.9 (65.3 to 98.6)	76.5 (50.1 to 93.2)	83.3 (51.6 to 97.9)	62.5 (35.4 to 84.8)
RSV-B: ≥2-fold Rise- Day 141 (n=18,19,13,16,14,3)	94.4 (72.7 to 99.9)	89.5 (66.9 to 98.7)	100.0 (75.3 to 100.0)	81.3 (54.4 to 96.0)
RSV-B: ≥4-fold Rise- Day 141 (n=18,19,13,16,14,3)	83.3 (58.6 to 96.4)	68.4 (43.4 to 87.4)	100.0 (75.3 to 100.0)	62.5 (35.4 to 84.8)
RSV-B: ≥2-fold Rise- Day 169 (n=18,19,13,17,13,3)	94.4 (72.7 to 99.9)	84.2 (60.4 to 96.6)	100.0 (75.3 to 100.0)	88.2 (63.6 to 98.5)
RSV-B: ≥4-fold Rise- Day 169 (n=18,19,13,17,13,3)	88.9 (65.3 to 98.6)	73.7 (48.8 to 90.9)	92.3 (64.0 to 99.8)	52.9 (27.8 to 77.0)

RSV-B: ≥2-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	91.7 (61.5 to 99.8)	9999 (9999 to 9999)
RSV-B: ≥4-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	91.7 (61.5 to 99.8)	9999 (9999 to 9999)

End point values	Single Injection Placebo in Younger Adults (18 to 49 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	4		
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: ≥2-fold Rise- Day 29 (n=18,19,19,18,15,4)	0.0 (0.0 to 21.8)	0.0 (0.0 to 60.2)		
RSV-A: ≥4-fold Rise- Day 29 (n=18,19,19,18,15,4)	0.0 (0.0 to 21.8)	0.0 (0.0 to 60.2)		
RSV-A: ≥2-fold Rise- Day 57 (n=18,19,15,17,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
RSV-A: ≥4-fold Rise- Day 57 (n=18,19,15,17,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
RSV-A: ≥2-fold Rise- Day 85 (n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-A: ≥4-fold Rise- Day 85 (n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-A: ≥2-fold Rise- Day 113 (n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	33.3 (0.8 to 90.6)		
RSV-A: ≥4-fold Rise- Day 113 (n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-A: ≥2-fold Rise- Day 141 (n=18,19,13,16,14,3)	7.1 (0.2 to 33.9)	0.0 (0.0 to 70.8)		
RSV-A: ≥4-fold Rise- Day 141 (n=18,19,13,16,14,3)	7.1 (0.2 to 33.9)	0.0 (0.0 to 70.8)		
RSV-A: ≥2-fold Rise- Day 169 (n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-A: ≥4-fold Rise- Day 169 (n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-A: ≥2-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		
RSV-A: ≥4-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		
RSV-B: ≥2-fold Rise- Day 29 (n=18,19,19,18,15,4)	0.0 (0.0 to 21.8)	25.0 (0.6 to 80.6)		
RSV-B: ≥4-fold Rise- Day 29 (n=18,19,19,18,15,4)	0.0 (0.0 to 21.8)	0.0 (0.0 to 60.2)		
RSV-B: ≥2-fold Rise- Day 57 (n=18,19,15,17,14,4)	7.1 (0.2 to 33.9)	50.0 (6.8 to 93.2)		
RSV-B: ≥4-fold Rise- Day 57 (n=18,19,15,17,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
RSV-B: ≥2-fold Rise- Day 85 (n=18,19,13,17,13,3)	15.4 (1.9 to 45.4)	0.0 (0.0 to 70.8)		
RSV-B: ≥4-fold Rise- Day 85 (n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-B: ≥2-fold Rise- Day 113 (n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-B: ≥4-fold Rise- Day 113 (n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		

RSV-B: ≥2-fold Rise- Day 141 (n=18,19,13,16,14,3)	0.0 (0.0 to 23.2)	33.3 (0.8 to 90.6)		
RSV-B: ≥4-fold Rise- Day 141 (n=18,19,13,16,14,3)	0.0 (0.0 to 23.2)	0.0 (0.0 to 70.8)		
RSV-B: ≥2-fold Rise- Day 169 (n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-B: ≥4-fold Rise- Day 169 (n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
RSV-B: ≥2-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		
RSV-B: ≥4-fold Rise- Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Older Adults Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Older Adults Cohorts[43]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 169, and 365

Notes:

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

End point values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	46	47	46
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: ≥2-fold Rise- Day 29 (n=44,43,47,45,44,56)	100.0 (92.0 to 100.0)	97.7 (87.7 to 99.9)	97.9 (87.7 to 99.9)	97.8 (88.2 to 99.9)
RSV-A: ≥4-fold Rise- Day 29 (n=44,43,47,45,44,56)	84.1 (69.9 to 93.4)	93.0 (80.9 to 98.5)	93.6 (82.5 to 98.7)	88.9 (75.9 to 96.3)
RSV-A: ≥2-fold Rise-Day 57 (n=46,39,44,42,45,58)	93.5 (82.1 to 98.6)	94.9 (82.7 to 99.4)	95.5 (84.5 to 99.4)	92.9 (80.5 to 98.5)
RSV-A: ≥4-fold Rise-Day 57 (n=46,39,44,42,45,58)	78.3 (63.6 to 89.1)	74.4 (57.9 to 87.0)	90.9 (78.3 to 97.5)	85.7 (71.5 to 94.6)

RSV-A: ≥2-fold Rise-Day 85 (n=44,42,46,45,43,55)	90.9 (78.3 to 97.5)	97.6 (97.4 to 99.9)	95.7 (85.2 to 99.5)	95.6 (84.9 to 99.5)
RSV-A: ≥4-fold Rise-Day 85 (n=44,42,46,45,43,55)	75.0 (59.7 to 86.8)	83.3 (68.6 to 93.0)	82.6 (68.6 to 92.2)	73.3 (58.1 to 85.4)
RSV-A: ≥2-fold Rise-Day 169 (n=43,42,44,44,44,55)	83.7 (69.3 to 93.2)	85.7 (71.5 to 94.6)	93.2 (81.3 to 98.6)	77.3 (62.2 to 88.5)
RSV-A: ≥4-fold Rise-Day 169 (n=43,42,44,44,44,55)	51.2 (35.5 to 66.7)	47.6 (32.0 to 63.6)	65.9 (50.1 to 79.5)	45.5 (30.4 to 61.2)
RSV-A: ≥2-fold Rise-Day 365 (n=38,33,36,41,40,49)	60.5 (43.4 to 76.0)	63.6 (45.1 to 79.6)	66.7 (49.0 to 81.4)	65.9 (49.4 to 79.9)
RSV-A: ≥4-fold Rise-Day 365 (n=38,33,36,41,40,49)	42.1 (26.3 to 59.2)	24.2 (11.1 to 42.3)	41.7 (25.5 to 59.2)	36.6 (22.1 to 53.1)
RSV-B: ≥2-fold Rise- Day 29 (n=44,43,47,45,44,56)	97.7 (88.0 to 99.9)	97.7 (87.7 to 99.9)	100.0 (92.5 to 100.0)	91.1 (78.8 to 97.5)
RSV-B: ≥4-fold Rise- Day 29 (n=44,43,47,45,44,56)	79.5 (64.7 to 90.2)	79.1 (64.0 to 90.0)	80.9 (66.7 to 90.9)	66.7 (51.0 to 80.0)
RSV-B: ≥2-fold Rise-Day 57 (n=46,39,44,42,45,58)	89.1 (76.4 to 96.4)	100.0 (91.0 to 100.0)	95.5 (84.5 to 99.4)	90.5 (77.4 to 97.3)
RSV-B: ≥4-fold Rise-Day 57 (n=46,39,44,42,45,58)	73.9 (58.9 to 85.7)	92.3 (79.1 to 98.4)	81.8 (67.3 to 91.8)	71.4 (55.4 to 84.3)
RSV-B: ≥2-fold Rise-Day 85 (n=44,42,46,45,43,55)	86.4 (72.6 to 94.8)	97.6 (87.4 to 99.9)	91.3 (79.2 to 97.6)	84.4 (70.5 to 93.5)
RSV-B: ≥4-fold Rise-Day 85 (n=44,42,46,45,43,55)	65.9 (50.1 to 79.5)	78.6 (63.2 to 89.7)	73.9 (58.9 to 85.7)	55.6 (40.0 to 70.4)
RSV-B: ≥2-fold Rise-Day 169 (n=43,42,44,44,44,55)	83.7 (69.3 to 93.2)	95.2 (83.8 to 99.4)	90.9 (78.3 to 97.5)	68.2 (52.4 to 81.4)
RSV-B: ≥4-fold Rise-Day 169 (n=43,42,44,44,44,55)	46.5 (31.2 to 62.3)	45.2 (29.8 to 61.3)	65.9 (50.1 to 79.5)	36.4 (22.4 to 52.2)
RSV-B: ≥2-fold Rise-Day 365 (n=38,33,36,41,40,49)	52.6 (35.8 to 69.0)	60.6 (42.1 to 77.1)	77.8 (60.8 to 89.9)	29.3 (16.1 to 45.5)
RSV-B: ≥4-fold Rise-Day 365 (n=38,33,36,41,40,49)	15.8 (6.0 to 31.3)	30.3 (15.6 to 48.7)	16.7 (6.4 to 32.8)	14.6 (5.6 to 29.2)

End point values	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	58		
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: ≥2-fold Rise- Day 29 (n=44,43,47,45,44,56)	93.2 (81.3 to 98.6)	7.1 (2.0 to 17.3)		
RSV-A: ≥4-fold Rise- Day 29 (n=44,43,47,45,44,56)	75.0 (59.7 to 86.8)	5.4 (1.1 to 14.9)		
RSV-A: ≥2-fold Rise-Day 57 (n=46,39,44,42,45,58)	93.3 (81.7 to 98.6)	6.9 (1.9 to 16.7)		
RSV-A: ≥4-fold Rise-Day 57 (n=46,39,44,42,45,58)	68.9 (53.4 to 81.8)	1.7 (0.0 to 9.2)		
RSV-A: ≥2-fold Rise-Day 85 (n=44,42,46,45,43,55)	83.7 (69.3 to 93.2)	3.6 (0.4 to 12.5)		
RSV-A: ≥4-fold Rise-Day 85 (n=44,42,46,45,43,55)	51.2 (35.5 to 66.7)	1.8 (0.0 to 9.7)		
RSV-A: ≥2-fold Rise-Day 169 (n=43,42,44,44,44,55)	59.1 (43.2 to 73.7)	3.6 (0.4 to 12.5)		
RSV-A: ≥4-fold Rise-Day 169 (n=43,42,44,44,44,55)	34.1 (20.5 to 49.9)	3.6 (0.4 to 12.5)		

RSV-A: ≥2-fold Rise-Day 365 (n=38,33,36,41,40,49)	47.5 (31.5 to 63.9)	16.3 (7.3 to 29.7)		
RSV-A: ≥4-fold Rise-Day 365 (n=38,33,36,41,40,49)	27.5 (14.6 to 43.9)	6.1 (1.3 to 16.9)		
RSV-B: ≥2-fold Rise- Day 29 (n=44,43,47,45,44,56)	77.3 (62.2 to 88.5)	7.1 (2.0 to 17.3)		
RSV-B: ≥4-fold Rise- Day 29 (n=44,43,47,45,44,56)	54.5 (38.8 to 69.6)	1.8 (0.0 to 9.6)		
RSV-B: ≥2-fold Rise-Day 57 (n=46,39,44,42,45,58)	73.3 (58.1 to 85.4)	13.8 (6.1 to 25.4)		
RSV-B: ≥4-fold Rise-Day 57 (n=46,39,44,42,45,58)	51.1 (35.8 to 66.3)	1.7 (.0 to 9.2)		
RSV-B: ≥2-fold Rise-Day 85 (n=44,42,46,45,43,55)	72.1 (56.3 to 84.7)	9.1 (3.0 to 20.0)		
RSV-B: ≥4-fold Rise-Day 85 (n=44,42,46,45,43,55)	41.9 (27.0 to 57.9)	1.8 (0.0 to 9.7)		
RSV-B: ≥2-fold Rise-Day 169 (n=43,42,44,44,44,55)	63.6 (47.8 to 77.6)	16.4 (7.8 to 28.8)		
RSV-B: ≥4-fold Rise-Day 169 (n=43,42,44,44,44,55)	27.3 (15.0 to 42.8)	7.3 (2.0 to 17.6)		
RSV-B: ≥2-fold Rise-Day 365 (n=38,33,36,41,40,49)	25.0 (12.7 to 41.2)	10.2 (3.4 to 22.2)		
RSV-B: ≥4-fold Rise-Day 365 (n=38,33,36,41,40,49)	12.5 (4.2 to 26.8)	6.1 (1.3 to 16.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Japanese Adult Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Japanese Adult Cohorts[44]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, and 169

Notes:

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

End point values	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	4		
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: ≥2-fold Rise- Day 29 (n=20,4)	100.0 (83.2 to 100.0)	0.0 (0.0 to 60.2)		
RSV-A: ≥4-fold Rise- Day 29 (n=20,4)	90.0 (68.3 to 98.8)	0.0 (0.0 to 60.2)		
RSV-A: ≥2-fold Rise- Day 57 (n=20,4)	100.0 (83.2 to 100.0)	0.0 (0.0 to 60.2)		
RSV-A: ≥4-fold Rise- Day 57 (n=20,4)	85.0 (62.1 to 96.8)	0.0 (0.0 to 60.2)		
RSV-A: ≥2-fold Rise- Day 85 (n=19,4)	94.7 (74.0 to 99.9)	0.0 (0.0 to 60.2)		
RSV-A: ≥4-fold Rise- Day 85 (n=19,4)	89.5 (66.9 to 98.7)	0.0 (0.0 to 60.2)		
RSV-A: ≥2-fold Rise- Day 169 (n=20,4)	90.0 (68.3 to 98.8)	0.0 (0.0 to 60.2)		
RSV-A: ≥4-fold Rise- Day 169 (n=20,4)	45.0 (23.1 to 68.5)	0.0 (0.0 to 60.2)		
RSV-B: ≥2-fold Rise- Day 29 (n=20,4)	100.0 (83.2 to 100.0)	0.0 (0.0 to 60.2)		
RSV-B: ≥4-fold Rise- Day 29 (n=20,4)	75.0 (50.9 to 91.3)	0.0 (0.0 to 60.2)		
RSV-B: ≥2-fold Rise- Day 57 (n=20,4)	85.0 (62.1 to 96.8)	0.0 (0.0 to 60.2)		
RSV-B: ≥4-fold Rise- Day 57 (n=20,4)	65.0 (40.8 to 84.6)	0.0 (0.0 to 60.2)		
RSV-B: ≥2-fold Rise- Day 85 (n=19,4)	94.7 (74.0 to 99.9)	0.0 (0.0 to 60.2)		
RSV-B: ≥4-fold Rise- Day 85 (n=19,4)	47.4 (24.4 to 71.1)	0.0 (0.0 to 60.2)		
RSV-B: ≥2-fold Rise- Day 169 (n=20,4)	65.0 (40.8 to 84.6)	0.0 (0.0 to 60.2)		
RSV-B: ≥4-fold Rise- Day 169 (n=20,4)	30.0 (11.9 to 54.3)	0.0 (0.0 to 60.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in WOCBP Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in WOCBP Cohorts[45]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the

immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, and 169

Notes:

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

End point values	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	44	29
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: ≥2-fold Rise-Day 29 (n=49,46,41,28)	95.9 (86.0 to 99.5)	97.8 (88.5 to 99.9)	95.1 (83.5 to 99.4)	7.1 (0.9 to 23.5)
RSV-A: ≥4-fold Rise-Day 29 (n=49,46,41,28)	83.7 (70.3 to 92.7)	84.8 (71.1 to 93.7)	92.7 (80.1 to 98.5)	3.6 (0.1 to 18.3)
RSV-A: ≥2-fold Rise-Day 57 (n=45,45,42,28)	95.6 (84.9 to 99.5)	95.6 (84.9 to 99.5)	97.6 (87.4 to 99.9)	21.4 (8.3 to 41.0)
RSV-A: ≥4-fold Rise-Day 57 (n=45,45,42,28)	82.2 (67.9 to 92.0)	80.0 (65.4 to 90.4)	88.1 (74.4 to 96.0)	10.7 (2.3 to 28.2)
RSV-A: ≥2-fold Rise-Day 85 (n=43,41,37,24)	90.7 (77.9 to 97.4)	95.1 (83.5 to 99.4)	97.3 (85.8 to 99.9)	25.0 (9.8 to 46.7)
RSV-A: ≥4-fold Rise-Day 85 (n=43,41,37,24)	67.4 (51.5 to 80.9)	85.4 (70.8 to 94.4)	83.8 (68.0 to 93.8)	4.2 (0.1 to 21.1)
RSV-A: ≥2-fold Rise-Day 113 (n=44,43,37,25)	86.4 (72.6 to 94.8)	90.7 (77.9 to 97.4)	97.3 (77.9 to 97.4)	20.0 (6.8 to 40.7)
RSV-A: ≥4-fold Rise-Day 113 (n=44,43,37,25)	61.4 (45.5 to 75.6)	76.7 (61.4 to 88.2)	75.7 (58.8 to 88.2)	8.0 (1.0 to 26.0)
RSV-A: ≥2-fold Rise-Day 141 (n=40,42,36,25)	80.0 (64.4 to 90.9)	90.5 (77.4 to 97.3)	94.4 (81.3 to 99.3)	16.0 (4.5 to 36.1)
RSV-A: ≥4-fold Rise-Day 141 (n=40,42,36,25)	47.5 (31.5 to 63.9)	69.0 (52.9 to 82.4)	66.7 (49.0 to 81.4)	4.0 (0.1 to 20.4)
RSV-A: ≥2-fold Rise-Day 169 (n=41,43,34,23)	75.6 (59.7 to 87.6)	79.1 (64.0 to 90.0)	91.2 (76.3 to 98.1)	13.0 (2.8 to 33.6)
RSV-A: ≥4-fold Rise-Day 169 (n=41,43,34,23)	43.9 (28.5 to 60.3)	67.4 (51.5 to 80.9)	61.8 (43.6 to 77.8)	0.0 (0.0 to 14.8)
RSV-B: ≥2-fold Rise-Day 29 (n=49,46,41,28)	87.8 (75.2 to 95.4)	87.0 (73.7 to 95.1)	85.4 (70.8 to 94.4)	10.7 (2.3 to 28.2)
RSV-B: ≥4-fold Rise-Day 29 (n=49,46,41,28)	73.5 (58.9 to 85.1)	63.0 (47.5 to 76.8)	73.2 (57.1 to 85.8)	3.6 (0.1 to 18.3)
RSV-B: ≥2-fold Rise-Day 57 (n=45,45,42,28)	84.4 (70.5 to 93.5)	82.2 (67.9 to 92.0)	88.1 (74.4 to 96.0)	14.3 (4.0 to 32.7)
RSV-B: ≥4-fold Rise-Day 57 (n=45,45,42,28)	55.6 (40.0 to 70.4)	57.8 (42.2 to 72.3)	66.7 (50.5 to 80.4)	7.1 (0.9 to 23.5)
RSV-B: ≥2-fold Rise-Day 85 (n=43,41,37,24)	86.0 (72.1 to 94.7)	78.0 (62.4 to 89.4)	89.2 (74.6 to 97.0)	20.8 (7.1 to 42.2)
RSV-B: ≥4-fold Rise-Day 85 (n=43,41,37,24)	67.4 (51.5 to 80.9)	53.7 (37.4 to 69.3)	62.2 (44.8 to 77.5)	8.3 (1.0 to 27.0)
RSV-B: ≥2-fold Rise-Day 113 (n=44,43,37,25)	75.0 (59.7 to 86.8)	74.4 (58.8 to 86.5)	89.2 (74.6 to 97.0)	24.0 (9.4 to 45.1)
RSV-B: ≥4-fold Rise-Day 113 (n=44,43,37,25)	47.7 (32.5 to 63.3)	48.8 (33.3 to 64.5)	56.8 (39.5 to 72.9)	16.0 (4.5 to 36.1)

RSV-B: ≥2-fold Rise-Day 141 (n=40,42,36,25)	72.5 (56.1 to 85.4)	66.7 (50.5 to 80.4)	83.3 (67.2 to 93.6)	28.0 (12.1 to 49.4)
RSV-B: ≥4-fold Rise-Day 141 (n=40,42,36,25)	32.5 (18.6 to 49.1)	45.2 (29.8 to 61.3)	44.4 (27.9 to 61.9)	8.0 (1.0 to 26.0)
RSV-B: ≥2-fold Rise-Day 169 (n=41,43,34,23)	65.9 (49.4 to 79.9)	67.4 (51.5 to 80.9)	76.5 (58.8 to 89.3)	8.7 (1.1 to 28.0)
RSV-B: ≥4-fold Rise-Day 169 (n=41,43,34,23)	41.5 (26.3 to 57.9)	39.5 (25.0 to 55.6)	38.2 (22.2 to 56.4)	0.0 (0.0 to 14.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Children Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in RSV Neutralizing Abs (RSV-A and RSV-B) Titers from Baseline in Children Cohorts[46]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 85, and 141

Notes:

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	13	11	
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: ≥2-fold Rise- Day 29 (n=14,12,11)	100.0 (76.8 to 100.0)	75.0 (42.8 to 94.5)	27.3 (6.0 to 61.0)	
RSV-A: ≥4-fold Rise- Day 29 (n=14,12,11)	92.9 (66.1 to 99.8)	75.0 (42.8 to 94.5)	18.2 (2.3 to 51.8)	
RSV-A: ≥2-fold Rise- Day 85 (n=5,9,4)	100.0 (47.8 to 100.0)	77.8 (40.0 to 97.5)	0.0 (0.0 to 60.2)	
RSV-A: ≥4-fold Rise- Day 85 (n=5,9,4)	100.0 (47.8 to 100.0)	77.8 (40.0 to 97.5)	0.0 (0.0 to 60.2)	
RSV-A: ≥2-fold Rise- Day 141 (n=4,5,5)	100.0 (39.8 to 100)	80.0 (28.4 to 99.5)	40.0 (5.3 to 85.3)	
RSV-A: ≥4-fold Rise- Day 141 (n=4,5,5)	100 (39.8 to 100.0)	80.0 (28.4 to 99.5)	20.0 (0.5 to 71.6)	

RSV-B: ≥2-fold Rise- Day 29 (n=14,12,11)	100.0 (76.8 to 100.0)	83.3 (51.6 to 97.9)	18.2 (2.3 to 51.8)	
RSV-B: ≥4-fold Rise- Day 29 (n=14,12,11)	71.4 (41.9 to 91.6)	83.3 (51.6 to 97.9)	18.2 (2.3 to 51.8)	
RSV-B: ≥2-fold Rise- Day 85 (n=5,9,4)	100.0 (47.8 to 100.0)	88.9 (51.8 to 99.7)	0.0 (0.0 to 60.2)	
RSV-B: ≥4-fold Rise- Day 85 (n=5,9,4)	100.0 (47.8 to 100.0)	44.4 (13.7 to 78.8)	0.0 (0.0 to 60.2)	
RSV-B: ≥2-fold Rise- Day 141 (n=4,5,5)	100.0 (39.8 to 100.0)	100.0 (47.8 to 100.0)	40.0 (5.3 to 85.3)	
RSV-B: ≥4-fold Rise- Day 141 (n=4,5,5)	100.0 (39.8 to 100.0)	60.0 (14.7 to 94.7)	40.0 (5.3 to 85.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Young Adults Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Young Adults Cohorts[47]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories. '9999' represents data not collected for specified cohorts.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, 169, and 281

Notes:

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

End point values	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	15	18
Units: percentage of participants				
number (confidence interval 95%)				
PreF-bAb: ≥2-fold Rise-Day 29 (n=18,19,15,18,14,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (78.2 to 100.0)	100.0 (81.5 to 100.0)
PreF-bAb: ≥4-fold Rise-Day 29 (n=18,19,15,18,14,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (78.2 to 100.0)	100.0 (81.5 to 100.0)
PreF-bAb: ≥2-fold Rise-Day 57 (n=18,19,14,17,14,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (76.8 to 100.0)	100.0 (80.5 to 100.0)

PreF-bAb: ≥4-fold Rise-Day 57 (n=18,19,14,17,14,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (76.8 to 100.0)	94.1 (71.3 to 99.9)
PreF-bAb: ≥2-fold Rise-Day 85 (n=18,19,12,17,13,3)	94.4 (72.7 to 99.9)	100.0 (82.4 to 100.0)	100.0 (73.5 to 100.0)	100.0 (80.5 to 100.0)
PreF-bAb: ≥4-fold Rise-Day 85 (n=18,19,12,17,13,3)	88.9 (65.3 to 98.6)	94.7 (74.0 to 99.9)	100.0 (73.5 to 100.0)	94.1 (71.3 to 99.9)
PreF-bAb: ≥2-fold Rise-Day 113(n=18,17,12,16,13,3)	100.0 (81.5 to 100.0)	100.0 (80.5 to 100.0)	100.0 (73.5 to 100.0)	100.0 (79.4 to 100.0)
PreF-bAb: ≥4-fold Rise-Day 113(n=18,17,12,16,13,3)	88.9 (65.3 to 98.6)	88.2 (63.6 to 98.5)	100.0 (73.5 to 100.0)	87.5 (61.7 to 98.4)
PreF-bAb: ≥2-fold Rise-Day 141(n=18,19,13,16,14,3)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (75.3 to 100.0)	100.0 (79.4 to 100.0)
PreF-bAb: ≥4-fold Rise-Day 141(n=18,19,13,16,14,3)	83.3 (58.6 to 96.4)	84.2 (60.4 to 96.6)	100.0 (75.3 to 100.0)	87.5 (61.7 to 98.4)
PreF-bAb: ≥2-fold Rise-Day 169(n=18,19,13,17,13,3)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (75.3 to 100.0)	100.0 (80.5 to 100.0)
PreF-bAb: ≥4-fold Rise-Day 169(n=18,19,13,17,13,3)	66.7 (41.0 to 86.7)	68.4 (43.4 to 87.4)	100.0 (75.3 to 100.0)	82.4 (56.6 to 96.2)
PreF-bAb: ≥2-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	100.0 (73.5 to 100.0)	9999 (9999 to 9999)
PreF-bAb: ≥4-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	91.7 (61.5 to 99.8)	9999 (9999 to 9999)
PostF-bAb: ≥2-fold Rise-Day 29(n=18,19,15,18,14,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	100.0 (78.2 to 100.0)	100.0 (81.5 to 100.0)
PostF-bAb: ≥4-fold Rise-Day 29(n=18,19,15,18,14,4)	88.9 (65.3 to 98.6)	100.0 (82.4 to 100.0)	93.3 (68.1 to 99.8)	100.0 (81.5 to 100.0)
PostF-bAb: ≥2-fold Rise-Day 57(n=18,19,14,17,14,4)	100.0 (81.5 to 100.0)	100.0 (82.4 to 100.0)	92.9 (66.1 to 99.8)	100.0 (80.5 to 100.0)
PostF-bAb: ≥4-fold Rise-Day 57(n=18,19,14,17,14,4)	83.3 (58.6 to 96.4)	94.7 (74.0 to 99.9)	92.9 (66.1 to 99.8)	94.1 (71.3 to 99.9)
PostF-bAb: ≥2-fold Rise-Day 85(n=18,19,12,17,13,3)	94.4 (72.7 to 99.9)	100.0 (82.4 to 100.0)	91.7 (61.5 to 99.8)	100.0 (80.5 to 100.0)
PostF-bAb: ≥4-fold Rise-Day 85(n=18,19,12,17,13,3)	83.3 (58.6 to 96.4)	78.9 (54.4 to 93.9)	91.7 (61.5 to 99.8)	76.5 (66.5 to 89.4)
PostF-bAb:≥2-fold Rise-Day 113(n=18,17,12,16,13,3)	94.4 (72.7 to 99.9)	100.0 (80.5 to 100.0)	91.7 (61.5 to 99.8)	100.0 (79.4 to 100.0)
PostF-bAb:≥4-fold Rise-Day 113(n=18,17,12,16,13,3)	72.2 (46.5 to 90.3)	64.7 (38.3 to 85.8)	91.7 (61.5 to 99.8)	68.8 (41.3 to 89.0)
PostF-bAb:≥2-fold Rise-Day 141(n=18,19,13,16,14,3)	94.4 (72.7 to 99.9)	94.7 (74.0 to 99.9)	92.3 (64.0 to 99.8)	93.8 (69.8 to 99.8)
PostF-bAb:≥4-fold Rise-Day 141(n=18,19,13,16,14,3)	72.2 (46.5 to 90.3)	57.9 (33.5 to 79.7)	92.3 (64.0 to 99.8)	62.5 (35.4 to 84.8)
PostF-bAb:≥2-fold Rise-Day 169(n=18,19,13,17,13,3)	94.4 (72.7 to 99.9)	94.7 (74.0 to 99.9)	92.3 (64.0 to 99.8)	88.2 (63.6 to 98.5)
PostF-bAb:≥4-fold Rise-Day 169(n=18,19,13,17,13,3)	55.6 (30.8 to 78.5)	52.6 (28.9 to 75.6)	92.3 (64.0 to 99.8)	52.9 (27.8 to 77.0)
PostF-bAb: ≥2-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	91.7 (61.5 to 99.8)	9999 (9999 to 9999)
PostF-bAb: ≥4-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	9999 (9999 to 9999)	66.7 (34.9 to 90.1)	9999 (9999 to 9999)

End point values	Single Injection Placebo in Younger Adults (18 to 49 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	4		
Units: percentage of participants				

number (confidence interval 95%)				
PreF-bAb: ≥2-fold Rise-Day 29 (n=18,19,15,18,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥4-fold Rise-Day 29 (n=18,19,15,18,14,4)	0.0 (0.0 to 23.0)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥2-fold Rise-Day 57 (n=18,19,14,17,14,4)	0.0 (0.0 to 23.0)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥4-fold Rise-Day 57 (n=18,19,14,17,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥2-fold Rise-Day 85 (n=18,19,12,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥4-fold Rise-Day 85 (n=18,19,12,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥2-fold Rise-Day 113(n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥4-fold Rise-Day 113(n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥2-fold Rise-Day 141(n=18,19,13,16,14,3)	0.0 (0.0 to 23.2)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥4-fold Rise-Day 141(n=18,19,13,16,14,3)	0.0 (0.0 to 23.2)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥2-fold Rise-Day 169(n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥4-fold Rise-Day 169(n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥2-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		
PreF-bAb: ≥4-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		
PostF-bAb: ≥2-fold Rise-Day 29(n=18,19,15,18,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥4-fold Rise-Day 29(n=18,19,15,18,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥2-fold Rise-Day 57(n=18,19,14,17,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥4-fold Rise-Day 57(n=18,19,14,17,14,4)	0.0 (0.0 to 23.2)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥2-fold Rise-Day 85(n=18,19,12,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PostF-bAb: ≥4-fold Rise-Day 85(n=18,19,12,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PostF-bAb:≥2-fold Rise-Day 113(n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PostF-bAb:≥4-fold Rise-Day 113(n=18,17,12,16,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PostF-bAb:≥2-fold Rise-Day 141(n=18,19,13,16,14,3)	0.0 (0.0 to 23.2)	0.0 (0.0 to 70.8)		
PostF-bAb:≥4-fold Rise-Day 141(n=18,19,13,16,14,3)	0.0 (0.0 to 23.2)	0.0 (0.0 to 70.8)		
PostF-bAb:≥2-fold Rise-Day 169(n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PostF-bAb:≥4-fold Rise-Day 169(n=18,19,13,17,13,3)	0.0 (0.0 to 24.7)	0.0 (0.0 to 70.8)		
PostF-bAb: ≥2-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		
PostF-bAb: ≥4-fold Rise-Day 281 (n=0,0,12,0,0,3)	9999 (9999 to 9999)	0.0 (0.0 to 70.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Older Adult Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Older Adult Cohorts[48]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 169, and 365

Notes:

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

End point values	Cohort 7: mRNA-1345 Dose A in Older Adults (65 to 79 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (65 to 79 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (65 to 79 Years)	Cohort 10: mRNA-1345 Dose E in Older Adults (65 to 79 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	43	47	45
Units: percentage of participants				
number (confidence interval 95%)				
PreF-bAb: ≥2-fold Rise-Day 29(n=44,43,47,45,44,56)	100.0 (92.0 to 100.0)	100.0 (91.8 to 100.0)	100.0 (92.5 to 100.0)	97.8 (88.2 to 99.9)
PreF-bAb: ≥4-fold Rise-Day 29(n=44,43,47,45,44,56)	86.4 (72.6 to 94.8)	88.4 (74.9 to 96.1)	80.9 (66.7 to 90.9)	88.9 (75.9 to 96.3)
PreF-bAb: ≥2-fold Rise-Day 57(n=46,39,44,42,45,58)	97.8 (88.5 to 99.9)	100.0 (91.0 to 100.0)	100.0 (92.0 to 100.0)	95.2 (83.8 to 99.4)
PreF-bAb: ≥4-fold Rise-Day 57(n=46,39,44,42,45,58)	76.1 (61.2 to 87.4)	84.6 (69.5 to 94.1)	81.8 (67.3 to 91.8)	78.6 (63.2 to 89.7)
PreF-bAb: ≥2-fold Rise-Day 85(n=44,42,46,45,43,55)	90.9 (78.3 to 97.5)	95.2 (83.8 to 99.4)	95.7 (85.2 to 99.5)	97.8 (88.2 to 99.9)
PreF-bAb: ≥4-fold Rise-Day 85(n=44,42,46,45,43,55)	65.9 (50.1 to 79.5)	73.8 (58.0 to 86.1)	76.1 (61.2 to 87.4)	64.4 (48.8 to 78.1)
PreF-bAb:≥2-fold Rise-Day 169(n=43,42,44,44,44,55)	90.7 (77.9 to 97.4)	85.7 (71.5 to 94.6)	88.6 (75.4 to 96.2)	77.3 (62.2 to 88.5)
PreF-bAb:≥4-fold Rise-Day 169(n=43,42,44,44,44,55)	46.5 (31.2 to 62.3)	50.0 (34.2 to 65.8)	56.8 (41.0 to 71.7)	43.2 (28.3 to 59.0)
PreF-bAb:≥2-fold Rise-Day 365(n=38,33,36,41,40,49)	68.4 (51.3 to 82.5)	81.8 (64.5 to 93.0)	69.4 (51.9 to 83.7)	58.5 (42.1 to 73.7)
PreF-bAb:≥4-fold Rise-Day 365(n=38,33,36,41,40,49)	28.9 (15.4 to 45.9)	30.3 (15.6 to 48.7)	33.3 (18.6 to 51.0)	17.1 (7.2 to 32.1)
PostF-bAb:≥2-fold Rise-Day 29(n=44,43,47,45,44,56)	95.5 (84.5 to 99.4)	100.0 (91.8 to 100.0)	95.7 (85.5 to 99.5)	93.3 (81.7 to 98.6)
PostF-bAb:≥4-fold Rise-Day 29(n=44,43,47,45,44,56)	65.9 (50.1 to 79.5)	79.1 (64.0 to 90.0)	83.0 (69.2 to 92.4)	66.7 (51.0 to 80.0)

PostF-bAb:≥2-fold Rise-Day 57(n=46,39,44,42,45,58)	93.5 (82.1 to 98.6)	92.3 (79.1 to 98.4)	95.5 (84.5 to 99.4)	78.6 (63.2 to 89.7)
PostF-bAb:≥4-fold Rise-Day 57(n=46,39,44,42,45,58)	52.2 (36.9 to 67.1)	61.5 (44.6 to 76.6)	81.8 (67.3 to 91.8)	57.1 (41.0 to 72.3)
PostF-bAb:≥2-fold Rise-Day 85(n=44,42,46,45,43,55)	79.5 (64.7 to 90.2)	88.1 (74.4 to 96.0)	87.0 (73.7 to 95.1)	80.0 (65.4 to 90.4)
PostF-bAb:≥4-fold Rise-Day 85(n=44,42,46,45,43,55)	54.5 (38.8 to 69.6)	54.8 (38.7 to 70.2)	71.7 (56.5 to 84.0)	51.1 (35.8 to 66.3)
PostF-bAb:≥2-fold Rise-Day 169(n=43,42,44,44,44,55	67.4 (51.5 to 80.9)	61.9 (45.6 to 76.4)	84.1 (69.9 to 93.4)	63.6 (47.8 to 77.6)
PostF-bAb:≥4-fold Rise-Day 169(n=43,42,44,44,44,55	37.2 (23.0 to 53.3)	26.2 (13.9 to 42.0)	50.0 (34.6 to 65.4)	29.5 (16.8 to 45.2)
PostF-bAb:≥2-fold Rise-Day 365(n=38,33,36,41,40,49	50.0 (33.4 to 66.6)	51.5 (33.5 to 69.2)	66.7 (49.0 to 81.4)	43.9 (28.5 to 60.3)
PostF-bAb:≥4-fold Rise-Day 365(n=38,33,36,41,40,49	13.2 (4.4 to 28.1)	18.2 (7.0 to 35.5)	19.4 (8.2 to 36.0)	9.8 (2.7 to 23.1)

End point values	Cohort 11: mRNA-1345 Dose F in Older Adults (65 to 79 Years)	Two Injection Placebo in Older Adults (65 to 79 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	58		
Units: percentage of participants				
number (confidence interval 95%)				
PreF-bAb: ≥2-fold Rise-Day 29(n=44,43,47,45,44,56)	93.2 (81.3 to 98.6)	1.8 (0.0 to 9.6)		
PreF-bAb: ≥4-fold Rise-Day 29(n=44,43,47,45,44,56)	75.0 (59.7 to 86.8)	1.8 (0.0 to 9.6)		
PreF-bAb: ≥2-fold Rise-Day 57(n=46,39,44,42,45,58)	84.4 (70.5 to 93.5)	1.7 (0.0 to 9.2)		
PreF-bAb: ≥4-fold Rise-Day 57(n=46,39,44,42,45,58)	57.8 (42.2 to 72.3)	1.7 (0.0 to 9.2)		
PreF-bAb: ≥2-fold Rise-Day 85(n=44,42,46,45,43,55)	86.0 (72.1 to 94.7)	1.8 (0.0 to 9.7)		
PreF-bAb: ≥4-fold Rise-Day 85(n=44,42,46,45,43,55)	58.1 (42.1 to 73.0)	1.8 (0.0 to 9.7)		
PreF-bAb:≥2-fold Rise-Day 169(n=43,42,44,44,44,55)	63.6 (47.8 to 77.6)	3.6 (0.4 to 12.5)		
PreF-bAb:≥4-fold Rise-Day 169(n=43,42,44,44,44,55)	29.5 (16.8 to 45.2)	3.6 (0.4 to 12.5)		
PreF-bAb:≥2-fold Rise-Day 365(n=38,33,36,41,40,49)	55.0 (38.5 to 70.7)	14.3 (5.9 to 27.2)		
PreF-bAb:≥4-fold Rise-Day 365(n=38,33,36,41,40,49)	17.5 (7.3 to 32.8)	10.2 (3.4 to 22.2)		
PostF-bAb:≥2-fold Rise-Day 29(n=44,43,47,45,44,56)	93.2 (81.3 to 98.6)	1.8 (0.0 to 9.6)		
PostF-bAb:≥4-fold Rise-Day 29(n=44,43,47,45,44,56)	54.5 (38.8 to 69.6)	1.8 (0.0 to 9.6)		
PostF-bAb:≥2-fold Rise-Day 57(n=46,39,44,42,45,58)	82.2 (67.9 to 92.0)	1.7 (0.0 to 9.2)		
PostF-bAb:≥4-fold Rise-Day 57(n=46,39,44,42,45,58)	40.0 (25.7 to 55.7)	1.7 (0.0 to 9.2)		
PostF-bAb:≥2-fold Rise-Day 85(n=44,42,46,45,43,55)	74.4 (58.8 to 86.5)	1.8 (0.0 to 9.7)		
PostF-bAb:≥4-fold Rise-Day 85(n=44,42,46,45,43,55)	25.6 (13.5 to 41.2)	1.8 (0.0 to 9.7)		

PostF-bAb:≥2-fold Rise-Day 169(n=43,42,44,44,44,55	45.5 (30.4 to 61.2)	3.6 (0.4 to 12.5)		
PostF-bAb:≥4-fold Rise-Day 169(n=43,42,44,44,44,55	9.1 (2.5 to 21.7)	1.8 (0.0 to 9.7)		
PostF-bAb:≥2-fold Rise-Day 365(n=38,33,36,41,40,49	22.5 (10.8 to 38.5)	14.3 (5.9 to 27.2)		
PostF-bAb:≥4-fold Rise-Day 365(n=38,33,36,41,40,49	5.0 (0.6 to 16.9)	6.1 (1.3 to 16.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Japanese Adults Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Japanese Adults Cohorts[49]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, and 169

Notes:

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

End point values	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	4		
Units: percentage of participants				
number (confidence interval 95%)				
PreF-bAb: ≥2-fold Rise- Day 29 (n=20,4)	100.0 (83.2 to 100.0)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥4-fold Rise- Day 29 (n=20,4)	90.0 (68.3 to 98.8)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥2-fold Rise- Day 57 (n=20,4)	100.0 (83.2 to 100.0)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥4-fold Rise- Day 57 (n=20,4)	85.0 (62.1 to 96.8)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥2-fold Rise- Day 85 (n=19,4)	94.7 (74.0 to 99.9)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥4-fold Rise- Day 85 (n=19,4)	68.4 (43.4 to 87.4)	0.0 (0.0 to 60.2)		

PreF-bAb: ≥2-fold Rise- Day 169 (n=20,4)	85.0 (62.1 to 96.8)	0.0 (0.0 to 60.2)		
PreF-bAb: ≥4-fold Rise- Day 169 (n=20,4)	40.0 (19.1 to 63.9)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥2-fold Rise- Day 29 (n=20,4)	95.0 (75.1 to 99.9)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥4-fold Rise- Day 29 (n=20,4)	80.0 (56.3 to 94.3)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥2-fold Rise- Day 57 (n=20,4)	95.0 (75.1 to 99.9)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥4-fold Rise- Day 57 (n=20,4)	70.0 (45.7 to 88.1)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥2-fold Rise- Day 85 (n=19,4)	89.5 (66.9 to 98.7)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥4-fold Rise- Day 85 (n=19,4)	42.1 (20.3 to 66.5)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥2-fold Rise- Day 169 (n=20,4)	75.0 (50.9 to 91.3)	0.0 (0.0 to 60.2)		
PostF-bAb: ≥4-fold Rise- Day 169 (n=20,4)	30.0 (11.9 to 54.3)	0.0 (0.0 to 60.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for WOCBP Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for WOCBP Cohorts[50]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 57, 85, 113, 141, and 169

Notes:

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

End point values	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Single Injection Placebo in WOCBP (18 to 40 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	46	42	28
Units: percentage of participants				
number (confidence interval 95%)				

PreF-bAb: ≥2-fold Rise-Day 29 (n=49,46,41,28)	98.0 (89.1 to 99.9)	97.8 (88.5 to 99.9)	97.6 (87.1 to 99.9)	3.6 (0.1 to 18.3)
PreF-bAb: ≥4-fold Rise-Day 29 (n=49,46,41,28)	83.7 (70.3 to 92.7)	89.1 (76.4 to 96.4)	85.4 (70.8 to 94.4)	0.0 (0.0 to 12.3)
PreF-bAb: ≥2-fold Rise-Day 57 (n=45,45,42,28)	93.3 (81.7 to 98.6)	97.8 (88.2 to 99.9)	100.0 (91.6 to 100.0)	3.6 (0.1 to 18.3)
PreF-bAb: ≥4-fold Rise-Day 57 (n=45,45,42,28)	80.0 (65.4 to 90.4)	82.2 (67.9 to 92.0)	85.7 (71.5 to 94.6)	0.0 (0.0 to 12.3)
PreF-bAb: ≥2-fold Rise-Day 85 (n=43,41,37,24)	88.4 (74.9 to 96.1)	97.6 (87.1 to 99.9)	97.3 (85.8 to 99.9)	8.3 (1.0 to 27.0)
PreF-bAb: ≥4-fold Rise-Day 85 (n=43,41,37,24)	65.1 (49.1 to 79.0)	82.9 (67.9 to 92.8)	73.0 (55.9 to 86.2)	0.0 (0.0 to 14.2)
PreF-bAb: ≥2-fold Rise-Day 113 (n=44,43,37,25)	90.9 (78.3 to 97.5)	93.0 (80.9 to 98.5)	91.9 (78.1 to 98.3)	8.0 (1.0 to 26.0)
PreF-bAb: ≥4-fold Rise-Day 113 (n=44,43,37,25)	52.3 (36.7 to 67.5)	69.8 (53.9 to 82.8)	62.2 (44.8 to 77.5)	4.0 (0.1 to 20.4)
PreF-bAb: ≥2-fold Rise-Day 141 (n=40,42,36,24)	82.5 (67.2 to 92.7)	97.6 (87.4 to 99.9)	94.4 (81.3 to 99.3)	8.3 (1.0 to 27.0)
PreF-bAb: ≥4-fold Rise-Day 141 (n=40,42,36,24)	45.0 (29.3 to 61.5)	66.7 (50.5 to 80.4)	55.6 (38.1 to 72.1)	4.2 (0.1 to 21.1)
PreF-bAb: ≥2-fold Rise-Day 169 (n=41,43,34,23)	78.0 (62.4 to 89.4)	93.0 (80.9 to 98.5)	91.2 (76.3 to 98.1)	4.3 (0.1 to 21.9)
PreF-bAb: ≥4-fold Rise-Day 169 (n=41,43,34,23)	41.5 (26.3 to 57.9)	55.8 (39.9 to 70.9)	55.9 (37.9 to 72.8)	0.0 (0.0 to 14.8)
PostF-bAb: ≥2-fold Rise-Day 29 (n=49,46,41,28)	98.0 (89.1 to 99.9)	95.7 (85.2 to 99.5)	95.1 (83.5 to 99.4)	0.0 (0.0 to 12.3)
PostF-bAb: ≥4-fold Rise-Day 29 (n=49,46,41,28)	73.5 (58.9 to 85.1)	82.6 (68.6 to 92.2)	82.9 (67.9 to 92.8)	0.0 (0.0 to 12.3)
PostF-bAb: ≥2-fold Rise-Day 57 (n=45,45,42,28)	93.3 (81.7 to 98.6)	88.9 (75.9 to 96.3)	95.2 (83.8 to 99.4)	3.6 (0.1 to 18.3)
PostF-bAb: ≥4-fold Rise-Day 57 (n=45,45,42,28)	66.7 (51.0 to 80.0)	66.7 (51.0 to 80.0)	76.2 (60.5 to 87.9)	0.0 (0.0 to 12.3)
PostF-bAb: ≥2-fold Rise-Day 85 (n=43,41,37,24)	86.0 (72.1 to 94.7)	87.8 (73.8 to 95.9)	91.9 (78.1 to 98.3)	0.0 (0.0 to 14.2)
PostF-bAb: ≥4-fold Rise-Day 85 (n=43,41,37,24)	51.2 (35.5 to 66.7)	53.7 (37.4 to 69.3)	54.1 (36.9 to 70.5)	0.0 (0.0 to 14.2)
PostF-bAb: ≥2-fold Rise-Day 113 (n=44,43,37,25)	90.9 (78.3 to 97.5)	83.7 (69.3 to 93.2)	86.5 (71.2 to 95.5)	8.0 (1.0 to 26.0)
PostF-bAb: ≥4-fold Rise-Day 113 (n=44,43,37,25)	43.2 (28.3 to 59.0)	55.8 (39.9 to 70.9)	48.6 (31.9 to 65.6)	4.0 (0.1 to 20.4)
PostF-bAb: ≥2-fold Rise-Day 141 (n=40,42,36,24)	80.0 (64.4 to 90.9)	85.7 (71.5 to 94.6)	80.6 (64.0 to 91.8)	4.2 (0.1 to 21.1)
PostF-bAb: ≥4-fold Rise-Day 141 (n=40,42,36,24)	32.5 (18.6 to 49.1)	38.1 (23.6 to 54.4)	36.1 (20.8 to 53.8)	0.0 (0.0 to 14.2)
PostF-bAb: ≥2-fold Rise-Day 169 (n=41,43,34,23)	73.2 (57.1 to 85.2)	79.1 (64.0 to 90.0)	79.4 (62.1 to 91.3)	0.0 (0.0 to 14.8)
PostF-bAb: ≥4-fold Rise-Day 169 (n=41,43,34,23)	31.7 (18.1 to 48.1)	27.9 (15.3 to 43.7)	26.5 (12.9 to 44.4)	0.0 (0.0 to 14.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Children Cohorts

End point title	Percentage of Participants with ≥2-fold and ≥4-fold Increases in Serum Binding Abs (PreF and PostF) Titers from Baseline for Children Cohorts[51]

End point description:

PP Set included all FAS participants (all randomized participants who received any study injection, had baseline data for those analyses that require baseline data, and had at least 1 postinjection assessment for the analysis endpoint) who a) complied with the injection schedule, b) complied with the timing of immunogenicity blood sampling in order to have baseline and postinjection results available for at least 1 assay component corresponding to the immunogenicity analysis objective, and c) had no major protocol violations that impacted immune response during the period corresponding to the immunogenicity analysis objective. Participants were included in the treatment arm to which they were randomized. 'n' = participants evaluable for specified categories.

End point type	Secondary

End point timeframe:

Days 29, 85, and 141

Notes:

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

End point values	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Three Injection Placebo in Children (12 to 59 Months)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	11	11	
Units: percentage of participants				
number (confidence interval 95%)				
PreF-bAb: ≥2-fold Rise-Day 29 (n=14,11,11)	100.0 (76.8 to 100.0)	90.9 (58.7 to 99.8)	27.3 (6.0 to 61.0)	
PreF-bAb: ≥4-fold Rise-Day 29 (n=14,11,11)	92.9 (66.1 to 99.8)	90.9 (58.7 to 99.8)	18.2 (2.3 to 51.8)	
PreF-bAb: ≥2-fold Rise-Day 85 (n=5,9,4)	100.0 (47.8 to 100.0)	88.9 (51.8 to 99.7)	0.0 (0.0 to 60.2)	
PreF-bAb: ≥4-fold Rise-Day 85 (n=5,9,4)	100.0 (47.8 to 100.0)	77.8 (40.0 to 97.2)	0.0 (0.0 to 60.2)	
PreF-bAb: ≥2-fold Rise-Day 141 (n=4,5,5)	100.0 (39.8 to 100.0)	100.0 (47.8 to 100.0)	40.0 (5.3 to 85.3)	
PreF-bAb: ≥4-fold Rise-Day 141 (n=4,5,5)	100.0 (39.8 to 100.0)	100.0 (47.8 to 100.0)	40.0 (5.3 to 85.3)	
PostF-bAb: ≥2-fold Rise-Day 29 (n=14,11,11)	100.0 (76.8 to 100.0)	90.9 (58.7 to 99.8)	27.3 (6.0 to 61.0)	
PostF-bAb: ≥4-fold Rise-Day 29 (n=14,11,11)	92.9 (66.1 to 99.8)	72.7 (39.0 to 94.0)	18.2 (2.3 to 51.8)	
PostF-bAb: ≥2-fold Rise-Day 85 (n=5,9,4)	100.0 (47.8 to 100.0)	88.9 (51.8 to 99.7)	0.0 (0.0 to 60.2)	
PostF-bAb: ≥4-fold Rise-Day 85 (n=5,9,4)	80.0 (28.4 to 99.5)	66.7 (29.9 to 92.5)	0.0 (0.0 to 60.2)	
PostF-bAb: ≥2-fold Rise-Day 141 (n=4,5,5)	100.0 (39.8 to 100.0)	80.0 (28.4 to 99.5)	20.0 (0.5 to 71.6)	
PostF-bAb: ≥4-fold Rise-Day 141 (n=4,5,5)	75.0 (19.4 to 99.4)	40.0 (5.3 to 85.3)	0.0 (0.0 to 52.2)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 through Day 1095 (end of study)

Adverse event reporting additional description:

Safety Set included all randomized participants who received any study injection. Participants were included in the treatment arm corresponding to the study drug they actually received. Non-serious SARs persisting beyond 7 days, leading to discontinuation, or medically attended were not considered AEs unless they were serious.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Single Injection Placebo in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Reporting group title	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults

Reporting group description:

Participants received a single injection of Dose B of mRNA-1345 on Day 1.

Reporting group title	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)

Reporting group description:

Participants received a single injection of Dose B of mRNA-1345 on Day 1.

Reporting group title	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)

Reporting group description:

Participants received a single injection of Dose C of mRNA-1345 on Day 1.

Reporting group title	Two Injection Placebo in Older Adults (After 1st Dose)

Reporting group description:

Participants received 1 injection of mRNA-1345 matching-placebo on Day 1.

Reporting group title	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)

Reporting group description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Reporting group title	Single Injection Placebo in Younger Adults (18 to 49 Years)

Reporting group description:

Participants received a single injection of mRNA-1345 matching-placebo on Day 1.

Reporting group title	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)

Reporting group description:

Participants received a single injection of Dose A of mRNA-1345 on Day 1.

Reporting group title	Cohort 8: mRNA-1345 Dose B in Older Adults (After 1st Dose)

Reporting group description:

Participants received 1 injection of Dose B of mRNA-1345 on Day 1.

Reporting group title	Cohort 9: mRNA-1345 Dose C in Older Adults (After 1st Dose)

Reporting group description:

Participants received 1 injection of Dose C of mRNA-1345 on Day 1.

Reporting group title	Cohort 11: mRNA-1345 Dose F in Older Adults (After 1st Dose)

Reporting group description:

Participants received 1 injection of Dose F of mRNA-1345 on Day 1.

Reporting group title	Cohort 7: mRNA-1345 Dose A in Older Adults (After 1st Dose)

Reporting group description:

Participants received 1 injection of Dose A of mRNA-1345 on Day 1.

Reporting group title	Cohort 10: mRNA-1345 Dose E in Older Adults (After 1st Dose)

Reporting group description:

Participants received 1 injection of Dose E of mRNA-1345 on Day 1.

Reporting group title	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose F of mRNA-1345 on Day 1.

Reporting group title	Cohort 9: mRNA-1345 Dose C in Older Adults (After Month 12)

Reporting group description:

Participants received 1 injection of Dose C of mRNA-1345 approximately 12 months later.

Reporting group title	Cohort 8: mRNA-1345 Dose B in Older Adults (After Month 12)

Reporting group description:

Participants received 1 injection of Dose B of mRNA-1345 approximately 12 months later.

Reporting group title	Cohort 7: mRNA-1345 Dose A in Older Adults (After Month 12)

Reporting group description:

Participants received 1 injection of Dose A of mRNA-1345 approximately 12 months later.

Reporting group title	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose E of mRNA-1345 on Day 1.

Reporting group title	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)

Reporting group description:

Participants received a single injection of Dose A of mRNA-1345 on Day 1.

Reporting group title	Three Injection Placebo in Younger Adults (18 to 49 Years)

Reporting group description:

Participants received a total of 3 injections, 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.

Reporting group title	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)

Reporting group description:

Participants received a total of 3 injections, 1 injection of Dose B of mRNA-1345 per day on Day 1, Day 57, and Day 113.

Reporting group title	Three Injection Placebo in Children (12 to 59 Months)

Reporting group description:

Participants received a total of 3 injections, 1 injection of mRNA-1345 matching-placebo per day on Day 1, Day 57, and Day 113.

Reporting group title	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)

Reporting group description:

Participants received a total of 3 injections, 1 injection of Dose G of mRNA-1345 per day on Day 1, Day 57, and Day 113.

Reporting group title	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)

Reporting group description:

Participants received a total of 3 injections, 1 injection of Dose D of mRNA-1345 per day on Day 1, Day 57, and Day 113.

Reporting group title	Cohort 11: mRNA-1345 Dose F in Older Adults (After Month 12)

Reporting group description:

Participants received 1 injection of Dose F of mRNA-1345 approximately 12 months later.

Reporting group title	Two Injection Placebo in Older Adults (After Month 12)

Reporting group description:

Participants received 1 injection of mRNA-1345 matching-placebo approximately 12 months later.

Reporting group title	Cohort 10: mRNA-1345 Dose E in Older Adults (After Month 12)

Reporting group description:

Participants received 1 injection of Dose E of mRNA-1345 approximately 12 months later.

Reporting group title	Older Adult Cohorts: After Month 24: mRNA-1345 Dose A

Reporting group description:

Participants received second booster injection of Dose A of mRNA-1345 at Month 24.

Serious adverse events	Single Injection Placebo in WOCBP (18 to 40 Years)	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			

subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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 arrest			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			

subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			

Papilloedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			
Pancreatitis acute			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			
Appendicitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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 perforated			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
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	Cohort 4: mRNA-	Two Injection	Single Injection

	1345 Dose C in Younger Adults (18 to 49 Years)	Placebo in Older Adults (After 1st Dose)	Placebo in Japanese Older Adults (≥ 60 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			

subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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 arrest			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Pancreatitis acute			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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 perforated			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
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	Single Injection Placebo in Younger Adults (18 to 49 Years)	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (After 1st Dose)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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 arrest			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Hospitalisation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Pancreatitis acute			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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 perforated			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
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	Cohort 9: mRNA-1345 Dose C in Older Adults (After 1st Dose)	Cohort 11: mRNA-1345 Dose F in Older Adults (After 1st Dose)	Cohort 7: mRNA-1345 Dose A in Older Adults (After 1st Dose)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 48 (2.08%)	5 / 48 (10.42%)	4 / 47 (8.51%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (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
Periprosthetic fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Hospitalisation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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			
Pancreatitis acute			

subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (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			
Arthropathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (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
COVID-19			

subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (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
Intervertebral discitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (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
Localised infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
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	Cohort 10: mRNA-1345 Dose E in Older Adults (After 1st Dose)	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (After Month 12)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 48 (6.25%)	1 / 51 (1.96%)	0 / 19 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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			
Concussion			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (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
Pelvic fracture			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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 arrest			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Hospitalisation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (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
Vertebral artery occlusion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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			
Pancreatitis acute			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (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
Reproductive system and breast disorders			
Pelvic organ prolapse			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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 perforated			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
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	Cohort 8: mRNA-1345 Dose B in Older Adults (After Month 12)	Cohort 7: mRNA-1345 Dose A in Older Adults (After Month 12)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 18 (5.56%)	1 / 18 (5.56%)	0 / 49 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (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 arrest			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Hospitalisation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	1 / 18 (5.56%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Pancreatitis acute			

subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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 perforated			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
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	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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 arrest			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Hospitalisation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Pancreatitis acute			

subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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 perforated			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
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	Three Injection Placebo in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 arrest			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Hospitalisation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Headache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Pancreatitis acute			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 perforated			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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	Cohort 11: mRNA-1345 Dose F in Older Adults (After Month 12)	Two Injection Placebo in Older Adults (After Month 12)	Cohort 10: mRNA-1345 Dose E in Older Adults (After Month 12)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 22 (4.55%)	7 / 148 (4.73%)	2 / 22 (9.09%)
number of deaths (all causes)	0	3	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	1 / 22 (4.55%)	0 / 148 (0.00%)	0 / 22 (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			
Concussion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (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
Gun shot wound			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Hospitalisation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery occlusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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			
Papilloedema			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (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			
Pancreatitis acute			

subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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			
Pelvic organ prolapse			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (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
Spinal stenosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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 perforated			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (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			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
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	Older Adult Cohorts: After Month 24: mRNA-1345 Dose A		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 109 (4.59%)		
number of deaths (all causes)	1		
number of deaths resulting from			

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone sarcoma			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gun shot wound			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periprosthetic fracture			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			

subjects affected / exposed	0 / 109 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Bradycardia				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Sinus bradycardia				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				

Hospitalisation			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebral artery occlusion			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Pancreatitis acute			

subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Pelvic organ prolapse			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal stenosis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			

subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral discitis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Localised infection			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Single Injection Placebo in WOCBP (18 to 40 Years)	Cohort 15: mRNA-1345 Dose B in Japanese Older Adults	Cohort 2: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 30 (23.33%)	1 / 21 (4.76%)	0 / 20 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Arthropod bite			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Radial head dislocation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Morton's neuralgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			

subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Toothache			

subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Splinter haemorrhages			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Osteoporosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Trigger finger			

subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Adenovirus infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bordetella infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 30 (3.33%)	1 / 21 (4.76%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Ear infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Eye infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Parainfluenzae virus infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 21 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 4: mRNA-1345 Dose C in Younger Adults (18 to 49 Years)	Two Injection Placebo in Older Adults (After 1st Dose)	Single Injection Placebo in Japanese Older Adults (≥ 60 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 20 (65.00%)	14 / 59 (23.73%)	2 / 4 (50.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 20 (5.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Injection site erythema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pyrexia			

subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vaccination site pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 20 (10.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radial head dislocation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			

subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 20 (10.00%)	0 / 59 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	1
Migraine			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Morton's neuralgia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	2 / 20 (10.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Large intestine polyp			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Angioedema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Nail dystrophy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Splinter haemorrhages			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urticaria papular			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 20 (5.00%)	3 / 59 (5.08%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Arthritis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 20 (0.00%)	2 / 59 (3.39%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Osteoporosis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Trigger finger			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Adenovirus infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bordetella infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Coronavirus infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 20 (0.00%)	2 / 59 (3.39%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Ear infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	2 / 20 (10.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Onychomycosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 20 (5.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Tonsillitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 59 (1.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 20 (0.00%)	0 / 59 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Single Injection Placebo in Younger Adults (18 to 49 Years)	Cohort 1: mRNA-1345 Dose A in Younger Adults (18 to 49 Years)	Cohort 8: mRNA-1345 Dose B in Older Adults (After 1st Dose)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 15 (33.33%)	2 / 19 (10.53%)	15 / 48 (31.25%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	4 / 48 (8.33%)
occurrences (all)	0	0	4
Injection site erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 15 (0.00%)	2 / 19 (10.53%)	1 / 48 (2.08%)
occurrences (all)	0	2	1
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Limb injury			

subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Radial head dislocation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Upper limb fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 15 (26.67%)	0 / 19 (0.00%)	3 / 48 (6.25%)
occurrences (all)	6	0	3
Migraine			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Morton's neuralgia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Sensory disturbance			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Angioedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Splinter haemorrhages			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Basedow's disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Arthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	3 / 48 (6.25%)
occurrences (all)	0	0	4
Osteoarthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Osteoporosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Adenovirus infection			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bordetella infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Onychomycosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

Type 2 diabetes mellitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 15 (0.00%)	0 / 19 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 9: mRNA-1345 Dose C in Older Adults (After 1st Dose)	Cohort 11: mRNA-1345 Dose F in Older Adults (After 1st Dose)	Cohort 7: mRNA-1345 Dose A in Older Adults (After 1st Dose)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 48 (47.92%)	19 / 48 (39.58%)	17 / 47 (36.17%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 48 (4.17%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	2	2	0
Injection site erythema			
subjects affected / exposed	1 / 48 (2.08%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Injection site pain			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
Dyspnoea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Respiratory tract congestion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	1 / 47 (2.13%)
occurrences (all)	0	1	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 48 (4.17%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Investigations			

Blood pressure increased			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Radial head dislocation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
Upper limb fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 48 (0.00%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	0	2	0

Migraine			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Morton's neuralgia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Large intestine polyp			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Teething			

subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	1 / 48 (2.08%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	1	2	0
Ecchymosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Solar lentigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Splinter haemorrhages			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	2 / 48 (4.17%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 48 (8.33%)	3 / 48 (6.25%)	2 / 47 (4.26%)
occurrences (all)	4	4	2
Arthritis			
subjects affected / exposed	2 / 48 (4.17%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	2	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	2
Osteoarthritis			

subjects affected / exposed	2 / 48 (4.17%)	1 / 48 (2.08%)	1 / 47 (2.13%)
occurrences (all)	2	1	1
Osteoporosis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Trigger finger			
subjects affected / exposed	3 / 48 (6.25%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	3	0	1
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Adenovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Bordetella infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	3 / 48 (6.25%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	3	1	0
Coronavirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	3 / 48 (6.25%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	3	0	1

Ear infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Croup infectious			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 48 (2.08%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	2	2	0
Onychomycosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 48 (0.00%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	2 / 48 (4.17%)	0 / 48 (0.00%)	1 / 47 (2.13%)
occurrences (all)	2	0	1

Viral upper respiratory tract infection			
subjects affected / exposed	1 / 48 (2.08%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 48 (2.08%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences (all)	1	1	0
Hyperlipidaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 48 (0.00%)	2 / 48 (4.17%)	0 / 47 (0.00%)
occurrences (all)	0	2	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 48 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 10: mRNA-1345 Dose E in Older Adults (After 1st Dose)	Cohort 12: mRNA-1345 Dose F in WOCBP (18 to 40 Years)	Cohort 9: mRNA-1345 Dose C in Older Adults (After Month 12)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 48 (31.25%)	8 / 51 (15.69%)	10 / 19 (52.63%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Injection site erythema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Injection site pain			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 48 (2.08%)	2 / 51 (3.92%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Oppositional defiant disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Meniscus injury			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Limb injury			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Radial head dislocation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Skin laceration			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Morton's neuralgia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Large intestine polyp			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Ecchymosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Splinter haemorrhages			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	3 / 48 (6.25%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Arthritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Osteoarthritis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Osteoporosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bordetella infection			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	3 / 48 (6.25%)	2 / 51 (3.92%)	1 / 19 (5.26%)
occurrences (all)	3	2	1
Ear infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 48 (4.17%)	2 / 51 (3.92%)	0 / 19 (0.00%)
occurrences (all)	2	2	0
Tonsillitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 8: mRNA-1345 Dose B in Older Adults (After Month 12)	Cohort 7: mRNA-1345 Dose A in Older Adults (After Month 12)	Cohort 13: mRNA-1345 Dose E in WOCBP (18 to 40 Years)

Total subjects affected by non-serious adverse events subjects affected / exposed	8 / 18 (44.44%)	7 / 18 (38.89%)	13 / 49 (26.53%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Melanocytic naevus subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 18 (5.56%) 1	0 / 49 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 18 (0.00%) 0	0 / 49 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 18 (5.56%) 1	0 / 49 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 18 (0.00%) 0	0 / 49 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 18 (0.00%) 0	0 / 49 (0.00%) 0
Vaccination site pain subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 18 (0.00%) 0	0 / 49 (0.00%) 0
Vessel puncture site bruise subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	1 / 18 (5.56%) 1	0 / 49 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	1 / 18 (5.56%) 1	0 / 18 (0.00%) 0	0 / 49 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 18 (0.00%) 0	0 / 49 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	0 / 18 (0.00%) 0	0 / 18 (0.00%) 0	0 / 49 (0.00%) 0

Bronchospasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Oppositional defiant disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 18 (5.56%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Meniscus injury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Radial head dislocation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	1 / 18 (5.56%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Morton's neuralgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Nail dystrophy			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 18 (5.56%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Solar lentigo			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Splinter haemorrhages			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1

Urticaria papular			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Osteoarthritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Trigger finger			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Acute sinusitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Adenovirus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bordetella infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 18 (5.56%)	2 / 18 (11.11%)	4 / 49 (8.16%)
occurrences (all)	1	2	4
Ear infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Otitis media acute			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
Tonsillitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 18 (11.11%)	0 / 18 (0.00%)	1 / 49 (2.04%)
occurrences (all)	2	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Hyperlipidaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)	1 / 18 (5.56%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 18 (5.56%)	0 / 18 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Cohort 14: mRNA-1345 Dose A in WOCBP (18 to 40 Years)	Three Injection Placebo in Younger Adults (18 to 49 Years)	Cohort 3: mRNA-1345 Dose B in Younger Adults (18 to 49 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 48 (14.58%)	0 / 5 (0.00%)	5 / 20 (25.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Injection site pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			

subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			

subjects affected / exposed	1 / 48 (2.08%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Radial head dislocation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Upper limb fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Palpitations			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Migraine			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Morton's neuralgia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 48 (2.08%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			

subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Teething			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Splinter haemorrhages			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Arthritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bordetella infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Coronavirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	4 / 48 (8.33%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
Ear infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Onychomycosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 48 (0.00%)	0 / 5 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Three Injection Placebo in Children (12 to 59 Months)	Cohort 6: mRNA-1345 Dose G in Children (12 to 59 Months)	Cohort 5: mRNA-1345 Dose D in Children (12 to 59 Months)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 15 (60.00%)	11 / 15 (73.33%)	7 / 15 (46.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vaccination site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vessel puncture site bruise			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Drug hypersensitivity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	4	2	0
Bronchospasm			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	2	3
Dyspnoea			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Radial head dislocation			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Morton's neuralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vertigo			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Large intestine polyp			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tooth disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Angioedema			

subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Skin lesion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Splinter haemorrhages			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Urticaria papular			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Hyperthyroidism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Adenovirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Appendicitis			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Asymptomatic COVID-19			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bordetella infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Bronchiolitis			
subjects affected / exposed	1 / 15 (6.67%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Ear infection			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Croup infectious			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Eye infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Impetigo			

subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 15 (6.67%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Metapneumovirus infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	2 / 15 (13.33%)	3 / 15 (20.00%)	2 / 15 (13.33%)
occurrences (all)	3	3	2
Parainfluenzae virus infection			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Otitis media acute			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			

subjects affected / exposed	2 / 15 (13.33%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Respiratory tract infection viral			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Rhinovirus infection			
subjects affected / exposed	3 / 15 (20.00%)	1 / 15 (6.67%)	3 / 15 (20.00%)
occurrences (all)	5	1	3
Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 15 (6.67%)	3 / 15 (20.00%)	1 / 15 (6.67%)
occurrences (all)	2	3	1
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 15 (6.67%)	4 / 15 (26.67%)	0 / 15 (0.00%)
occurrences (all)	9	13	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Vitamin B12 deficiency			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 11: mRNA-1345 Dose F in Older Adults (After Month 12)	Two Injection Placebo in Older Adults (After Month 12)	Cohort 10: mRNA-1345 Dose E in Older Adults (After Month 12)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 22 (36.36%)	43 / 148 (29.05%)	8 / 22 (36.36%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 22 (0.00%)	3 / 148 (2.03%)	1 / 22 (4.55%)
occurrences (all)	0	3	1
Injection site erythema			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			

subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural			

complications			
Concussion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Radial head dislocation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Upper limb fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 22 (0.00%)	2 / 148 (1.35%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 22 (0.00%)	3 / 148 (2.03%)	1 / 22 (4.55%)
occurrences (all)	0	3	1
Migraine			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Morton's neuralgia			

subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 22 (0.00%)	2 / 148 (1.35%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Teething			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			

subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nail dystrophy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Solar lentigo			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Splinter haemorrhages			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Urticaria papular			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	2 / 22 (9.09%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 22 (0.00%)	5 / 148 (3.38%)	0 / 22 (0.00%)
occurrences (all)	0	5	0
Arthritis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 22 (0.00%)	2 / 148 (1.35%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
Osteoarthritis			
subjects affected / exposed	2 / 22 (9.09%)	1 / 148 (0.68%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
Osteoporosis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Trigger finger			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Asymptomatic COVID-19			
subjects affected / exposed	2 / 22 (9.09%)	4 / 148 (2.70%)	0 / 22 (0.00%)
occurrences (all)	2	4	0
Bordetella infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Coronavirus infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 22 (4.55%)	10 / 148 (6.76%)	2 / 22 (9.09%)
occurrences (all)	1	10	2
Ear infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Croup infectious			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HCoV-OC43 infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Metapneumovirus infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Oral fungal infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)	2 / 148 (1.35%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)	3 / 148 (2.03%)	2 / 22 (9.09%)
occurrences (all)	0	3	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0

Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 148 (0.68%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Hyperlipidaemia			
subjects affected / exposed	0 / 22 (0.00%)	2 / 148 (1.35%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 22 (0.00%)	3 / 148 (2.03%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 22 (0.00%)	0 / 148 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Older Adult Cohorts: After Month 24: mRNA-1345 Dose A		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 109 (21.10%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 109 (2.75%)		
occurrences (all)	3		
Injection site erythema			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Pyrexia			

subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Vaccination site pain subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Vessel puncture site bruise subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Bronchospasm subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Cough subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Dyspnoea subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Respiratory tract congestion subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Oppositional defiant disorder			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Meniscus injury			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Radial head dislocation			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Skin laceration			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Upper limb fracture			

subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Morton's neuralgia			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Sensory disturbance			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Diarrhoea			

subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Large intestine polyp			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Teething			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Tooth disorder			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	2 / 109 (1.83%)		
occurrences (all)	2		
Angioedema			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Dermatitis atopic			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		

Nail dystrophy subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Skin lesion subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Solar lentigo subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Splinter haemorrhages subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Urticaria subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Urticaria papular subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Endocrine disorders Basedow's disease subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Arthritis			

subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Osteoarthritis			
subjects affected / exposed	1 / 109 (0.92%)		
occurrences (all)	1		
Osteoporosis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Trigger finger			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Adenovirus infection			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Appendicitis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Asymptomatic COVID-19			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Bordetella infection			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
subjects affected / exposed	0 / 109 (0.00%)		
occurrences (all)	0		

Bronchitis				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Coronavirus infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
COVID-19				
subjects affected / exposed	2 / 109 (1.83%)			
occurrences (all)	2			
Ear infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Croup infectious				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Eye infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Impetigo				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
HCoV-OC43 infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Metapneumovirus infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			

Nasopharyngitis				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Onychomycosis				
subjects affected / exposed	1 / 109 (0.92%)			
occurrences (all)	1			
Oral fungal infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Otitis media acute				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Pharyngitis streptococcal				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Rhinovirus infection				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 109 (0.00%)			
occurrences (all)	0			

Tonsillitis subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2		
Urinary tract infection subjects affected / exposed occurrences (all)	4 / 109 (3.67%) 4		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		
Hyperlipidaemia subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2		
Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1		
Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 November 2020	This amendment was issued to add 3 cohorts (mRNA-1345 or placebo [Cohort 7 to 9]) of healthy adults of 65 to 79 years of age in order to establish the dose in this population. Additionally, the age range of participants in the pediatric cohorts was increased to 12 to 59 months in order to increase the potential pool of seropositive children in the study.
21 April 2021	This amendment was issued to add 2 cohorts of adults aged 65 to 79 to receive mRNA-1345 or placebo (Cohort 10 and 11) and to include a WOCBP population to enable future studies to address RSV disease in neonates (Cohort 12, Cohort 13, and Cohort 14).
27 August 2021	This amendment was issued to include adults of Japanese descent aged 60 years or older (Cohort 15) in order to expand the population and to enable subsequent late-stage clinical studies in Japan.
06 December 2021	This amendment updated dosing in Cohort 6 and participant numbers in Cohorts 5 and 6.
22 February 2023	This amendment was issued to add a second booster injection of mRNA-1345 for Cohorts 7 to 11, 24 months after receiving the primary injection, which allowed for an evaluation of the benefit of a second booster in the older adult population and assessed its impact on waning antibody titers and the durability of conferred immune protection.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported