

Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11412)	Total (N=22830)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects									
Received First Injection	11418 (100)	11412 (100)	22830 (100)	3752 (100)	3768 (100)	7520 (100)	15170 (100)	15180 (100)	30350 (100)
Received Second Injection	10348 (90.6)	10382 (91.0)	20730 (90.8)	3568 (95.1)	3600 (95.5)	7168 (95.3)	13916 (91.7)	13982 (92.1)	27898 (91.9)
Discontinued Study Vaccine	201 (1.8)	154 (1.3)	355 (1.6)	40 (1.1)	26 (0.7)	66 (0.9)	241 (1.6)	180 (1.2)	421 (1.4)
Reason for Discontinuation of Study Vaccine									
Adverse Event	24 (0.2)	18 (0.2)	42 (0.2)	4 (0.1)	5 (0.1)	9 (0.1)	28 (0.2)	23 (0.2)	51 (0.2)
Serious Adverse Event	6 (<0.1)	3 (<0.1)	9 (<0.1)	8 (0.2)	2 (<0.1)	10 (0.1)	14 (<0.1)	5 (<0.1)	19 (<0.1)
Death	1 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lost to Follow-Up	20 (0.2)	18 (0.2)	38 (0.2)	0 (0.2)	0 (<0.1)	0 (<0.1)	20 (0.1)	18 (0.1)	38 (0.1)
Physician Decision	8 (<0.1)	12 (0.1)	20 (<0.1)	0 (<0.1)	2 (<0.1)	2 (<0.1)	8 (<0.1)	14 (<0.1)	22 (<0.1)
Pregnancy	2 (<0.1)	2 (<0.1)	4 (<0.1)	0 (<0.1)	0 (<0.1)	0 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Protocol Deviation	3 (<0.1)	2 (<0.1)	5 (<0.1)	1 (<0.1)	0 (<0.1)	1 (<0.1)	4 (<0.1)	2 (<0.1)	6 (<0.1)

Percentages are based on the number of subjects in Full Analysis Set.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	(N=11418)	(N=11412)	(N=22830)	(N=3752)	(N=3768)	(N=7520)	(N=15170)	(N=15180)	(N=30350)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	66 (0.6)	36 (0.3)	102 (0.4)	18 (0.5)	10 (0.3)	28 (0.4)	84 (0.6)	46 (0.3)	130 (0.4)
Due to SARS-CoV-2	45 (0.4)	31 (0.3)	76 (0.3)	4 (0.1)	4 (0.1)	8 (0.1)	49 (0.3)	35 (0.2)	84 (0.3)
Other	26 (0.2)	30 (0.3)	56 (0.2)	4 (0.1)	2 (<0.1)	6 (<0.1)	30 (0.2)	32 (0.2)	62 (0.2)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	124 (1.1)	96 (0.8)	220 (1.0)	28 (0.7)	15 (0.4)	43 (0.6)	152 (1.0)	111 (0.7)	263 (0.9)
Reason for Discontinuation of Study									
Adverse Event	0	0	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)
Serious Adverse Event	0	0	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)

Percentages are based on the number of subjects in Full Analysis Set.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	(N=11418)	(N=11412)	(N=22830)	(N=3752)	(N=3768)	(N=7520)	(N=15170)	(N=15180)	(N=30350)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Reason for Discontinuation of Study (Cont.)									
Death	1 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	4 (<0.1)	3 (<0.1)	7 (<0.1)
Lost to Follow-Up	31 (0.3)	20 (0.2)	51 (0.2)	0	0	0	31 (0.2)	20 (0.1)	51 (0.2)
Physician Decision	1 (<0.1)	15 (0.1)	16 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	16 (0.1)	17 (<0.1)
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol Deviation	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	88 (0.8)	53 (0.5)	141 (0.6)	24 (0.6)	11 (0.3)	35 (0.5)	112 (0.7)	64 (0.4)	176 (0.6)
Other	3 (<0.1)	5 (<0.1)	8 (<0.1)	1 (<0.1)	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)

Percentages are based on the number of subjects in Full Analysis Set.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	(N=10384)	(N=10407)	(N=20791)	(N=3499)	(N=3527)	(N=7026)	(N=13883)	(N=13934)	(N=27817)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects									
Received First Injection	10384 (100)	10407 (100)	20791 (100)	3499 (100)	3527 (100)	7026 (100)	13883 (100)	13934 (100)	27817 (100)
Received Second Injection	9757 (94.0)	9789 (94.1)	19546 (94.0)	3407 (97.4)	3429 (97.2)	6836 (97.3)	13164 (94.8)	13218 (94.9)	26382 (94.8)
Discontinued Study Vaccine	0	0	0	0	0	0	0	0	0
Reason for Discontinuation of Study Vaccine									
Adverse Event	0	0	0	0	0	0	0	0	0
Serious Adverse Event	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0
Lost to Follow-Up	0	0	0	0	0	0	0	0	0
Physician Decision	0	0	0	0	0	0	0	0	0
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol Deviation	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	(N=10384)	(N=10407)	(N=20791)	(N=3499)	(N=3527)	(N=7026)	(N=13883)	(N=13934)	(N=27817)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	0	0	0	0	0	0	0	0	0
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	28 (0.3)	24 (0.2)	52 (0.3)	6 (0.2)	0	6 (<0.1)	34 (0.2)	24 (0.2)	58 (0.2)
Reason for Discontinuation of Study									
Adverse Event	0	0	0	0	0	0	0	0	0
Serious Adverse Event	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	(N=10384)	(N=10407)	(N=20791)	(N=3499)	(N=3527)	(N=7026)	(N=13883)	(N=13934)	(N=27817)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Reason for Discontinuation of Study (Cont.)									
Death	0	0	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Lost to Follow-Up	9 (<0.1)	2 (<0.1)	11 (<0.1)	0	0	0	9 (<0.1)	2 (<0.1)	11 (<0.1)
Physician Decision	0	2 (<0.1)	2 (<0.1)	0	0	0	0	2 (<0.1)	2 (<0.1)
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol Deviation	0	0	0	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	18 (0.2)	18 (0.2)	36 (0.2)	4 (0.1)	0	4 (<0.1)	22 (0.2)	18 (0.1)	40 (0.1)
Other	1 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)

Percentages are based on the number of subjects in Per-Protocol Set.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Age at Screening (Years)			
n	15170	15180	30350
Mean (SD)	51.3 (15.60)	51.4 (15.50)	51.4 (15.55)
Median	52.0	53.0	52.0
Min, Max	18, 95	18, 95	18, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	11418 (75.3)	11412 (75.2)	22830 (75.2)
>=65 Years	3752 (24.7)	3768 (24.8)	7520 (24.8)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11418 (75.3)	11412 (75.2)	22830 (75.2)
>=65 and <70 Years	1817 (12.0)	1905 (12.5)	3722 (12.3)
>=70 and <75 Years	1194 (7.9)	1204 (7.9)	2398 (7.9)
>=75 and <80 Years	507 (3.3)	468 (3.1)	975 (3.2)
>=80 Years	234 (1.5)	191 (1.3)	425 (1.4)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11418 (75.3)	11412 (75.2)	22830 (75.2)
>=65 and <75 Years	3011 (19.8)	3109 (20.5)	6120 (20.2)
>=75 and <85 Years	692 (4.6)	618 (4.1)	1310 (4.3)
>=85 Years	49 (0.3)	41 (0.3)	90 (0.3)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8886 (58.6)	8887 (58.5)	17773 (58.6)
>=18 and <65 Years and at Risk	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	3749 (24.7)	3763 (24.8)	7512 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	741 (4.9)	707 (4.7)	1448 (4.8)
Significant Cardiac Disease	741 (4.9)	742 (4.9)	1483 (4.9)
Severe Obesity	978 (6.4)	986 (6.5)	1964 (6.5)
Diabetes	1431 (9.4)	1427 (9.4)	2858 (9.4)
Liver Disease	96 (0.6)	100 (0.7)	196 (0.6)
Human Immunodeficiency Virus Infection	86 (0.6)	90 (0.6)	176 (0.6)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	3382 (22.3)	3360 (22.1)	6742 (22.2)
No	11788 (77.7)	11820 (77.9)	23608 (77.8)
Baseline RT-PCR Results, n (%)			
Negative	14880 (98.1)	14879 (98.0)	29759 (98.1)
Positive	95 (0.6)	87 (0.6)	182 (0.6)
Missing	195 (1.3)	214 (1.4)	409 (1.3)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	14510 (95.6)	14463 (95.3)	28973 (95.5)
Positive	299 (2.0)	303 (2.0)	602 (2.0)
Missing	361 (2.4)	414 (2.7)	775 (2.6)
Baseline SARS-CoV-2 Status, n (%) [3]			
Negative	14370 (94.7)	14312 (94.3)	28682 (94.5)
Positive	334 (2.2)	341 (2.2)	675 (2.2)
Missing	466 (3.1)	527 (3.5)	993 (3.3)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Sex, n (%)			
Male	8067 (53.2)	7928 (52.2)	15995 (52.7)
Female	7103 (46.8)	7252 (47.8)	14355 (47.3)
Race, n (%)			
White	11994 (79.1)	12029 (79.2)	24023 (79.2)
Black or African American	1528 (10.1)	1562 (10.3)	3090 (10.2)
Asian	732 (4.8)	653 (4.3)	1385 (4.6)
American Indian or Alaska Native	120 (0.8)	110 (0.7)	230 (0.8)
Native Hawaiian or Other Pacific Islander	32 (0.2)	34 (0.2)	66 (0.2)
Multiracial	320 (2.1)	314 (2.1)	634 (2.1)
Other	315 (2.1)	321 (2.1)	636 (2.1)
Not Reported	75 (0.5)	99 (0.7)	174 (0.6)
Unknown	54 (0.4)	58 (0.4)	112 (0.4)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Ethnicity, n (%)			
Hispanic or Latino	3114 (20.5)	3120 (20.6)	6234 (20.5)
Not Hispanic or Latino	11917 (78.6)	11917 (78.5)	23834 (78.5)
Not Reported	84 (0.6)	104 (0.7)	188 (0.6)
Unknown	55 (0.4)	39 (0.3)	94 (0.3)
Race and Ethnicity Group, n (%) [4]			
Minority	4632 (30.5)	4644 (30.6)	9276 (30.6)
Non-minority	10511 (69.3)	10510 (69.2)	21021 (69.3)
Missing	27 (0.2)	26 (0.2)	53 (0.2)
Race and Ethnicity Group, n (%) [5]			
White	9460 (62.4)	9532 (62.8)	18992 (62.6)
Communities of Color	5683 (37.5)	5622 (37.0)	11305 (37.2)
Missing	27 (0.2)	26 (0.2)	53 (0.2)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Weight (kg)			
n	14957	14948	29905
Mean (SD)	85.85 (21.642)	85.68 (21.982)	85.76 (21.812)
Median	83.00	83.00	83.00
Min, Max	3.5, 223.0	30.3, 236.4	3.5, 236.4
Height (cm)			
n	14957	14948	29905
Mean (SD)	170.88 (10.068)	170.71 (9.935)	170.80 (10.002)
Median	170.50	170.18	170.20
Min, Max	110.6, 223.5	104.1, 208.5	104.1, 223.5

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Body Mass Index (kg/m ²)			
n	14955	14944	29899
Mean (SD)	29.32 (6.710)	29.32 (6.866)	29.32 (6.788)
Median	28.12	28.12	28.12
Min, Max	1.5, 87.3	10.5, 86.1	1.5, 87.3

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Occupational Risk, n (%) [2]	12491 (82.3)	12416 (81.8)	24907 (82.1)
Healthcare Workers	3829 (25.2)	3784 (24.9)	7613 (25.1)
Emergency Response	297 (2.0)	303 (2.0)	600 (2.0)
Retail or Restaurant Operations	971 (6.4)	954 (6.3)	1925 (6.3)
Manufacturing and Production Operations	420 (2.8)	426 (2.8)	846 (2.8)
Warehouse Shipping and Fulfillment Centers	174 (1.1)	193 (1.3)	367 (1.2)
Transportation and Delivery Services	473 (3.1)	485 (3.2)	958 (3.2)
Border Protection and Military Personnel	68 (0.4)	69 (0.5)	137 (0.5)
Personal Care and In-Home Services	470 (3.1)	469 (3.1)	939 (3.1)
Hospitality and Tourism Workers	233 (1.5)	238 (1.6)	471 (1.6)
Pastoral, Social or Public Health Workers	501 (3.3)	535 (3.5)	1036 (3.4)
Educators and Students	1546 (10.2)	1540 (10.1)	3086 (10.2)
Other	4797 (31.6)	4807 (31.7)	9604 (31.6)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15170)	mRNA-1273 (N=15180)	Total (N=30350)
Location and Living Circumstances Risk, n (%) [2]	12573 (82.9)	12599 (83.0)	25172 (82.9)
Resides in Nursing Home or Assisted Living Facility	29 (0.2)	33 (0.2)	62 (0.2)
Resides in Multi-Family Dwelling	408 (2.7)	462 (3.0)	870 (2.9)
Resides in High Density Housing	1304 (8.6)	1282 (8.4)	2586 (8.5)
Resides in Low Density, Multi-Family Setting	1475 (9.7)	1470 (9.7)	2945 (9.7)
Resides in a Single Family Home	8311 (54.8)	8288 (54.6)	16599 (54.7)
Other	2166 (14.3)	2184 (14.4)	4350 (14.3)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Age at Screening (Years)			
n	8886	8887	17773
Mean (SD)	43.8 (12.33)	44.0 (12.39)	43.9 (12.36)
Median	44.0	44.0	44.0
Min, Max	18, 72	18, 64	18, 72
Age Group at Screening, n (%)			
>=18 and <65 Years	8885 (>99.9)	8887 (100)	17772 (>99.9)
>=65 Years	1 (<0.1)	0	1 (<0.1)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8885 (>99.9)	8887 (100)	17772 (>99.9)
>=65 and <70 Years	0	0	0
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Age Subgroup at Screening, n (%)			
≥ 18 and < 65 Years	8885 (>99.9)	8887 (100)	17772 (>99.9)
≥ 65 and < 75 Years	1 (<0.1)	0	1 (<0.1)
≥ 75 and < 85 Years	0	0	0
≥ 85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
≥ 18 and < 65 Years and Not at Risk	8886 (100)	8887 (100)	17773 (100)
≥ 18 and < 65 Years and at Risk	0	0	0
≥ 65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	17 (0.2)	18 (0.2)	35 (0.2)
Significant Cardiac Disease	11 (0.1)	10 (0.1)	21 (0.1)
Severe Obesity	64 (0.7)	55 (0.6)	119 (0.7)
Diabetes	33 (0.4)	32 (0.4)	65 (0.4)
Liver Disease	8 (<0.1)	5 (<0.1)	13 (<0.1)
Human Immunodeficiency Virus Infection	13 (0.1)	13 (0.1)	26 (0.1)

Percentages are based on the number of subjects in Full Analysis Set.

[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.

[2] Subjects could be under one or more categories, and are counted once at each category.

[3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	136 (1.5)	120 (1.4)	256 (1.4)
No	8750 (98.5)	8767 (98.6)	17517 (98.6)
Baseline RT-PCR Results, n (%)			
Negative	8731 (98.3)	8702 (97.9)	17433 (98.1)
Positive	65 (0.7)	64 (0.7)	129 (0.7)
Missing	90 (1.0)	121 (1.4)	211 (1.2)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	8488 (95.5)	8442 (95.0)	16930 (95.3)
Positive	214 (2.4)	229 (2.6)	443 (2.5)
Missing	184 (2.1)	216 (2.4)	400 (2.3)
Baseline SARS-CoV-2 Status, n (%) [3]			
Negative	8418 (94.7)	8346 (93.9)	16764 (94.3)
Positive	238 (2.7)	259 (2.9)	497 (2.8)
Missing	230 (2.6)	282 (3.2)	512 (2.9)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Sex, n (%)			
Male	4635 (52.2)	4547 (51.2)	9182 (51.7)
Female	4251 (47.8)	4340 (48.8)	8591 (48.3)
Race, n (%)			
White	6787 (76.4)	6757 (76.0)	13544 (76.2)
Black or African American	899 (10.1)	967 (10.9)	1866 (10.5)
Asian	571 (6.4)	502 (5.6)	1073 (6.0)
American Indian or Alaska Native	72 (0.8)	64 (0.7)	136 (0.8)
Native Hawaiian or Other Pacific Islander	20 (0.2)	24 (0.3)	44 (0.2)
Multiracial	231 (2.6)	230 (2.6)	461 (2.6)
Other	229 (2.6)	233 (2.6)	462 (2.6)
Not Reported	44 (0.5)	69 (0.8)	113 (0.6)
Unknown	33 (0.4)	41 (0.5)	74 (0.4)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Ethnicity, n (%)			
Hispanic or Latino	2228 (25.1)	2208 (24.8)	4436 (25.0)
Not Hispanic or Latino	6584 (74.1)	6600 (74.3)	13184 (74.2)
Not Reported	43 (0.5)	57 (0.6)	100 (0.6)
Unknown	31 (0.3)	22 (0.2)	53 (0.3)
Race and Ethnicity Group, n (%) [4]			
Minority	3104 (34.9)	3140 (35.3)	6244 (35.1)
Non-minority	5773 (65.0)	5733 (64.5)	11506 (64.7)
Missing	9 (0.1)	14 (0.2)	23 (0.1)
Race and Ethnicity Group, n (%) [5]			
White	4973 (56.0)	5008 (56.4)	9981 (56.2)
Communities of Color	3904 (43.9)	3865 (43.5)	7769 (43.7)
Missing	9 (0.1)	14 (0.2)	23 (0.1)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Weight (kg)			
n	8754	8750	17504
Mean (SD)	82.26 (18.034)	81.96 (18.178)	82.11 (18.106)
Median	80.80	80.45	80.64
Min, Max	30.6,182.4	32.2,178.7	30.6,182.4
Height (cm)			
n	8755	8748	17503
Mean (SD)	171.24 (9.931)	171.02 (9.875)	171.13 (9.903)
Median	171.00	170.20	170.70
Min, Max	110.6,205.7	104.1,208.5	104.1,208.5

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Body Mass Index (kg/m ²)			
n	8754	8746	17500
Mean (SD)	27.95 (5.190)	27.91 (5.267)	27.93 (5.228)
Median	27.33	27.34	27.33
Min, Max	10.3, 87.3	10.5, 57.9	10.3, 87.3

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Occupational Risk, n (%) [2]	7953 (89.5)	7922 (89.1)	15875 (89.3)
Healthcare Workers	2732 (30.7)	2732 (30.7)	5464 (30.7)
Emergency Response	220 (2.5)	234 (2.6)	454 (2.6)
Retail or Restaurant Operations	687 (7.7)	683 (7.7)	1370 (7.7)
Manufacturing and Production Operations	305 (3.4)	290 (3.3)	595 (3.3)
Warehouse Shipping and Fulfillment Centers	120 (1.4)	140 (1.6)	260 (1.5)
Transportation and Delivery Services	314 (3.5)	337 (3.8)	651 (3.7)
Border Protection and Military Personnel	51 (0.6)	53 (0.6)	104 (0.6)
Personal Care and In-Home Services	331 (3.7)	299 (3.4)	630 (3.5)
Hospitality and Tourism Workers	149 (1.7)	164 (1.8)	313 (1.8)
Pastoral, Social or Public Health Workers	262 (2.9)	298 (3.4)	560 (3.2)
Educators and Students	1108 (12.5)	1081 (12.2)	2189 (12.3)
Other	2590 (29.1)	2575 (29.0)	5165 (29.1)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

	Placebo (N=8886)	mRNA-1273 (N=8887)	Total (N=17773)
Location and Living Circumstances Risk, n (%) [2]	7416 (83.5)	7453 (83.9)	14869 (83.7)
Resides in Nursing Home or Assisted Living Facility	6 (<0.1)	11 (0.1)	17 (<0.1)
Resides in Multi-Family Dwelling	265 (3.0)	304 (3.4)	569 (3.2)
Resides in High Density Housing	870 (9.8)	836 (9.4)	1706 (9.6)
Resides in Low Density, Multi-Family Setting	949 (10.7)	929 (10.5)	1878 (10.6)
Resides in a Single Family Home	4713 (53.0)	4748 (53.4)	9461 (53.2)
Other	1304 (14.7)	1320 (14.9)	2624 (14.8)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age at Screening (Years)			
n	2535	2530	5065
Mean (SD)	49.2 (11.28)	48.9 (11.40)	49.0 (11.34)
Median	51.0	51.0	51.0
Min, Max	18, 79	18, 76	18, 79
Age Group at Screening, n (%)			
≥ 18 and < 65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
≥ 65 Years	3 (0.1)	6 (0.2)	9 (0.2)
Age Subgroup at Screening, n (%)			
≥ 18 and < 65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
≥ 65 and < 70 Years	1 (< 0.1)	5 (0.2)	6 (0.1)
≥ 70 and < 75 Years	1 (< 0.1)	0	1 (< 0.1)
≥ 75 and < 80 Years	1 (< 0.1)	1 (< 0.1)	2 (< 0.1)
≥ 80 Years	0	0	0

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
>=65 and <75 Years	2 (<0.1)	5 (0.2)	7 (0.1)
>=75 and <85 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	2535 (100)	2530 (100)	5065 (100)
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	484 (19.1)	454 (17.9)	938 (18.5)
Significant Cardiac Disease	285 (11.2)	302 (11.9)	587 (11.6)
Severe Obesity	790 (31.2)	792 (31.3)	1582 (31.2)
Diabetes	866 (34.2)	870 (34.4)	1736 (34.3)
Liver Disease	62 (2.4)	77 (3.0)	139 (2.7)
Human Immunodeficiency Virus Infection	59 (2.3)	62 (2.5)	121 (2.4)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	2149 (84.8)	2158 (85.3)	4307 (85.0)
No	386 (15.2)	372 (14.7)	758 (15.0)
Baseline RT-PCR Results, n (%)			
Negative	2464 (97.2)	2475 (97.8)	4939 (97.5)
Positive	20 (0.8)	16 (0.6)	36 (0.7)
Missing	51 (2.0)	39 (1.5)	90 (1.8)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	2393 (94.4)	2391 (94.5)	4784 (94.5)
Positive	57 (2.2)	42 (1.7)	99 (2.0)
Missing	85 (3.4)	97 (3.8)	182 (3.6)
Baseline SARS-CoV-2 Status, n (%) [3]			
Negative	2358 (93.0)	2369 (93.6)	4727 (93.3)
Positive	63 (2.5)	47 (1.9)	110 (2.2)
Missing	114 (4.5)	114 (4.5)	228 (4.5)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Sex, n (%)			
Male	1329 (52.4)	1306 (51.6)	2635 (52.0)
Female	1206 (47.6)	1224 (48.4)	2430 (48.0)
Race, n (%)			
White	1870 (73.8)	1899 (75.1)	3769 (74.4)
Black or African American	414 (16.3)	374 (14.8)	788 (15.6)
Asian	84 (3.3)	86 (3.4)	170 (3.4)
American Indian or Alaska Native	22 (0.9)	25 (1.0)	47 (0.9)
Native Hawaiian or Other Pacific Islander	9 (0.4)	7 (0.3)	16 (0.3)
Multiracial	51 (2.0)	50 (2.0)	101 (2.0)
Other	54 (2.1)	61 (2.4)	115 (2.3)
Not Reported	18 (0.7)	17 (0.7)	35 (0.7)
Unknown	13 (0.5)	11 (0.4)	24 (0.5)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Ethnicity, n (%)			
Hispanic or Latino	552 (21.8)	558 (22.1)	1110 (21.9)
Not Hispanic or Latino	1960 (77.3)	1952 (77.2)	3912 (77.2)
Not Reported	15 (0.6)	15 (0.6)	30 (0.6)
Unknown	8 (0.3)	5 (0.2)	13 (0.3)
Race and Ethnicity Group, n (%) [4]			
Minority	968 (38.2)	926 (36.6)	1894 (37.4)
Non-minority	1562 (61.6)	1598 (63.2)	3160 (62.4)
Missing	5 (0.2)	6 (0.2)	11 (0.2)
Race and Ethnicity Group, n (%) [5]			
White	1426 (56.3)	1456 (57.5)	2882 (56.9)
Communities of Color	1104 (43.6)	1068 (42.2)	2172 (42.9)
Missing	5 (0.2)	6 (0.2)	11 (0.2)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Weight (kg)			
n	2504	2495	4999
Mean (SD)	102.33 (28.386)	102.57 (28.854)	102.45 (28.618)
Median	99.00	99.60	99.20
Min, Max	3.5, 223.0	30.3, 236.4	3.5, 236.4
Height (cm)			
n	2503	2496	4999
Mean (SD)	170.89 (10.230)	170.73 (9.982)	170.81 (10.106)
Median	170.40	170.18	170.18
Min, Max	123.5, 203.2	111.0, 202.8	111.0, 203.2

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Body Mass Index (kg/m ²)			
n	2503	2495	4998
Mean (SD)	35.01 (9.200)	35.20 (9.538)	35.10 (9.370)
Median	33.76	33.68	33.73
Min, Max	1.5, 72.7	11.7, 86.1	1.5, 86.1

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Occupational Risk, n (%) [2]	2160 (85.2)	2140 (84.6)	4300 (84.9)
Healthcare Workers	593 (23.4)	592 (23.4)	1185 (23.4)
Emergency Response	58 (2.3)	49 (1.9)	107 (2.1)
Retail or Restaurant Operations	185 (7.3)	171 (6.8)	356 (7.0)
Manufacturing and Production Operations	85 (3.4)	102 (4.0)	187 (3.7)
Warehouse Shipping and Fulfillment Centers	42 (1.7)	44 (1.7)	86 (1.7)
Transportation and Delivery Services	97 (3.8)	98 (3.9)	195 (3.8)
Border Protection and Military Personnel	11 (0.4)	13 (0.5)	24 (0.5)
Personal Care and In-Home Services	78 (3.1)	103 (4.1)	181 (3.6)
Hospitality and Tourism Workers	40 (1.6)	38 (1.5)	78 (1.5)
Pastoral, Social or Public Health Workers	101 (4.0)	90 (3.6)	191 (3.8)
Educators and Students	269 (10.6)	276 (10.9)	545 (10.8)
Other	786 (31.0)	808 (31.9)	1594 (31.5)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Location and Living Circumstances Risk, n (%) [2]	2074 (81.8)	2038 (80.6)	4112 (81.2)
Resides in Nursing Home or Assisted Living Facility	3 (0.1)	11 (0.4)	14 (0.3)
Resides in Multi-Family Dwelling	80 (3.2)	92 (3.6)	172 (3.4)
Resides in High Density Housing	194 (7.7)	195 (7.7)	389 (7.7)
Resides in Low Density, Multi-Family Setting	272 (10.7)	299 (11.8)	571 (11.3)
Resides in a Single Family Home	1363 (53.8)	1279 (50.6)	2642 (52.2)
Other	332 (13.1)	319 (12.6)	651 (12.9)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Age at Screening (Years)			
n	3749	3763	7512
Mean (SD)	70.7 (4.90)	70.4 (4.67)	70.6 (4.79)
Median	70.0	69.0	70.0
Min, Max	40, 95	64, 95	40, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 Years	3748 (>99.9)	3762 (>99.9)	7510 (>99.9)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <70 Years	1816 (48.4)	1900 (50.5)	3716 (49.5)
>=70 and <75 Years	1192 (31.8)	1204 (32.0)	2396 (31.9)
>=75 and <80 Years	506 (13.5)	467 (12.4)	973 (13.0)
>=80 Years	234 (6.2)	191 (5.1)	425 (5.7)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <75 Years	3008 (80.2)	3104 (82.5)	6112 (81.4)
>=75 and <85 Years	691 (18.4)	617 (16.4)	1308 (17.4)
>=85 Years	49 (1.3)	41 (1.1)	90 (1.2)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	3749 (100)	3763 (100)	7512 (100)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	240 (6.4)	235 (6.2)	475 (6.3)
Significant Cardiac Disease	445 (11.9)	430 (11.4)	875 (11.6)
Severe Obesity	124 (3.3)	139 (3.7)	263 (3.5)
Diabetes	532 (14.2)	525 (14.0)	1057 (14.1)
Liver Disease	26 (0.7)	18 (0.5)	44 (0.6)
Human Immunodeficiency Virus Infection	14 (0.4)	15 (0.4)	29 (0.4)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1097 (29.3)	1082 (28.8)	2179 (29.0)
No	2652 (70.7)	2681 (71.2)	5333 (71.0)
Baseline RT-PCR Results, n (%)			
Negative	3685 (98.3)	3702 (98.4)	7387 (98.3)
Positive	10 (0.3)	7 (0.2)	17 (0.2)
Missing	54 (1.4)	54 (1.4)	108 (1.4)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	3629 (96.8)	3630 (96.5)	7259 (96.6)
Positive	28 (0.7)	32 (0.9)	60 (0.8)
Missing	92 (2.5)	101 (2.7)	193 (2.6)
Baseline SARS-CoV-2 Status, n (%) [3]			
Negative	3594 (95.9)	3597 (95.6)	7191 (95.7)
Positive	33 (0.9)	35 (0.9)	68 (0.9)
Missing	122 (3.3)	131 (3.5)	253 (3.4)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Sex, n (%)			
Male	2103 (56.1)	2075 (55.1)	4178 (55.6)
Female	1646 (43.9)	1688 (44.9)	3334 (44.4)
Race, n (%)			
White	3337 (89.0)	3373 (89.6)	6710 (89.3)
Black or African American	215 (5.7)	221 (5.9)	436 (5.8)
Asian	77 (2.1)	65 (1.7)	142 (1.9)
American Indian or Alaska Native	26 (0.7)	21 (0.6)	47 (0.6)
Native Hawaiian or Other Pacific Islander	3 (<0.1)	3 (<0.1)	6 (<0.1)
Multiracial	38 (1.0)	34 (0.9)	72 (1.0)
Other	32 (0.9)	27 (0.7)	59 (0.8)
Not Reported	13 (0.3)	13 (0.3)	26 (0.3)
Unknown	8 (0.2)	6 (0.2)	14 (0.2)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Ethnicity, n (%)			
Hispanic or Latino	334 (8.9)	354 (9.4)	688 (9.2)
Not Hispanic or Latino	3373 (90.0)	3365 (89.4)	6738 (89.7)
Not Reported	26 (0.7)	32 (0.9)	58 (0.8)
Unknown	16 (0.4)	12 (0.3)	28 (0.4)
Race and Ethnicity Group, n (%) [4]			
Minority	560 (14.9)	578 (15.4)	1138 (15.1)
Non-minority	3176 (84.7)	3179 (84.5)	6355 (84.6)
Missing	13 (0.3)	6 (0.2)	19 (0.3)
Race and Ethnicity Group, n (%) [5]			
White	3061 (81.6)	3068 (81.5)	6129 (81.6)
Communities of Color	675 (18.0)	689 (18.3)	1364 (18.2)
Missing	13 (0.3)	6 (0.2)	19 (0.3)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Weight (kg)			
n	3699	3703	7402
Mean (SD)	83.18 (18.910)	83.11 (19.429)	83.14 (19.170)
Median	81.60	81.20	81.36
Min, Max	34.8, 184.5	31.5, 168.6	31.5, 184.5
Height (cm)			
n	3699	3704	7403
Mean (SD)	170.05 (10.233)	169.95 (10.006)	170.00 (10.119)
Median	170.18	170.18	170.18
Min, Max	124.5, 223.5	123.0, 208.3	123.0, 223.5

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Body Mass Index (kg/m ²)			
n	3698	3703	7401
Mean (SD)	28.70 (5.858)	28.68 (5.927)	28.69 (5.892)
Median	27.71	27.85	27.78
Min, Max	12.1, 71.1	11.2, 66.7	11.2, 71.1

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Occupational Risk, n (%) [2]	2378 (63.4)	2354 (62.6)	4732 (63.0)
Healthcare Workers	504 (13.4)	460 (12.2)	964 (12.8)
Emergency Response	19 (0.5)	20 (0.5)	39 (0.5)
Retail or Restaurant Operations	99 (2.6)	100 (2.7)	199 (2.6)
Manufacturing and Production Operations	30 (0.8)	34 (0.9)	64 (0.9)
Warehouse Shipping and Fulfillment Centers	12 (0.3)	9 (0.2)	21 (0.3)
Transportation and Delivery Services	62 (1.7)	50 (1.3)	112 (1.5)
Border Protection and Military Personnel	6 (0.2)	3 (<0.1)	9 (0.1)
Personal Care and In-Home Services	61 (1.6)	67 (1.8)	128 (1.7)
Hospitality and Tourism Workers	44 (1.2)	36 (1.0)	80 (1.1)
Pastoral, Social or Public Health Workers	138 (3.7)	147 (3.9)	285 (3.8)
Educators and Students	169 (4.5)	183 (4.9)	352 (4.7)
Other	1421 (37.9)	1424 (37.8)	2845 (37.9)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3763)	Total (N=7512)
Location and Living Circumstances Risk, n (%) [2]	3083 (82.2)	3108 (82.6)	6191 (82.4)
Resides in Nursing Home or Assisted Living Facility	20 (0.5)	11 (0.3)	31 (0.4)
Resides in Multi-Family Dwelling	63 (1.7)	66 (1.8)	129 (1.7)
Resides in High Density Housing	240 (6.4)	251 (6.7)	491 (6.5)
Resides in Low Density, Multi-Family Setting	254 (6.8)	242 (6.4)	496 (6.6)
Resides in a Single Family Home	2235 (59.6)	2261 (60.1)	4496 (59.9)
Other	530 (14.1)	545 (14.5)	1075 (14.3)

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Age at Screening (Years)									
n	10384	10407	20791	3499	3527	7026	13883	13934	27817
Mean (SD)	45.1 (12.25)	45.2 (12.30)	45.2 (12.27)	70.7 (4.84)	70.4 (4.65)	70.6 (4.74)	51.5 (15.55)	51.6 (15.45)	51.6 (15.50)
Median	46.0	46.0	46.0	70.0	69.0	70.0	52.0	53.0	53.0
Min, Max	18, 64	18, 64	18, 64	65, 95	65, 95	65, 95	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	10384 (100)	10407 (100)	20791 (100)	0	0	0	10384 (74.8)	10407 (74.7)	20791 (74.7)
>=65 Years	0	0	0	3499 (100)	3527 (100)	7026 (100)	3499 (25.2)	3527 (25.3)	7026 (25.3)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	10384 (100)	10407 (100)	20791 (100)	0	0	0	10384 (74.8)	10407 (74.7)	20791 (74.7)
>=65 and <70 Years	0	0	0	1705 (48.7)	1787 (50.7)	3492 (49.7)	1705 (12.3)	1787 (12.8)	3492 (12.6)
>=70 and <75 Years	0	0	0	1118 (32.0)	1117 (31.7)	2235 (31.8)	1118 (8.1)	1117 (8.0)	2235 (8.0)
>=75 and <80 Years	0	0	0	467 (13.3)	447 (12.7)	914 (13.0)	467 (3.4)	447 (3.2)	914 (3.3)
>=80 Years	0	0	0	209 (6.0)	176 (5.0)	385 (5.5)	209 (1.5)	176 (1.3)	385 (1.4)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	10384 (100)	10407 (100)	20791 (100)	0	0	0	10384 (74.8)	10407 (74.7)	20791 (74.7)
>=65 and <75 Years	0	0	0	2823 (80.7)	2904 (82.3)	5727 (81.5)	2823 (20.3)	2904 (20.8)	5727 (20.6)
>=75 and <85 Years	0	0	0	631 (18.0)	586 (16.6)	1217 (17.3)	631 (4.5)	586 (4.2)	1217 (4.4)
>=85 Years	0	0	0	45 (1.3)	37 (1.0)	82 (1.2)	45 (0.3)	37 (0.3)	82 (0.3)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8110 (78.1)	8097 (77.8)	16207 (78.0)	1 (<0.1)	0	1 (<0.1)	8111 (58.4)	8097 (58.1)	16208 (58.3)
>=18 and <65 Years and at Risk	2273 (21.9)	2309 (22.2)	4582 (22.0)	3 (<0.1)	6 (0.2)	9 (0.1)	2276 (16.4)	2315 (16.6)	4591 (16.5)
>=65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)	3495 (99.9)	3521 (99.8)	7016 (99.9)	3496 (25.2)	3522 (25.3)	7018 (25.2)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	452 (4.4)	439 (4.2)	891 (4.3)	221 (6.3)	222 (6.3)	443 (6.3)	673 (4.8)	661 (4.7)	1334 (4.8)
Significant Cardiac Disease	265 (2.6)	277 (2.7)	542 (2.6)	413 (11.8)	409 (11.6)	822 (11.7)	678 (4.9)	686 (4.9)	1364 (4.9)
Severe Obesity	775 (7.5)	770 (7.4)	1545 (7.4)	109 (3.1)	131 (3.7)	240 (3.4)	884 (6.4)	901 (6.5)	1785 (6.4)
Diabetes	810 (7.8)	844 (8.1)	1654 (8.0)	499 (14.3)	494 (14.0)	993 (14.1)	1309 (9.4)	1338 (9.6)	2647 (9.5)
Liver Disease	66 (0.6)	77 (0.7)	143 (0.7)	24 (0.7)	16 (0.5)	40 (0.6)	90 (0.6)	93 (0.7)	183 (0.7)
Human Immunodeficiency Virus Infection	63 (0.6)	67 (0.6)	130 (0.6)	13 (0.4)	13 (0.4)	26 (0.4)	76 (0.5)	80 (0.6)	156 (0.6)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	2061 (19.8)	2098 (20.2)	4159 (20.0)	1014 (29.0)	1018 (28.9)	2032 (28.9)	3075 (22.1)	3116 (22.4)	6191 (22.3)
No	8323 (80.2)	8309 (79.8)	16632 (80.0)	2485 (71.0)	2509 (71.1)	4994 (71.1)	10808 (77.9)	10818 (77.6)	21626 (77.7)
Baseline RT-PCR Results, n (%)									
Negative	10384 (100)	10407 (100)	20791 (100)	3499 (100)	3527 (100)	7026 (100)	13883 (100)	13934 (100)	27817 (100)
Positive	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Baseline Elecsys									
Anti-SARS-CoV-2 Results, n (%)									
Negative	10384 (100)	10407 (100)	20791 (100)	3499 (100)	3527 (100)	7026 (100)	13883 (100)	13934 (100)	27817 (100)
Positive	0	0	0	0	0	0	0	0	0
Baseline SARS-CoV-2 Status, n (%) [3]									
Negative	10384 (100)	10407 (100)	20791 (100)	3499 (100)	3527 (100)	7026 (100)	13883 (100)	13934 (100)	27817 (100)
Positive	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Sex, n (%)									
Male	5407 (52.1)	5325 (51.2)	10732 (51.6)	1962 (56.1)	1948 (55.2)	3910 (55.7)	7369 (53.1)	7273 (52.2)	14642 (52.6)
Female	4977 (47.9)	5082 (48.8)	10059 (48.4)	1537 (43.9)	1579 (44.8)	3116 (44.3)	6514 (46.9)	6661 (47.8)	13175 (47.4)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Race, n (%)									
White	7886 (75.9)	7916 (76.1)	15802 (76.0)	3119 (89.1)	3162 (89.7)	6281 (89.4)	11005 (79.3)	11078 (79.5)	22083 (79.4)
Black or African American	1146 (11.0)	1167 (11.2)	2313 (11.1)	192 (5.5)	202 (5.7)	394 (5.6)	1338 (9.6)	1369 (9.8)	2707 (9.7)
Asian	611 (5.9)	551 (5.3)	1162 (5.6)	73 (2.1)	65 (1.8)	138 (2.0)	684 (4.9)	616 (4.4)	1300 (4.7)
American Indian or Alaska Native	86 (0.8)	86 (0.8)	172 (0.8)	24 (0.7)	21 (0.6)	45 (0.6)	110 (0.8)	107 (0.8)	217 (0.8)
Native Hawaiian or Other Pacific Islander	27 (0.3)	30 (0.3)	57 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	30 (0.2)	33 (0.2)	63 (0.2)
Multiracial	268 (2.6)	261 (2.5)	529 (2.5)	36 (1.0)	32 (0.9)	68 (1.0)	304 (2.2)	293 (2.1)	597 (2.1)
Other	261 (2.5)	272 (2.6)	533 (2.6)	32 (0.9)	26 (0.7)	58 (0.8)	293 (2.1)	298 (2.1)	591 (2.1)
Not Reported	54 (0.5)	75 (0.7)	129 (0.6)	12 (0.3)	12 (0.3)	24 (0.3)	66 (0.5)	87 (0.6)	153 (0.6)
Unknown	45 (0.4)	49 (0.5)	94 (0.5)	8 (0.2)	4 (0.1)	12 (0.2)	53 (0.4)	53 (0.4)	106 (0.4)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Ethnicity, n (%)									
Hispanic or Latino	2466 (23.7)	2459 (23.6)	4925 (23.7)	303 (8.7)	324 (9.2)	627 (8.9)	2769 (19.9)	2783 (20.0)	5552 (20.0)
Not Hispanic or Latino	7833 (75.4)	7859 (75.5)	15692 (75.5)	3154 (90.1)	3160 (89.6)	6314 (89.9)	10987 (79.1)	11019 (79.1)	22006 (79.1)
Not Reported	49 (0.5)	64 (0.6)	113 (0.5)	26 (0.7)	31 (0.9)	57 (0.8)	75 (0.5)	95 (0.7)	170 (0.6)
Unknown	36 (0.3)	25 (0.2)	61 (0.3)	16 (0.5)	12 (0.3)	28 (0.4)	52 (0.4)	37 (0.3)	89 (0.3)
Race and Ethnicity Group, n (%)									
[4]									
Minority	3612 (34.8)	3610 (34.7)	7222 (34.7)	505 (14.4)	529 (15.0)	1034 (14.7)	4117 (29.7)	4139 (29.7)	8256 (29.7)
Non-minority	6759 (65.1)	6780 (65.1)	13539 (65.1)	2981 (85.2)	2993 (84.9)	5974 (85.0)	9740 (70.2)	9773 (70.1)	19513 (70.1)
Missing	13 (0.1)	17 (0.2)	30 (0.1)	13 (0.4)	5 (0.1)	18 (0.3)	26 (0.2)	22 (0.2)	48 (0.2)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Race and Ethnicity Group, n (%)									
[5]									
White	5883 (56.7)	5976 (57.4)	11859 (57.0)	2872 (82.1)	2882 (81.7)	5754 (81.9)	8755 (63.1)	8858 (63.6)	17613 (63.3)
Communities of Color	4488 (43.2)	4414 (42.4)	8902 (42.8)	614 (17.5)	640 (18.1)	1254 (17.8)	5102 (36.7)	5054 (36.3)	10156 (36.5)
Missing	13 (0.1)	17 (0.2)	30 (0.1)	13 (0.4)	5 (0.1)	18 (0.3)	26 (0.2)	22 (0.2)	48 (0.2)
Weight (kg)									
n	10267	10287	20554	3459	3479	6938	13726	13766	27492
Mean (SD)	86.62 (22.387)	86.40 (22.631)	86.51 (22.509)	83.10 (18.870)	83.08 (19.420)	83.09 (19.146)	85.73 (21.608)	85.56 (21.911)	85.65 (21.760)
Median	83.60	83.60	83.60	81.36	81.09	81.30	82.80	83.00	82.90
Min, Max	3.5, 216.5	30.3, 236.4	3.5, 236.4	34.8, 184.5	31.5, 168.6	31.5, 184.5	3.5, 216.5	30.3, 236.4	3.5, 236.4

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Height (cm)									
n	10267	10287	20554	3459	3480	6939	13726	13767	27493
Mean (SD)	171.21 (9.996)	170.97 (9.896)	171.09 (9.946)	170.09 (10.171)	170.01 (9.952)	170.05 (10.061)	170.93 (10.052)	170.73 (9.919)	170.83 (9.986)
Median	171.00	170.20	170.69	170.18	170.18	170.18	170.69	170.18	170.20
Min, Max	110.6, 205.7	104.1, 208.5	104.1, 208.5	124.5, 223.5	123.0, 208.3	123.0, 223.5	110.6, 223.5	104.1, 208.5	104.1, 223.5
Body Mass Index (kg/m ²)									
n	10266	10284	20550	3458	3479	6937	13724	13763	27487
Mean (SD)	29.46 (6.929)	29.48 (7.083)	29.47 (7.006)	28.66 (5.828)	28.65 (5.919)	28.65 (5.873)	29.26 (6.677)	29.27 (6.817)	29.26 (6.748)
Median	28.22	28.20	28.21	27.67	27.82	27.74	28.05	28.09	28.08
Min, Max	1.5, 87.3	10.5, 82.0	1.5, 87.3	12.1, 71.1	12.8, 66.7	12.1, 71.1	1.5, 87.3	10.5, 82.0	1.5, 87.3

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Occupational Risk, n (%) [2]	9200 (88.6)	9192 (88.3)	18392 (88.5)	2208 (63.1)	2205 (62.5)	4413 (62.8)	11408 (82.2)	11397 (81.8)	22805 (82.0)
Healthcare Workers	3067 (29.5)	3103 (29.8)	6170 (29.7)	464 (13.3)	438 (12.4)	902 (12.8)	3531 (25.4)	3541 (25.4)	7072 (25.4)
Emergency Response	255 (2.5)	262 (2.5)	517 (2.5)	17 (0.5)	21 (0.6)	38 (0.5)	272 (2.0)	283 (2.0)	555 (2.0)
Retail or Restaurant Operations	769 (7.4)	753 (7.2)	1522 (7.3)	90 (2.6)	96 (2.7)	186 (2.6)	859 (6.2)	849 (6.1)	1708 (6.1)
Manufacturing and Production Operations	358 (3.4)	347 (3.3)	705 (3.4)	25 (0.7)	32 (0.9)	57 (0.8)	383 (2.8)	379 (2.7)	762 (2.7)
Warehouse Shipping and Fulfillment Centers	145 (1.4)	163 (1.6)	308 (1.5)	10 (0.3)	9 (0.3)	19 (0.3)	155 (1.1)	172 (1.2)	327 (1.2)
Transportation and Delivery Services	363 (3.5)	383 (3.7)	746 (3.6)	57 (1.6)	43 (1.2)	100 (1.4)	420 (3.0)	426 (3.1)	846 (3.0)
Border Protection and Military Personnel	60 (0.6)	59 (0.6)	119 (0.6)	4 (0.1)	3 (<0.1)	7 (<0.1)	64 (0.5)	62 (0.4)	126 (0.5)
Personal Care and In-Home Services	357 (3.4)	341 (3.3)	698 (3.4)	53 (1.5)	65 (1.8)	118 (1.7)	410 (3.0)	406 (2.9)	816 (2.9)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
	(N=10384)	(N=10407)	(N=20791)	(N=3499)	(N=3527)	(N=7026)	(N=13883)	(N=13934)	(N=27817)
Occupational Risk, n (%) [2] (Cont.)									
Hospitality and Tourism Workers	157 (1.5)	178 (1.7)	335 (1.6)	40 (1.1)	31 (0.9)	71 (1.0)	197 (1.4)	209 (1.5)	406 (1.5)
Pastoral, Social or Public Health Workers	338 (3.3)	355 (3.4)	693 (3.3)	132 (3.8)	135 (3.8)	267 (3.8)	470 (3.4)	490 (3.5)	960 (3.5)
Educators and Students	1278 (12.3)	1259 (12.1)	2537 (12.2)	162 (4.6)	172 (4.9)	334 (4.8)	1440 (10.4)	1431 (10.3)	2871 (10.3)
Other	3067 (29.5)	3100 (29.8)	6167 (29.7)	1318 (37.7)	1332 (37.8)	2650 (37.7)	4385 (31.6)	4432 (31.8)	8817 (31.7)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10384)	mRNA-1273 (N=10407)	Total (N=20791)	Placebo (N=3499)	mRNA-1273 (N=3527)	Total (N=7026)	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Location and Living	8624	8655	17279	2867	2913	5780	11491	11568	23059
Circumstances Risk, n (%) [2]	(83.1)	(83.2)	(83.1)	(81.9)	(82.6)	(82.3)	(82.8)	(83.0)	(82.9)
Resides in Nursing Home or	9	20	29	19	10	29	28	30	58
Assisted Living Facility	(<0.1)	(0.2)	(0.1)	(0.5)	(0.3)	(0.4)	(0.2)	(0.2)	(0.2)
Resides in Multi-Family	312	350	662	60	62	122	372	412	784
Dwelling	(3.0)	(3.4)	(3.2)	(1.7)	(1.8)	(1.7)	(2.7)	(3.0)	(2.8)
Resides in High Density	953	936	1889	227	233	460	1180	1169	2349
Housing	(9.2)	(9.0)	(9.1)	(6.5)	(6.6)	(6.5)	(8.5)	(8.4)	(8.4)
Resides in Low Density,	1090	1098	2188	237	229	466	1327	1327	2654
Multi-Family Setting	(10.5)	(10.6)	(10.5)	(6.8)	(6.5)	(6.6)	(9.6)	(9.5)	(9.5)
Resides in a Single Family	5537	5515	11052	2072	2124	4196	7609	7639	15248
Home	(53.3)	(53.0)	(53.2)	(59.2)	(60.2)	(59.7)	(54.8)	(54.8)	(54.8)
Other	1503	1527	3030	493	513	1006	1996	2040	4036
	(14.5)	(14.7)	(14.6)	(14.1)	(14.5)	(14.3)	(14.4)	(14.6)	(14.5)

Percentages are based on the number of subjects in Per-Protocol Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
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Table 14.1.6.4
Summary of Study Duration
Per-Protocol Set

	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Number of Subjects, n (%)			
Received First Injection	13883 (100)	13934 (100)	27817 (100)
Received Second Injection	13164 (94.8)	13218 (94.9)	26382 (94.8)
>= 49 Days Since First Injection	12209 (87.9)	12303 (88.3)	24512 (88.1)
>= 56 Days Since First Injection	11528 (83.0)	11636 (83.5)	23164 (83.3)
>= 28 Days Since Second Injection	11383 (82.0)	11506 (82.6)	22889 (82.3)
>= 56 Days Since Second Injection	4785 (34.5)	4832 (34.7)	9617 (34.6)
Study Duration from Randomization (Days)			
Mean (SD)	75.1 (20.48)	75.2 (20.38)	75.1 (20.43)
Median	78.0+	78.0+	78.0+
Q1, Q3	63.0+, 91.0+	64.0+, 91.0+	64.0+, 91.0+
Min, Max	20+, 108+	20+, 108+	20+, 108+
Study Duration from First Injection (Days)			
Mean (SD)	75.1 (20.48)	75.2 (20.38)	75.1 (20.43)
Median	78.0+	78.0+	78.0+
Q1, Q3	63.0+, 91.0+	64.0+, 91.0+	64.0+, 91.0+
Min, Max	20+, 108+	20+, 108+	20+, 108+
Study Duration from Second Injection (Days) [1]			
Mean (SD)	46.1 (19.96)	46.2 (19.89)	46.1 (19.92)
Median	49.0+	49.0+	49.0+
Q1, Q3	35.0+, 61.0+	35.0+, 62.0+	35.0+, 62.0+
Min, Max	0+, 83+	0+, 83+	0+, 83+

+ indicates ongoing subjects.

Percentages are based on the number of subjects in Per-Protocol Set.

[1] Study duration from second injection is 0 day for subjects who did not receive second injection.

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Table 14.1.6.4
Summary of Study Duration
Per-Protocol Set

	Placebo (N=13883)	mRNA-1273 (N=13934)	Total (N=27817)
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	13164	13218	26382
Mean (SD)	48.6 (17.26)	48.7 (17.18)	48.7 (17.22)
Median	50.0+	50.0+	50.0+
Q1, Q3	37.0+, 62.0+	37.0+, 62.0+	37.0+, 62.0+
Min, Max	1+, 83+	1+, 83+	1+, 83+

+ indicates ongoing subjects.

Percentages are based on the number of subjects in Per-Protocol Set.

[1] Study duration from second injection is 0 day for subjects who did not receive second injection.

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Table 14.2.2.1.1.6.2.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 and < 75 Years, ≥ 75 Years)
Per-Protocol Set

Age Group: ≥ 18 and < 65 Years

	Placebo (N=10384)	mRNA-1273 (N=10407)
Number of Subjects with COVID-19, n (%)	75 (0.7)	5 (<0.1)
Number of Subjects Censored, n (%)	10309 (99.3)	10402 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.837, 0.973)
Person-Years [2]	1984.8	1996.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	37.788 (29.723, 47.368)	2.504 (0.813, 5.843)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.934 (0.838, 0.979)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.2.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 and < 75 Years, ≥ 75 Years)
Per-Protocol Set

Age Group: ≥ 65 and < 75 Years

	Placebo (N=2823)	mRNA-1273 (N=2904)
Number of Subjects with COVID-19, n (%)	12 (0.4)	0
Number of Subjects Censored, n (%)	2811 (99.6)	2904 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	574.6	591.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	20.883 (10.791, 36.479)	0.000 (NE, 6.238)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.650, NE)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.2.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 and < 75 Years, ≥ 75 Years)
Per-Protocol Set

Age Group: ≥ 75 Years

	Placebo (N=676)	mRNA-1273 (N=623)
Number of Subjects with COVID-19, n (%)	3 (0.4)	0
Number of Subjects Censored, n (%)	673 (99.6)	623 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	138.1	128.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.726 (4.480, 63.493)	0.000 (NE, 28.664)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-1.597, NE)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: White

	Placebo (N=11005)	mRNA-1273 (N=11078)
Number of Subjects with COVID-19, n (%)	80 (0.7)	5 (<0.1)
Number of Subjects Censored, n (%)	10925 (99.3)	11073 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.938 (0.848, 0.975)
Person-Years [2]	2233.3	2256.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	35.821 (28.404, 44.582)	2.215 (0.719, 5.170)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.938 (0.850, 0.980)

- [1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Black or African American

	Placebo (N=1338)	mRNA-1273 (N=1369)
Number of Subjects with COVID-19, n (%)	4 (0.3)	0
Number of Subjects Censored, n (%)	1334 (99.7)	1369 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	215.4	218.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	18.566 (5.059, 47.536)	0.000 (NE, 16.886)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.494, NE)

- [1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Asian

	Placebo (N=684)	mRNA-1273 (N=616)
Number of Subjects with COVID-19, n (%)	3 (0.4)	0
Number of Subjects Censored, n (%)	681 (99.6)	616 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	113.0	101.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	26.549 (5.475, 77.589)	0.000 (NE, 36.331)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-1.693, NE)

- [1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: American Indian or Alaska Native

	Placebo (N=110)	mRNA-1273 (N=107)
Number of Subjects with COVID-19, n (%)	0	0
Number of Subjects Censored, n (%)	110 (100)	107 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	17.9	18.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 206.556)	0.000 (NE, 204.456)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Native Hawaiian or Other Pacific Islander

	Placebo (N=30)	mRNA-1273 (N=33)
Number of Subjects with COVID-19, n (%)	0	0
Number of Subjects Censored, n (%)	30 (100)	33 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	5.4	5.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 682.901)	0.000 (NE, 630.788)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Other

	Placebo (N=293)	mRNA-1273 (N=298)
Number of Subjects with COVID-19, n (%)	2 (0.7)	0
Number of Subjects Censored, n (%)	291 (99.3)	298 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	43.8	45.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	45.645 (5.528, 164.885)	0.000 (NE, 80.344)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-4.081, NE)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Multiple

	Placebo (N=304)	mRNA-1273 (N=293)
Number of Subjects with COVID-19, n (%)	1 (0.3)	0
Number of Subjects Censored, n (%)	303 (99.7)	293 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	49.6	48.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	20.161 (0.510, 112.328)	0.000 (NE, 75.775)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-38.737, NE)

- [1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Not Reported

	Placebo (N=66)	mRNA-1273 (N=87)
Number of Subjects with COVID-19, n (%)	0	0
Number of Subjects Censored, n (%)	66 (100)	87 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	11.9	14.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 309.810)	0.000 (NE, 256.836)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Unknown

	Placebo (N=53)	mRNA-1273 (N=53)
Number of Subjects with COVID-19, n (%)	0	0
Number of Subjects Censored, n (%)	53 (100)	53 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	7.1	7.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 519.015)	0.000 (NE, 515.638)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 18 and < 65 Years and Not At Risk

	Placebo (N=8323)	mRNA-1273 (N=8309)
Number of Subjects with COVID-19, n (%)	57 (0.7)	4 (<0.1)
Number of Subjects Censored, n (%)	8266 (99.3)	8305 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.808, 0.975)
Person-Years [2]	1581.8	1585.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	36.034 (27.292, 46.687)	2.524 (0.688, 6.462)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.811, 0.982)

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 18 and < 65 Years and At Risk

	Placebo (N=2061)	mRNA-1273 (N=2098)
Number of Subjects with COVID-19, n (%)	18 (0.9)	1 (<0.1)
Number of Subjects Censored, n (%)	2043 (99.1)	2097 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.946 (0.594, 0.993)
Person-Years [2]	402.9	411.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	44.673 (26.476, 70.602)	2.428 (0.061, 13.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.946 (0.656, 0.999)

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 65 Years and Not At Risk

	Placebo (N=2485)	mRNA-1273 (N=2509)
Number of Subjects with COVID-19, n (%)	9 (0.4)	0
Number of Subjects Censored, n (%)	2476 (99.6)	2509 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	503.0	508.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	17.891 (8.181, 33.963)	0.000 (NE, 7.258)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.499, NE)

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 65 Years and At Risk

	Placebo (N=1014)	mRNA-1273 (N=1018)
Number of Subjects with COVID-19, n (%)	6 (0.6)	0
Number of Subjects Censored, n (%)	1008 (99.4)	1018 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	209.7	211.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	28.616 (10.502, 62.286)	0.000 (NE, 17.422)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.159, NE)

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.3.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Solicited Adverse Reactions - N1	15162	15176	30339
Any Solicited Adverse Reactions	9027 (59.5)	14338 (94.5)	23365 (77.0)
95% CI	58.8, 60.3	94.1, 94.8	76.5, 77.5
Grade 1	5812 (38.3)	5037 (33.2)	10849 (35.8)
Grade 2	2550 (16.8)	6025 (39.7)	8575 (28.3)
Grade 3	656 (4.3)	3259 (21.5)	3915 (12.9)
Grade 4	9 (<0.1)	17 (0.1)	26 (<0.1)
Solicited Local Adverse Reactions - N1	15161	15176	30338
Any Solicited Local Adverse Reactions	4381 (28.9)	13962 (92.0)	18343 (60.5)
95% CI	28.2, 29.6	91.6, 92.4	59.9, 61.0
Grade 1	4088 (27.0)	9088 (59.9)	13176 (43.4)
Grade 2	150 (1.0)	3488 (23.0)	3638 (12.0)
Grade 3	143 (0.9)	1386 (9.1)	1529 (5.0)
Grade 4	0	0	0
Pain - N1	15161	15176	30338
Any	3975 (26.2)	13901 (91.6)	17876 (58.9)
Grade 1	3782 (24.9)	9887 (65.1)	13669 (45.1)
Grade 2	103 (0.7)	3113 (20.5)	3216 (10.6)
Grade 3	90 (0.6)	901 (5.9)	991 (3.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Erythema (Redness) - N1	15161	15176	30338
Any	114 (0.8)	1470 (9.7)	1584 (5.2)
Grade 1	77 (0.5)	582 (3.8)	659 (2.2)
Grade 2	10 (<0.1)	569 (3.7)	579 (1.9)
Grade 3	27 (0.2)	319 (2.1)	346 (1.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	15161	15176	30338
Any	95 (0.6)	2183 (14.4)	2278 (7.5)
Grade 1	65 (0.4)	1131 (7.5)	1196 (3.9)
Grade 2	14 (<0.1)	734 (4.8)	748 (2.5)
Grade 3	16 (0.1)	318 (2.1)	334 (1.1)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	15161	15176	30338
Any	1074 (7.1)	2914 (19.2)	3988 (13.1)
Grade 1	981 (6.5)	2461 (16.2)	3442 (11.3)
Grade 2	49 (0.3)	345 (2.3)	394 (1.3)
Grade 3	44 (0.3)	108 (0.7)	152 (0.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Solicited Systemic Adverse Reactions - N1	15162	15176	30339
Any Solicited Systemic Adverse Reactions	8032 (53.0)	12553 (82.7)	20585 (67.8)
95% CI	52.2, 53.8	82.1, 83.3	67.3, 68.4
Grade 1	4953 (32.7)	4136 (27.3)	9089 (30.0)
Grade 2	2519 (16.6)	5916 (39.0)	8435 (27.8)
Grade 3	551 (3.6)	2484 (16.4)	3035 (10.0)
Grade 4	9 (<0.1)	17 (0.1)	26 (<0.1)
Fever - N1	15161	15175	30337
Any	88 (0.6)	2252 (14.8)	2340 (7.7)
Grade 1	64 (0.4)	1354 (8.9)	1418 (4.7)
Grade 2	12 (<0.1)	687 (4.5)	699 (2.3)
Grade 3	3 (<0.1)	196 (1.3)	199 (0.7)
Grade 4	9 (<0.1)	15 (<0.1)	24 (<0.1)
Headache - N1	15161	15176	30338
Any	5527 (36.5)	9566 (63.0)	15093 (49.7)
Grade 1	4303 (28.4)	5508 (36.3)	9811 (32.3)
Grade 2	887 (5.9)	3225 (21.3)	4112 (13.6)
Grade 3	337 (2.2)	833 (5.5)	1170 (3.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Fatigue - N1	15161	15176	30338
Any	5470 (36.1)	10393 (68.5)	15863 (52.3)
Grade 1	3329 (22.0)	3834 (25.3)	7163 (23.6)
Grade 2	1944 (12.8)	5107 (33.7)	7051 (23.2)
Grade 3	197 (1.3)	1451 (9.6)	1648 (5.4)
Grade 4	0	1 (<0.1)	1 (<0.1)
Myalgia - N1	15161	15176	30338
Any	3052 (20.1)	9039 (59.6)	12091 (39.9)
Grade 1	2169 (14.3)	3637 (24.0)	5806 (19.1)
Grade 2	788 (5.2)	4100 (27.0)	4888 (16.1)
Grade 3	95 (0.6)	1302 (8.6)	1397 (4.6)
Grade 4	0	0	0
Arthralgia - N1	15161	15176	30338
Any	2606 (17.2)	6803 (44.8)	9409 (31.0)
Grade 1	1849 (12.2)	3177 (20.9)	5026 (16.6)
Grade 2	678 (4.5)	2854 (18.8)	3532 (11.6)
Grade 3	79 (0.5)	771 (5.1)	850 (2.8)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Nausea/Vomiting - N1	15161	15176	30338
Any	1679 (11.1)	3366 (22.2)	5045 (16.6)
Grade 1	1350 (8.9)	2535 (16.7)	3885 (12.8)
Grade 2	306 (2.0)	803 (5.3)	1109 (3.7)
Grade 3	23 (0.2)	27 (0.2)	50 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Chills - N1	15161	15176	30338
Any	1439 (9.5)	6580 (43.4)	8019 (26.4)
Grade 1	1108 (7.3)	3035 (20.0)	4143 (13.7)
Grade 2	301 (2.0)	3346 (22.0)	3647 (12.0)
Grade 3	30 (0.2)	199 (1.3)	229 (0.8)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Solicited Adverse Reactions - N1	11412	11410	22823
Any Solicited Adverse Reactions	7017 (61.5)	10841 (95.0)	17858 (78.2)
95% CI	60.6, 62.4	94.6, 95.4	77.7, 78.8
Grade 1	4455 (39.0)	3463 (30.4)	7918 (34.7)
Grade 2	2068 (18.1)	4722 (41.4)	6790 (29.8)
Grade 3	488 (4.3)	2641 (23.1)	3129 (13.7)
Grade 4	6 (<0.1)	15 (0.1)	21 (<0.1)
Solicited Local Adverse Reactions - N1	11411	11410	22822
Any Solicited Local Adverse Reactions	3522 (30.9)	10625 (93.1)	14147 (62.0)
95% CI	30.0, 31.7	92.6, 93.6	61.4, 62.6
Grade 1	3331 (29.2)	6564 (57.5)	9895 (43.4)
Grade 2	114 (1.0)	2954 (25.9)	3068 (13.4)
Grade 3	77 (0.7)	1107 (9.7)	1184 (5.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Pain - N1	11411	11410	22822
Any	3224 (28.3)	10590 (92.8)	13814 (60.5)
Grade 1	3105 (27.2)	7144 (62.6)	10249 (44.9)
Grade 2	77 (0.7)	2686 (23.5)	2763 (12.1)
Grade 3	42 (0.4)	760 (6.7)	802 (3.5)
Grade 4	0	0	0
Erythema (Redness) - N1	11411	11410	22822
Any	82 (0.7)	1145 (10.0)	1227 (5.4)
Grade 1	53 (0.5)	454 (4.0)	507 (2.2)
Grade 2	7 (<0.1)	455 (4.0)	462 (2.0)
Grade 3	22 (0.2)	236 (2.1)	258 (1.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	11411	11410	22822
Any	65 (0.6)	1715 (15.0)	1780 (7.8)
Grade 1	49 (0.4)	898 (7.9)	947 (4.1)
Grade 2	10 (<0.1)	585 (5.1)	595 (2.6)
Grade 3	6 (<0.1)	232 (2.0)	238 (1.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Lymphadenopathy - N1 [1]	11411	11410	22822
Any	858 (7.5)	2447 (21.4)	3305 (14.5)
Grade 1	793 (6.9)	2054 (18.0)	2847 (12.5)
Grade 2	42 (0.4)	315 (2.8)	357 (1.6)
Grade 3	23 (0.2)	78 (0.7)	101 (0.4)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	11412	11410	22823
Any Solicited Systemic Adverse Reactions	6278 (55.0)	9631 (84.4)	15909 (69.7)
95% CI	54.1, 55.9	83.7, 85.1	69.1, 70.3
Grade 1	3791 (33.2)	2928 (25.7)	6719 (29.4)
Grade 2	2046 (17.9)	4646 (40.7)	6692 (29.3)
Grade 3	435 (3.8)	2042 (17.9)	2477 (10.9)
Grade 4	6 (<0.1)	15 (0.1)	21 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Fever - N1	11411	11409	22821
Any	76 (0.7)	1880 (16.5)	1956 (8.6)
Grade 1	58 (0.5)	1096 (9.6)	1154 (5.1)
Grade 2	10 (<0.1)	592 (5.2)	602 (2.6)
Grade 3	2 (<0.1)	178 (1.6)	180 (0.8)
Grade 4	6 (<0.1)	14 (0.1)	20 (<0.1)
Headache - N1	11411	11410	22822
Any	4453 (39.0)	7585 (66.5)	12038 (52.7)
Grade 1	3395 (29.8)	4157 (36.4)	7552 (33.1)
Grade 2	785 (6.9)	2742 (24.0)	3527 (15.5)
Grade 3	273 (2.4)	686 (6.0)	959 (4.2)
Grade 4	0	0	0
Fatigue - N1	11411	11410	22822
Any	4279 (37.5)	7986 (70.0)	12265 (53.7)
Grade 1	2543 (22.3)	2807 (24.6)	5350 (23.4)
Grade 2	1581 (13.9)	3997 (35.0)	5578 (24.4)
Grade 3	155 (1.4)	1181 (10.4)	1336 (5.9)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Myalgia - N1	11411	11410	22822
Any	2378 (20.8)	7125 (62.4)	9503 (41.6)
Grade 1	1652 (14.5)	2691 (23.6)	4343 (19.0)
Grade 2	650 (5.7)	3347 (29.3)	3997 (17.5)
Grade 3	76 (0.7)	1087 (9.5)	1163 (5.1)
Grade 4	0	0	0
Arthralgia - N1	11411	11410	22822
Any	1945 (17.0)	5315 (46.6)	7260 (31.8)
Grade 1	1346 (11.8)	2347 (20.6)	3693 (16.2)
Grade 2	535 (4.7)	2327 (20.4)	2862 (12.5)
Grade 3	64 (0.6)	640 (5.6)	704 (3.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Nausea/Vomiting - N1	11411	11410	22822
Any	1410 (12.4)	2813 (24.7)	4223 (18.5)
Grade 1	1129 (9.9)	2107 (18.5)	3236 (14.2)
Grade 2	265 (2.3)	692 (6.1)	957 (4.2)
Grade 3	16 (0.1)	14 (0.1)	30 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Chills - N1	11411	11410	22822
Any	1177 (10.3)	5388 (47.2)	6565 (28.8)
Grade 1	896 (7.9)	2401 (21.0)	3297 (14.4)
Grade 2	259 (2.3)	2820 (24.7)	3079 (13.5)
Grade 3	22 (0.2)	167 (1.5)	189 (0.8)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Solicited Adverse Reactions - N1	3750	3766	7516
Any Solicited Adverse Reactions	2010 (53.6)	3497 (92.9)	5507 (73.3)
95% CI	52.0, 55.2	92.0, 93.7	72.3, 74.3
Grade 1	1357 (36.2)	1574 (41.8)	2931 (39.0)
Grade 2	482 (12.9)	1303 (34.6)	1785 (23.7)
Grade 3	168 (4.5)	618 (16.4)	786 (10.5)
Grade 4	3 (<0.1)	2 (<0.1)	5 (<0.1)
Solicited Local Adverse Reactions - N1	3750	3766	7516
Any Solicited Local Adverse Reactions	859 (22.9)	3337 (88.6)	4196 (55.8)
95% CI	21.6, 24.3	87.6, 89.6	54.7, 57.0
Grade 1	757 (20.2)	2524 (67.0)	3281 (43.7)
Grade 2	36 (1.0)	534 (14.2)	570 (7.6)
Grade 3	66 (1.8)	279 (7.4)	345 (4.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Pain - N1	3750	3766	7516
Any	751 (20.0)	3311 (87.9)	4062 (54.0)
Grade 1	677 (18.1)	2743 (72.8)	3420 (45.5)
Grade 2	26 (0.7)	427 (11.3)	453 (6.0)
Grade 3	48 (1.3)	141 (3.7)	189 (2.5)
Grade 4	0	0	0
Erythema (Redness) - N1	3750	3766	7516
Any	32 (0.9)	325 (8.6)	357 (4.7)
Grade 1	24 (0.6)	128 (3.4)	152 (2.0)
Grade 2	3 (<0.1)	114 (3.0)	117 (1.6)
Grade 3	5 (0.1)	83 (2.2)	88 (1.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	3750	3766	7516
Any	30 (0.8)	468 (12.4)	498 (6.6)
Grade 1	16 (0.4)	233 (6.2)	249 (3.3)
Grade 2	4 (0.1)	149 (4.0)	153 (2.0)
Grade 3	10 (0.3)	86 (2.3)	96 (1.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Lymphadenopathy - N1 [1]	3750	3766	7516
Any	216 (5.8)	467 (12.4)	683 (9.1)
Grade 1	188 (5.0)	407 (10.8)	595 (7.9)
Grade 2	7 (0.2)	30 (0.8)	37 (0.5)
Grade 3	21 (0.6)	30 (0.8)	51 (0.7)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	3750	3766	7516
Any Solicited Systemic Adverse Reactions	1754 (46.8)	2922 (77.6)	4676 (62.2)
95% CI	45.2, 48.4	76.2, 78.9	61.1, 63.3
Grade 1	1162 (31.0)	1208 (32.1)	2370 (31.5)
Grade 2	473 (12.6)	1270 (33.7)	1743 (23.2)
Grade 3	116 (3.1)	442 (11.7)	558 (7.4)
Grade 4	3 (<0.1)	2 (<0.1)	5 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Fever - N1	3750	3766	7516
Any	12 (0.3)	372 (9.9)	384 (5.1)
Grade 1	6 (0.2)	258 (6.9)	264 (3.5)
Grade 2	2 (<0.1)	95 (2.5)	97 (1.3)
Grade 3	1 (<0.1)	18 (0.5)	19 (0.3)
Grade 4	3 (<0.1)	1 (<0.1)	4 (<0.1)
Headache - N1	3750	3766	7516
Any	1074 (28.6)	1981 (52.6)	3055 (40.6)
Grade 1	908 (24.2)	1351 (35.9)	2259 (30.1)
Grade 2	102 (2.7)	483 (12.8)	585 (7.8)
Grade 3	64 (1.7)	147 (3.9)	211 (2.8)
Grade 4	0	0	0
Fatigue - N1	3750	3766	7516
Any	1191 (31.8)	2407 (63.9)	3598 (47.9)
Grade 1	786 (21.0)	1027 (27.3)	1813 (24.1)
Grade 2	363 (9.7)	1110 (29.5)	1473 (19.6)
Grade 3	42 (1.1)	270 (7.2)	312 (4.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Myalgia - N1	3750	3766	7516
Any	674 (18.0)	1914 (50.8)	2588 (34.4)
Grade 1	517 (13.8)	946 (25.1)	1463 (19.5)
Grade 2	138 (3.7)	753 (20.0)	891 (11.9)
Grade 3	19 (0.5)	215 (5.7)	234 (3.1)
Grade 4	0	0	0
Arthralgia - N1	3750	3766	7516
Any	661 (17.6)	1488 (39.5)	2149 (28.6)
Grade 1	503 (13.4)	830 (22.0)	1333 (17.7)
Grade 2	143 (3.8)	527 (14.0)	670 (8.9)
Grade 3	15 (0.4)	131 (3.5)	146 (1.9)
Grade 4	0	0	0
Nausea/Vomiting - N1	3750	3766	7516
Any	269 (7.2)	553 (14.7)	822 (10.9)
Grade 1	221 (5.9)	428 (11.4)	649 (8.6)
Grade 2	41 (1.1)	111 (2.9)	152 (2.0)
Grade 3	7 (0.2)	13 (0.3)	20 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Chills - N1	3750	3766	7516
Any	262 (7.0)	1192 (31.7)	1454 (19.3)
Grade 1	212 (5.7)	634 (16.8)	846 (11.3)
Grade 2	42 (1.1)	526 (14.0)	568 (7.6)
Grade 3	8 (0.2)	32 (0.8)	40 (0.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Solicited Adverse Reactions - N1	14356	14301	28657
Any Solicited Adverse Reactions	6888 (48.0)	12591 (88.0)	19479 (68.0)
95% CI	47.2, 48.8	87.5, 88.6	67.4, 68.5
Grade 1	4886 (34.0)	8875 (62.1)	13761 (48.0)
Grade 2	1659 (11.6)	2930 (20.5)	4589 (16.0)
Grade 3	338 (2.4)	782 (5.5)	1120 (3.9)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)
Solicited Local Adverse Reactions - N1	14353	14297	28650
Any Solicited Local Adverse Reactions	2830 (19.7)	12080 (84.5)	14910 (52.0)
95% CI	19.1, 20.4	83.9, 85.1	51.5, 52.6
Grade 1	2680 (18.7)	10171 (71.1)	12851 (44.9)
Grade 2	79 (0.6)	1412 (9.9)	1491 (5.2)
Grade 3	71 (0.5)	497 (3.5)	568 (2.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade

First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Pain - N1	14353	14297	28650
Any	2507 (17.5)	12013 (84.0)	14520 (50.7)
Grade 1	2406 (16.8)	10418 (72.9)	12824 (44.8)
Grade 2	51 (0.4)	1203 (8.4)	1254 (4.4)
Grade 3	50 (0.3)	392 (2.7)	442 (1.5)
Grade 4	0	0	0
Erythema (Redness) - N1	14353	14296	28649
Any	60 (0.4)	406 (2.8)	466 (1.6)
Grade 1	42 (0.3)	251 (1.8)	293 (1.0)
Grade 2	7 (<0.1)	115 (0.8)	122 (0.4)
Grade 3	11 (<0.1)	40 (0.3)	51 (0.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	14353	14296	28649
Any	49 (0.3)	884 (6.2)	933 (3.3)
Grade 1	36 (0.3)	576 (4.0)	612 (2.1)
Grade 2	7 (<0.1)	230 (1.6)	237 (0.8)
Grade 3	6 (<0.1)	78 (0.5)	84 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade

First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Lymphadenopathy - N1 [1]	14353	14296	28649
Any	677 (4.7)	1445 (10.1)	2122 (7.4)
Grade 1	627 (4.4)	1308 (9.1)	1935 (6.8)
Grade 2	26 (0.2)	94 (0.7)	120 (0.4)
Grade 3	24 (0.2)	43 (0.3)	67 (0.2)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14356	14300	28656
Any Solicited Systemic Adverse Reactions	6053 (42.2)	7814 (54.6)	13867 (48.4)
95% CI	41.4, 43.0	53.8, 55.5	47.8, 49.0
Grade 1	4131 (28.8)	5079 (35.5)	9210 (32.1)
Grade 2	1628 (11.3)	2330 (16.3)	3958 (13.8)
Grade 3	289 (2.0)	401 (2.8)	690 (2.4)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade

First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Fever - N1	14355	14298	28653
Any	38 (0.3)	78 (0.5)	116 (0.4)
Grade 1	27 (0.2)	50 (0.3)	77 (0.3)
Grade 2	4 (<0.1)	16 (0.1)	20 (<0.1)
Grade 3	2 (<0.1)	9 (<0.1)	11 (<0.1)
Grade 4	5 (<0.1)	3 (<0.1)	8 (<0.1)
Headache - N1	14352	14296	28648
Any	3795 (26.4)	4634 (32.4)	8429 (29.4)
Grade 1	3124 (21.8)	3724 (26.0)	6848 (23.9)
Grade 2	487 (3.4)	668 (4.7)	1155 (4.0)
Grade 3	184 (1.3)	242 (1.7)	426 (1.5)
Grade 4	0	0	0
Fatigue - N1	14352	14296	28648
Any	3903 (27.2)	5303 (37.1)	9206 (32.1)
Grade 1	2569 (17.9)	3407 (23.8)	5976 (20.9)
Grade 2	1239 (8.6)	1760 (12.3)	2999 (10.5)
Grade 3	95 (0.7)	135 (0.9)	230 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Myalgia - N1	14352	14296	28648
Any	1937 (13.5)	3194 (22.3)	5131 (17.9)
Grade 1	1470 (10.2)	2282 (16.0)	3752 (13.1)
Grade 2	426 (3.0)	832 (5.8)	1258 (4.4)
Grade 3	41 (0.3)	80 (0.6)	121 (0.4)
Grade 4	0	0	0
Arthralgia - N1	14352	14296	28648
Any	1671 (11.6)	2337 (16.3)	4008 (14.0)
Grade 1	1265 (8.8)	1731 (12.1)	2996 (10.5)
Grade 2	372 (2.6)	553 (3.9)	925 (3.2)
Grade 3	34 (0.2)	52 (0.4)	86 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Nausea/Vomiting - N1	14352	14296	28648
Any	1012 (7.1)	1170 (8.2)	2182 (7.6)
Grade 1	842 (5.9)	982 (6.9)	1824 (6.4)
Grade 2	158 (1.1)	180 (1.3)	338 (1.2)
Grade 3	12 (<0.1)	8 (<0.1)	20 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Chills - N1	14352	14296	28648
Any	822 (5.7)	1124 (7.9)	1946 (6.8)
Grade 1	664 (4.6)	862 (6.0)	1526 (5.3)
Grade 2	145 (1.0)	242 (1.7)	387 (1.4)
Grade 3	13 (<0.1)	20 (0.1)	33 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade

First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Solicited Adverse Reactions - N1	334	340	674
Any Solicited Adverse Reactions	134 (40.1)	259 (76.2)	393 (58.3)
95% CI	34.8, 45.6	71.3, 80.6	54.5, 62.1
Grade 1	81 (24.3)	136 (40.0)	217 (32.2)
Grade 2	39 (11.7)	95 (27.9)	134 (19.9)
Grade 3	13 (3.9)	27 (7.9)	40 (5.9)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Solicited Local Adverse Reactions - N1	334	340	674
Any Solicited Local Adverse Reactions	58 (17.4)	244 (71.8)	302 (44.8)
95% CI	13.5, 21.9	66.7, 76.5	41.0, 48.7
Grade 1	54 (16.2)	176 (51.8)	230 (34.1)
Grade 2	1 (0.3)	55 (16.2)	56 (8.3)
Grade 3	3 (0.9)	13 (3.8)	16 (2.4)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade

First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Pain - N1	334	340	674
Any	54 (16.2)	242 (71.2)	296 (43.9)
Grade 1	52 (15.6)	181 (53.2)	233 (34.6)
Grade 2	1 (0.3)	51 (15.0)	52 (7.7)
Grade 3	1 (0.3)	10 (2.9)	11 (1.6)
Grade 4	0	0	0
Erythema (Redness) - N1	334	340	674
Any	3 (0.9)	9 (2.6)	12 (1.8)
Grade 1	1 (0.3)	5 (1.5)	6 (0.9)
Grade 2	0	2 (0.6)	2 (0.3)
Grade 3	2 (0.6)	2 (0.6)	4 (0.6)
Grade 4	0	0	0
Swelling (Hardness) - N1	334	340	674
Any	2 (0.6)	20 (5.9)	22 (3.3)
Grade 1	2 (0.6)	11 (3.2)	13 (1.9)
Grade 2	0	8 (2.4)	8 (1.2)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Lymphadenopathy - N1 [1]	334	340	674
Any	16 (4.8)	52 (15.3)	68 (10.1)
Grade 1	15 (4.5)	37 (10.9)	52 (7.7)
Grade 2	0	11 (3.2)	11 (1.6)
Grade 3	1 (0.3)	4 (1.2)	5 (0.7)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	334	340	674
Any Solicited Systemic Adverse Reactions	118 (35.3)	208 (61.2)	326 (48.4)
95% CI	30.2, 40.7	55.8, 66.4	44.5, 52.2
Grade 1	68 (20.4)	107 (31.5)	175 (26.0)
Grade 2	38 (11.4)	79 (23.2)	117 (17.4)
Grade 3	11 (3.3)	21 (6.2)	32 (4.7)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Fever - N1	333	340	673
Any	6 (1.8)	31 (9.1)	37 (5.5)
Grade 1	3 (0.9)	19 (5.6)	22 (3.3)
Grade 2	2 (0.6)	9 (2.6)	11 (1.6)
Grade 3	0	2 (0.6)	2 (0.3)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Headache - N1	334	340	674
Any	79 (23.7)	129 (37.9)	208 (30.9)
Grade 1	57 (17.1)	88 (25.9)	145 (21.5)
Grade 2	15 (4.5)	30 (8.8)	45 (6.7)
Grade 3	7 (2.1)	11 (3.2)	18 (2.7)
Grade 4	0	0	0
Fatigue - N1	334	340	674
Any	70 (21.0)	132 (38.8)	202 (30.0)
Grade 1	39 (11.7)	69 (20.3)	108 (16.0)
Grade 2	27 (8.1)	54 (15.9)	81 (12.0)
Grade 3	4 (1.2)	9 (2.6)	13 (1.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1). 95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade

First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Myalgia - N1	334	340	674
Any	46 (13.8)	122 (35.9)	168 (24.9)
Grade 1	26 (7.8)	68 (20.0)	94 (13.9)
Grade 2	18 (5.4)	48 (14.1)	66 (9.8)
Grade 3	2 (0.6)	6 (1.8)	8 (1.2)
Grade 4	0	0	0
Arthralgia - N1	334	340	674
Any	38 (11.4)	85 (25.0)	123 (18.2)
Grade 1	21 (6.3)	53 (15.6)	74 (11.0)
Grade 2	15 (4.5)	27 (7.9)	42 (6.2)
Grade 3	2 (0.6)	5 (1.5)	7 (1.0)
Grade 4	0	0	0
Nausea/Vomiting - N1	334	340	674
Any	25 (7.5)	40 (11.8)	65 (9.6)
Grade 1	17 (5.1)	28 (8.2)	45 (6.7)
Grade 2	8 (2.4)	12 (3.5)	20 (3.0)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Chills - N1	334	340	674
Any	26 (7.8)	80 (23.5)	106 (15.7)
Grade 1	17 (5.1)	43 (12.6)	60 (8.9)
Grade 2	8 (2.4)	34 (10.0)	42 (6.2)
Grade 3	1 (0.3)	3 (0.9)	4 (0.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade

First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Solicited Adverse Reactions - N1	464	526	991
Any Solicited Adverse Reactions	260 (56.0)	470 (89.4)	730 (73.7)
95% CI	51.4, 60.6	86.4, 91.9	70.8, 76.4
Grade 1	178 (38.4)	328 (62.4)	506 (51.1)
Grade 2	71 (15.3)	103 (19.6)	174 (17.6)
Grade 3	11 (2.4)	39 (7.4)	50 (5.0)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	463	526	990
Any Solicited Local Adverse Reactions	110 (23.8)	441 (83.8)	551 (55.7)
95% CI	20.0, 27.9	80.4, 86.9	52.5, 58.8
Grade 1	105 (22.7)	381 (72.4)	486 (49.1)
Grade 2	1 (0.2)	41 (7.8)	42 (4.2)
Grade 3	4 (0.9)	19 (3.6)	23 (2.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Pain - N1	463	526	990
Any	99 (21.4)	435 (82.7)	534 (53.9)
Grade 1	94 (20.3)	388 (73.8)	482 (48.7)
Grade 2	1 (0.2)	32 (6.1)	33 (3.3)
Grade 3	4 (0.9)	15 (2.9)	19 (1.9)
Grade 4	0	0	0
Erythema (Redness) - N1	463	526	990
Any	2 (0.4)	16 (3.0)	18 (1.8)
Grade 1	2 (0.4)	12 (2.3)	14 (1.4)
Grade 2	0	4 (0.8)	4 (0.4)
Grade 3	0	0	0
Grade 4	0	0	0
Swelling (Hardness) - N1	463	526	990
Any	1 (0.2)	30 (5.7)	31 (3.1)
Grade 1	1 (0.2)	21 (4.0)	22 (2.2)
Grade 2	0	6 (1.1)	6 (0.6)
Grade 3	0	3 (0.6)	3 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1). 95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Lymphadenopathy - N1 [1]	463	526	990
Any	29 (6.3)	56 (10.6)	85 (8.6)
Grade 1	27 (5.8)	50 (9.5)	77 (7.8)
Grade 2	0	5 (1.0)	5 (0.5)
Grade 3	2 (0.4)	1 (0.2)	3 (0.3)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	464	526	991
Any Solicited Systemic Adverse Reactions	227 (48.9)	299 (56.8)	526 (53.1)
95% CI	44.3, 53.6	52.5, 61.1	49.9, 56.2
Grade 1	146 (31.5)	184 (35.0)	330 (33.3)
Grade 2	72 (15.5)	90 (17.1)	162 (16.3)
Grade 3	9 (1.9)	25 (4.8)	34 (3.4)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Fever - N1	464	525	990
Any	2 (0.4)	6 (1.1)	8 (0.8)
Grade 1	1 (0.2)	5 (1.0)	6 (0.6)
Grade 2	1 (0.2)	1 (0.2)	2 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	463	526	990
Any	153 (33.0)	189 (35.9)	342 (34.5)
Grade 1	123 (26.6)	141 (26.8)	264 (26.7)
Grade 2	25 (5.4)	30 (5.7)	55 (5.6)
Grade 3	5 (1.1)	18 (3.4)	23 (2.3)
Grade 4	0	0	0
Fatigue - N1	463	526	990
Any	160 (34.6)	200 (38.0)	360 (36.4)
Grade 1	100 (21.6)	123 (23.4)	223 (22.5)
Grade 2	53 (11.4)	71 (13.5)	124 (12.5)
Grade 3	7 (1.5)	6 (1.1)	13 (1.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Myalgia - N1	463	526	990
Any	86 (18.6)	125 (23.8)	211 (21.3)
Grade 1	70 (15.1)	94 (17.9)	164 (16.6)
Grade 2	12 (2.6)	27 (5.1)	39 (3.9)
Grade 3	4 (0.9)	4 (0.8)	8 (0.8)
Grade 4	0	0	0
Arthralgia - N1	463	526	990
Any	74 (16.0)	88 (16.7)	162 (16.4)
Grade 1	56 (12.1)	60 (11.4)	116 (11.7)
Grade 2	17 (3.7)	25 (4.8)	42 (4.2)
Grade 3	1 (0.2)	3 (0.6)	4 (0.4)
Grade 4	0	0	0
Nausea/Vomiting - N1	463	526	990
Any	37 (8.0)	53 (10.1)	90 (9.1)
Grade 1	31 (6.7)	40 (7.6)	71 (7.2)
Grade 2	6 (1.3)	11 (2.1)	17 (1.7)
Grade 3	0	2 (0.4)	2 (0.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.7
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Chills - N1	463	526	990
Any	30 (6.5)	49 (9.3)	79 (8.0)
Grade 1	25 (5.4)	35 (6.7)	60 (6.1)
Grade 2	5 (1.1)	13 (2.5)	18 (1.8)
Grade 3	0	1 (0.2)	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Solicited Adverse Reactions - N1	13252	13286	26538
Any Solicited Adverse Reactions	5674 (42.8)	12291 (92.5)	17965 (67.7)
95% CI	42.0, 43.7	92.1, 93.0	67.1, 68.3
Grade 1	3987 (30.1)	4417 (33.2)	8404 (31.7)
Grade 2	1368 (10.3)	5248 (39.5)	6616 (24.9)
Grade 3	316 (2.4)	2614 (19.7)	2930 (11.0)
Grade 4	3 (<0.1)	12 (<0.1)	15 (<0.1)
Solicited Local Adverse Reactions - N1	13249	13283	26532
Any Solicited Local Adverse Reactions	2473 (18.7)	11821 (89.0)	14294 (53.9)
95% CI	18.0, 19.3	88.4, 89.5	53.3, 54.5
Grade 1	2337 (17.6)	7979 (60.1)	10316 (38.9)
Grade 2	71 (0.5)	2915 (21.9)	2986 (11.3)
Grade 3	65 (0.5)	927 (7.0)	992 (3.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Pain - N1	13249	13283	26532
Any	2242 (16.9)	11770 (88.6)	14012 (52.8)
Grade 1	2157 (16.3)	8645 (65.1)	10802 (40.7)
Grade 2	51 (0.4)	2580 (19.4)	2631 (9.9)
Grade 3	34 (0.3)	545 (4.1)	579 (2.2)
Grade 4	0	0	0
Erythema (Redness) - N1	13249	13283	26532
Any	51 (0.4)	1152 (8.7)	1203 (4.5)
Grade 1	34 (0.3)	399 (3.0)	433 (1.6)
Grade 2	3 (<0.1)	492 (3.7)	495 (1.9)
Grade 3	14 (0.1)	261 (2.0)	275 (1.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Swelling (Hardness) - N1	13249	13283	26532
Any	47 (0.4)	1639 (12.3)	1686 (6.4)
Grade 1	29 (0.2)	821 (6.2)	850 (3.2)
Grade 2	7 (<0.1)	586 (4.4)	593 (2.2)
Grade 3	11 (<0.1)	232 (1.7)	243 (0.9)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	13249	13283	26532
Any	502 (3.8)	1869 (14.1)	2371 (8.9)
Grade 1	462 (3.5)	1561 (11.8)	2023 (7.6)
Grade 2	22 (0.2)	244 (1.8)	266 (1.0)
Grade 3	18 (0.1)	64 (0.5)	82 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Solicited Systemic Adverse Reactions - N1	13251	13286	26537
Any Solicited Systemic Adverse Reactions	4833 (36.5)	10568 (79.5)	15401 (58.0)
95% CI	35.7, 37.3	78.8, 80.2	57.4, 58.6
Grade 1	3222 (24.3)	3387 (25.5)	6609 (24.9)
Grade 2	1347 (10.2)	5062 (38.1)	6409 (24.2)
Grade 3	261 (2.0)	2107 (15.9)	2368 (8.9)
Grade 4	3 (<0.1)	12 (<0.1)	15 (<0.1)
Fever - N1	13247	13279	26526
Any	42 (0.3)	2093 (15.8)	2135 (8.0)
Grade 1	33 (0.2)	1257 (9.5)	1290 (4.9)
Grade 2	5 (<0.1)	644 (4.8)	649 (2.4)
Grade 3	1 (<0.1)	181 (1.4)	182 (0.7)
Grade 4	3 (<0.1)	11 (<0.1)	14 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Headache - N1	13249	13283	26532
Any	3103 (23.4)	7834 (59.0)	10937 (41.2)
Grade 1	2478 (18.7)	4400 (33.1)	6878 (25.9)
Grade 2	474 (3.6)	2842 (21.4)	3316 (12.5)
Grade 3	151 (1.1)	592 (4.5)	743 (2.8)
Grade 4	0	0	0
Fatigue - N1	13247	13283	26530
Any	3062 (23.1)	8719 (65.6)	11781 (44.4)
Grade 1	1987 (15.0)	3141 (23.6)	5128 (19.3)
Grade 2	981 (7.4)	4277 (32.2)	5258 (19.8)
Grade 3	94 (0.7)	1301 (9.8)	1395 (5.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Myalgia - N1	13248	13283	26531
Any	1589 (12.0)	7673 (57.8)	9262 (34.9)
Grade 1	1149 (8.7)	2918 (22.0)	4067 (15.3)
Grade 2	395 (3.0)	3566 (26.8)	3961 (14.9)
Grade 3	45 (0.3)	1189 (9.0)	1234 (4.7)
Grade 4	0	0	0
Arthralgia - N1	13247	13283	26530
Any	1382 (10.4)	5680 (42.8)	7062 (26.6)
Grade 1	1011 (7.6)	2556 (19.2)	3567 (13.4)
Grade 2	331 (2.5)	2425 (18.3)	2756 (10.4)
Grade 3	40 (0.3)	699 (5.3)	739 (2.8)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Nausea/Vomiting - N1	13247	13283	26530
Any	841 (6.3)	2518 (19.0)	3359 (12.7)
Grade 1	686 (5.2)	1886 (14.2)	2572 (9.7)
Grade 2	145 (1.1)	614 (4.6)	759 (2.9)
Grade 3	10 (<0.1)	17 (0.1)	27 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Chills - N1	13247	13283	26530
Any	712 (5.4)	5850 (44.0)	6562 (24.7)
Grade 1	553 (4.2)	2621 (19.7)	3174 (12.0)
Grade 2	144 (1.1)	3055 (23.0)	3199 (12.1)
Grade 3	15 (0.1)	174 (1.3)	189 (0.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Solicited Adverse Reactions - N1	213	203	416
Any Solicited Adverse Reactions	74 (34.7)	164 (80.8)	238 (57.2)
95% CI	28.4, 41.5	74.7, 86.0	52.3, 62.0
Grade 1	47 (22.1)	78 (38.4)	125 (30.0)
Grade 2	24 (11.3)	59 (29.1)	83 (20.0)
Grade 3	3 (1.4)	27 (13.3)	30 (7.2)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	212	203	415
Any Solicited Local Adverse Reactions	37 (17.5)	151 (74.4)	188 (45.3)
95% CI	12.6, 23.2	67.8, 80.2	40.4, 50.2
Grade 1	30 (14.2)	110 (54.2)	140 (33.7)
Grade 2	5 (2.4)	29 (14.3)	34 (8.2)
Grade 3	2 (0.9)	12 (5.9)	14 (3.4)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Pain - N1	212	203	415
Any	31 (14.6)	148 (72.9)	179 (43.1)
Grade 1	27 (12.7)	110 (54.2)	137 (33.0)
Grade 2	3 (1.4)	30 (14.8)	33 (8.0)
Grade 3	1 (0.5)	8 (3.9)	9 (2.2)
Grade 4	0	0	0
Erythema (Redness) - N1	212	203	415
Any	1 (0.5)	8 (3.9)	9 (2.2)
Grade 1	0	2 (1.0)	2 (0.5)
Grade 2	0	3 (1.5)	3 (0.7)
Grade 3	1 (0.5)	3 (1.5)	4 (1.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Swelling (Hardness) - N1	212	203	415
Any	1 (0.5)	10 (4.9)	11 (2.7)
Grade 1	0	3 (1.5)	3 (0.7)
Grade 2	1 (0.5)	5 (2.5)	6 (1.4)
Grade 3	0	2 (1.0)	2 (0.5)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	212	203	415
Any	10 (4.7)	27 (13.3)	37 (8.9)
Grade 1	7 (3.3)	19 (9.4)	26 (6.3)
Grade 2	3 (1.4)	6 (3.0)	9 (2.2)
Grade 3	0	2 (1.0)	2 (0.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Solicited Systemic Adverse Reactions - N1	213	203	416
Any Solicited Systemic Adverse Reactions	66 (31.0)	135 (66.5)	201 (48.3)
95% CI	24.8, 37.7	59.6, 73.0	43.4, 53.2
Grade 1	40 (18.8)	54 (26.6)	94 (22.6)
Grade 2	25 (11.7)	62 (30.5)	87 (20.9)
Grade 3	1 (0.5)	19 (9.4)	20 (4.8)
Grade 4	0	0	0
Fever - N1	212	203	415
Any	1 (0.5)	27 (13.3)	28 (6.7)
Grade 1	1 (0.5)	18 (8.9)	19 (4.6)
Grade 2	0	7 (3.4)	7 (1.7)
Grade 3	0	2 (1.0)	2 (0.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Headache - N1	212	203	415
Any	40 (18.9)	88 (43.3)	128 (30.8)
Grade 1	35 (16.5)	55 (27.1)	90 (21.7)
Grade 2	5 (2.4)	28 (13.8)	33 (8.0)
Grade 3	0	5 (2.5)	5 (1.2)
Grade 4	0	0	0
Fatigue - N1	212	203	415
Any	49 (23.1)	92 (45.3)	141 (34.0)
Grade 1	28 (13.2)	35 (17.2)	63 (15.2)
Grade 2	20 (9.4)	46 (22.7)	66 (15.9)
Grade 3	1 (0.5)	11 (5.4)	12 (2.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Myalgia - N1	212	203	415
Any	29 (13.7)	101 (49.8)	130 (31.3)
Grade 1	19 (9.0)	51 (25.1)	70 (16.9)
Grade 2	10 (4.7)	40 (19.7)	50 (12.0)
Grade 3	0	10 (4.9)	10 (2.4)
Grade 4	0	0	0
Arthralgia - N1	212	203	415
Any	21 (9.9)	66 (32.5)	87 (21.0)
Grade 1	16 (7.5)	31 (15.3)	47 (11.3)
Grade 2	5 (2.4)	32 (15.8)	37 (8.9)
Grade 3	0	3 (1.5)	3 (0.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Nausea/Vomiting - N1	212	203	415
Any	11 (5.2)	32 (15.8)	43 (10.4)
Grade 1	8 (3.8)	25 (12.3)	33 (8.0)
Grade 2	3 (1.4)	7 (3.4)	10 (2.4)
Grade 3	0	0	0
Grade 4	0	0	0
Chills - N1	212	203	415
Any	14 (6.6)	69 (34.0)	83 (20.0)
Grade 1	12 (5.7)	34 (16.7)	46 (11.1)
Grade 2	2 (0.9)	35 (17.2)	37 (8.9)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Solicited Adverse Reactions - N1	405	458	863
Any Solicited Adverse Reactions	194 (47.9)	422 (92.1)	616 (71.4)
95% CI	42.9, 52.9	89.3, 94.4	68.2, 74.4
Grade 1	134 (33.1)	158 (34.5)	292 (33.8)
Grade 2	48 (11.9)	179 (39.1)	227 (26.3)
Grade 3	12 (3.0)	85 (18.6)	97 (11.2)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	405	458	863
Any Solicited Local Adverse Reactions	97 (24.0)	409 (89.3)	506 (58.6)
95% CI	19.9, 28.4	86.1, 92.0	55.3, 61.9
Grade 1	92 (22.7)	286 (62.4)	378 (43.8)
Grade 2	2 (0.5)	84 (18.3)	86 (10.0)
Grade 3	3 (0.7)	39 (8.5)	42 (4.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Pain - N1	405	458	863
Any	90 (22.2)	407 (88.9)	497 (57.6)
Grade 1	85 (21.0)	309 (67.5)	394 (45.7)
Grade 2	2 (0.5)	76 (16.6)	78 (9.0)
Grade 3	3 (0.7)	22 (4.8)	25 (2.9)
Grade 4	0	0	0
Erythema (Redness) - N1	405	458	863
Any	3 (0.7)	33 (7.2)	36 (4.2)
Grade 1	3 (0.7)	11 (2.4)	14 (1.6)
Grade 2	0	5 (1.1)	5 (0.6)
Grade 3	0	17 (3.7)	17 (2.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Swelling (Hardness) - N1	405	458	863
Any	0	46 (10.0)	46 (5.3)
Grade 1	0	17 (3.7)	17 (2.0)
Grade 2	0	18 (3.9)	18 (2.1)
Grade 3	0	11 (2.4)	11 (1.3)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	405	458	863
Any	22 (5.4)	60 (13.1)	82 (9.5)
Grade 1	21 (5.2)	49 (10.7)	70 (8.1)
Grade 2	1 (0.2)	11 (2.4)	12 (1.4)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Solicited Systemic Adverse Reactions - N1	405	458	863
Any Solicited Systemic Adverse Reactions	170 (42.0)	361 (78.8)	531 (61.5)
95% CI	37.1, 46.9	74.8, 82.5	58.2, 64.8
Grade 1	111 (27.4)	122 (26.6)	233 (27.0)
Grade 2	48 (11.9)	177 (38.6)	225 (26.1)
Grade 3	11 (2.7)	62 (13.5)	73 (8.5)
Grade 4	0	0	0
Fever - N1	405	457	862
Any	0	52 (11.4)	52 (6.0)
Grade 1	0	31 (6.8)	31 (3.6)
Grade 2	0	18 (3.9)	18 (2.1)
Grade 3	0	3 (0.7)	3 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Headache - N1	405	458	863
Any	109 (26.9)	243 (53.1)	352 (40.8)
Grade 1	93 (23.0)	134 (29.3)	227 (26.3)
Grade 2	11 (2.7)	84 (18.3)	95 (11.0)
Grade 3	5 (1.2)	25 (5.5)	30 (3.5)
Grade 4	0	0	0
Fatigue - N1	405	458	863
Any	114 (28.1)	285 (62.2)	399 (46.2)
Grade 1	67 (16.5)	104 (22.7)	171 (19.8)
Grade 2	41 (10.1)	146 (31.9)	187 (21.7)
Grade 3	6 (1.5)	35 (7.6)	41 (4.8)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Myalgia - N1	405	458	863
Any	79 (19.5)	262 (57.2)	341 (39.5)
Grade 1	53 (13.1)	99 (21.6)	152 (17.6)
Grade 2	22 (5.4)	129 (28.2)	151 (17.5)
Grade 3	4 (1.0)	34 (7.4)	38 (4.4)
Grade 4	0	0	0
Arthralgia - N1	405	458	863
Any	65 (16.0)	191 (41.7)	256 (29.7)
Grade 1	42 (10.4)	69 (15.1)	111 (12.9)
Grade 2	20 (4.9)	99 (21.6)	119 (13.8)
Grade 3	3 (0.7)	23 (5.0)	26 (3.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Nausea/Vomiting - N1	405	458	863
Any	31 (7.7)	84 (18.3)	115 (13.3)
Grade 1	21 (5.2)	67 (14.6)	88 (10.2)
Grade 2	9 (2.2)	16 (3.5)	25 (2.9)
Grade 3	1 (0.2)	1 (0.2)	2 (0.2)
Grade 4	0	0	0
Chills - N1	405	458	863
Any	29 (7.2)	181 (39.5)	210 (24.3)
Grade 1	18 (4.4)	82 (17.9)	100 (11.6)
Grade 2	10 (2.5)	95 (20.7)	105 (12.2)
Grade 3	1 (0.2)	4 (0.9)	5 (0.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Solicited Adverse Reactions - N1	14363	14309	28672
Any Solicited Adverse Reactions	8576 (59.7)	13566 (94.8)	22142 (77.2)
95% CI	58.9, 60.5	94.4, 95.2	76.7, 77.7
Grade 1	5543 (38.6)	4737 (33.1)	10280 (35.9)
Grade 2	2406 (16.8)	5716 (39.9)	8122 (28.3)
Grade 3	619 (4.3)	3097 (21.6)	3716 (13.0)
Grade 4	8 (<0.1)	16 (0.1)	24 (<0.1)
Solicited Local Adverse Reactions - N1	14362	14309	28671
Any Solicited Local Adverse Reactions	4147 (28.9)	13211 (92.3)	17358 (60.5)
95% CI	28.1, 29.6	91.9, 92.8	60.0, 61.1
Grade 1	3875 (27.0)	8580 (60.0)	12455 (43.4)
Grade 2	141 (1.0)	3324 (23.2)	3465 (12.1)
Grade 3	131 (0.9)	1307 (9.1)	1438 (5.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Pain - N1	14362	14309	28671
Any	3762 (26.2)	13156 (91.9)	16918 (59.0)
Grade 1	3585 (25.0)	9350 (65.3)	12935 (45.1)
Grade 2	96 (0.7)	2958 (20.7)	3054 (10.7)
Grade 3	81 (0.6)	848 (5.9)	929 (3.2)
Grade 4	0	0	0
Erythema (Redness) - N1	14362	14309	28671
Any	105 (0.7)	1410 (9.9)	1515 (5.3)
Grade 1	71 (0.5)	556 (3.9)	627 (2.2)
Grade 2	10 (<0.1)	557 (3.9)	567 (2.0)
Grade 3	24 (0.2)	297 (2.1)	321 (1.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Swelling (Hardness) - N1	14362	14309	28671
Any	91 (0.6)	2096 (14.6)	2187 (7.6)
Grade 1	62 (0.4)	1088 (7.6)	1150 (4.0)
Grade 2	13 (<0.1)	705 (4.9)	718 (2.5)
Grade 3	16 (0.1)	303 (2.1)	319 (1.1)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	14362	14309	28671
Any	1010 (7.0)	2754 (19.2)	3764 (13.1)
Grade 1	924 (6.4)	2337 (16.3)	3261 (11.4)
Grade 2	45 (0.3)	316 (2.2)	361 (1.3)
Grade 3	41 (0.3)	101 (0.7)	142 (0.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Solicited Systemic Adverse Reactions - N1	14363	14309	28672
Any Solicited Systemic Adverse Reactions	7628 (53.1)	11893 (83.1)	19521 (68.1)
95% CI	52.3, 53.9	82.5, 83.7	67.5, 68.6
Grade 1	4726 (32.9)	3900 (27.3)	8626 (30.1)
Grade 2	2373 (16.5)	5610 (39.2)	7983 (27.8)
Grade 3	521 (3.6)	2367 (16.5)	2888 (10.1)
Grade 4	8 (<0.1)	16 (0.1)	24 (<0.1)
Fever - N1	14363	14309	28672
Any	79 (0.6)	2145 (15.0)	2224 (7.8)
Grade 1	59 (0.4)	1288 (9.0)	1347 (4.7)
Grade 2	9 (<0.1)	654 (4.6)	663 (2.3)
Grade 3	3 (<0.1)	189 (1.3)	192 (0.7)
Grade 4	8 (<0.1)	14 (<0.1)	22 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Headache - N1	14362	14309	28671
Any	5236 (36.5)	9099 (63.6)	14335 (50.0)
Grade 1	4079 (28.4)	5239 (36.6)	9318 (32.5)
Grade 2	837 (5.8)	3082 (21.5)	3919 (13.7)
Grade 3	320 (2.2)	778 (5.4)	1098 (3.8)
Grade 4	0	0	0
Fatigue - N1	14362	14309	28671
Any	5178 (36.1)	9890 (69.1)	15068 (52.6)
Grade 1	3165 (22.0)	3647 (25.5)	6812 (23.8)
Grade 2	1832 (12.8)	4850 (33.9)	6682 (23.3)
Grade 3	181 (1.3)	1392 (9.7)	1573 (5.5)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Myalgia - N1	14362	14309	28671
Any	2866 (20.0)	8561 (59.8)	11427 (39.9)
Grade 1	2050 (14.3)	3427 (23.9)	5477 (19.1)
Grade 2	731 (5.1)	3883 (27.1)	4614 (16.1)
Grade 3	85 (0.6)	1251 (8.7)	1336 (4.7)
Grade 4	0	0	0
Arthralgia - N1	14362	14309	28671
Any	2451 (17.1)	6459 (45.1)	8910 (31.1)
Grade 1	1751 (12.2)	3027 (21.2)	4778 (16.7)
Grade 2	627 (4.4)	2692 (18.8)	3319 (11.6)
Grade 3	73 (0.5)	739 (5.2)	812 (2.8)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Nausea/Vomiting - N1	14362	14309	28671
Any	1592 (11.1)	3184 (22.3)	4776 (16.7)
Grade 1	1289 (9.0)	2400 (16.8)	3689 (12.9)
Grade 2	281 (2.0)	759 (5.3)	1040 (3.6)
Grade 3	22 (0.2)	24 (0.2)	46 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Chills - N1	14362	14309	28671
Any	1348 (9.4)	6262 (43.8)	7610 (26.5)
Grade 1	1044 (7.3)	2886 (20.2)	3930 (13.7)
Grade 2	276 (1.9)	3185 (22.3)	3461 (12.1)
Grade 3	28 (0.2)	191 (1.3)	219 (0.8)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Solicited Adverse Reactions - N1	334	340	674
Any Solicited Adverse Reactions	151 (45.2)	279 (82.1)	430 (63.8)
95% CI	39.8, 50.7	77.6, 86.0	60.0, 67.4
Grade 1	83 (24.9)	121 (35.6)	204 (30.3)
Grade 2	51 (15.3)	109 (32.1)	160 (23.7)
Grade 3	16 (4.8)	48 (14.1)	64 (9.5)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Solicited Local Adverse Reactions - N1	334	340	674
Any Solicited Local Adverse Reactions	74 (22.2)	268 (78.8)	342 (50.7)
95% CI	17.8, 27.0	74.1, 83.0	46.9, 54.6
Grade 1	63 (18.9)	179 (52.6)	242 (35.9)
Grade 2	6 (1.8)	66 (19.4)	72 (10.7)
Grade 3	5 (1.5)	23 (6.8)	28 (4.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Pain - N1	334	340	674
Any	67 (20.1)	265 (77.9)	332 (49.3)
Grade 1	61 (18.3)	183 (53.8)	244 (36.2)
Grade 2	4 (1.2)	66 (19.4)	70 (10.4)
Grade 3	2 (0.6)	16 (4.7)	18 (2.7)
Grade 4	0	0	0
Erythema (Redness) - N1	334	340	674
Any	4 (1.2)	16 (4.7)	20 (3.0)
Grade 1	1 (0.3)	6 (1.8)	7 (1.0)
Grade 2	0	5 (1.5)	5 (0.7)
Grade 3	3 (0.9)	5 (1.5)	8 (1.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Swelling (Hardness) - N1	334	340	674
Any	3 (0.9)	26 (7.6)	29 (4.3)
Grade 1	2 (0.6)	13 (3.8)	15 (2.2)
Grade 2	1 (0.3)	10 (2.9)	11 (1.6)
Grade 3	0	3 (0.9)	3 (0.4)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	334	340	674
Any	20 (6.0)	67 (19.7)	87 (12.9)
Grade 1	16 (4.8)	47 (13.8)	63 (9.3)
Grade 2	3 (0.9)	14 (4.1)	17 (2.5)
Grade 3	1 (0.3)	6 (1.8)	7 (1.0)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Solicited Systemic Adverse Reactions - N1	334	340	674
Any Solicited Systemic Adverse Reactions	137 (41.0)	237 (69.7)	374 (55.5)
95% CI	35.7, 46.5	64.5, 74.5	51.6, 59.3
Grade 1	72 (21.6)	96 (28.2)	168 (24.9)
Grade 2	52 (15.6)	104 (30.6)	156 (23.1)
Grade 3	12 (3.6)	36 (10.6)	48 (7.1)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Fever - N1	333	340	673
Any	7 (2.1)	52 (15.3)	59 (8.8)
Grade 1	4 (1.2)	33 (9.7)	37 (5.5)
Grade 2	2 (0.6)	14 (4.1)	16 (2.4)
Grade 3	0	4 (1.2)	4 (0.6)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Headache - N1	334	340	674
Any	95 (28.4)	161 (47.4)	256 (38.0)
Grade 1	69 (20.7)	100 (29.4)	169 (25.1)
Grade 2	19 (5.7)	45 (13.2)	64 (9.5)
Grade 3	7 (2.1)	16 (4.7)	23 (3.4)
Grade 4	0	0	0
Fatigue - N1	334	340	674
Any	93 (27.8)	165 (48.5)	258 (38.3)
Grade 1	49 (14.7)	66 (19.4)	115 (17.1)
Grade 2	39 (11.7)	81 (23.8)	120 (17.8)
Grade 3	5 (1.5)	18 (5.3)	23 (3.4)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Myalgia - N1	334	340	674
Any	61 (18.3)	173 (50.9)	234 (34.7)
Grade 1	33 (9.9)	85 (25.0)	118 (17.5)
Grade 2	26 (7.8)	73 (21.5)	99 (14.7)
Grade 3	2 (0.6)	15 (4.4)	17 (2.5)
Grade 4	0	0	0
Arthralgia - N1	334	340	674
Any	50 (15.0)	123 (36.2)	173 (25.7)
Grade 1	29 (8.7)	64 (18.8)	93 (13.8)
Grade 2	19 (5.7)	52 (15.3)	71 (10.5)
Grade 3	2 (0.6)	7 (2.1)	9 (1.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Nausea/Vomiting - N1	334	340	674
Any	34 (10.2)	62 (18.2)	96 (14.2)
Grade 1	23 (6.9)	45 (13.2)	68 (10.1)
Grade 2	11 (3.3)	17 (5.0)	28 (4.2)
Grade 3	0	0	0
Grade 4	0	0	0
Chills - N1	334	340	674
Any	36 (10.8)	119 (35.0)	155 (23.0)
Grade 1	25 (7.5)	58 (17.1)	83 (12.3)
Grade 2	10 (3.0)	58 (17.1)	68 (10.1)
Grade 3	1 (0.3)	3 (0.9)	4 (0.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Solicited Adverse Reactions - N1	465	527	993
Any Solicited Adverse Reactions	300 (64.5)	493 (93.5)	793 (79.9)
95% CI	60.0, 68.9	91.1, 95.5	77.2, 82.3
Grade 1	186 (40.0)	179 (34.0)	365 (36.8)
Grade 2	93 (20.0)	200 (38.0)	293 (29.5)
Grade 3	21 (4.5)	114 (21.6)	135 (13.6)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	465	527	993
Any Solicited Local Adverse Reactions	160 (34.4)	483 (91.7)	643 (64.8)
95% CI	30.1, 38.9	89.0, 93.9	61.7, 67.7
Grade 1	150 (32.3)	329 (62.4)	479 (48.2)
Grade 2	3 (0.6)	98 (18.6)	101 (10.2)
Grade 3	7 (1.5)	56 (10.6)	63 (6.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Pain - N1	465	527	993
Any	146 (31.4)	480 (91.1)	626 (63.0)
Grade 1	136 (29.2)	354 (67.2)	490 (49.3)
Grade 2	3 (0.6)	89 (16.9)	92 (9.3)
Grade 3	7 (1.5)	37 (7.0)	44 (4.4)
Grade 4	0	0	0
Erythema (Redness) - N1	465	527	993
Any	5 (1.1)	44 (8.3)	49 (4.9)
Grade 1	5 (1.1)	20 (3.8)	25 (2.5)
Grade 2	0	7 (1.3)	7 (0.7)
Grade 3	0	17 (3.2)	17 (1.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Swelling (Hardness) - N1	465	527	993
Any	1 (0.2)	61 (11.6)	62 (6.2)
Grade 1	1 (0.2)	30 (5.7)	31 (3.1)
Grade 2	0	19 (3.6)	19 (1.9)
Grade 3	0	12 (2.3)	12 (1.2)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	465	527	993
Any	44 (9.5)	93 (17.6)	137 (13.8)
Grade 1	41 (8.8)	77 (14.6)	118 (11.9)
Grade 2	1 (0.2)	15 (2.8)	16 (1.6)
Grade 3	2 (0.4)	1 (0.2)	3 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Solicited Systemic Adverse Reactions - N1	465	527	993
Any Solicited Systemic Adverse Reactions	267 (57.4)	423 (80.3)	690 (69.5)
95% CI	52.8, 62.0	76.6, 83.6	66.5, 72.3
Grade 1	155 (33.3)	140 (26.6)	295 (29.7)
Grade 2	94 (20.2)	202 (38.3)	296 (29.8)
Grade 3	18 (3.9)	81 (15.4)	99 (10.0)
Grade 4	0	0	0
Fever - N1	465	526	992
Any	2 (0.4)	55 (10.5)	57 (5.7)
Grade 1	1 (0.2)	33 (6.3)	34 (3.4)
Grade 2	1 (0.2)	19 (3.6)	20 (2.0)
Grade 3	0	3 (0.6)	3 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Headache - N1	465	527	993
Any	196 (42.2)	306 (58.1)	502 (50.6)
Grade 1	155 (33.3)	169 (32.1)	324 (32.6)
Grade 2	31 (6.7)	98 (18.6)	129 (13.0)
Grade 3	10 (2.2)	39 (7.4)	49 (4.9)
Grade 4	0	0	0
Fatigue - N1	465	527	993
Any	199 (42.8)	338 (64.1)	537 (54.1)
Grade 1	115 (24.7)	121 (23.0)	236 (23.8)
Grade 2	73 (15.7)	176 (33.4)	249 (25.1)
Grade 3	11 (2.4)	41 (7.8)	52 (5.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Myalgia - N1	465	527	993
Any	125 (26.9)	305 (57.9)	430 (43.3)
Grade 1	86 (18.5)	125 (23.7)	211 (21.2)
Grade 2	31 (6.7)	144 (27.3)	175 (17.6)
Grade 3	8 (1.7)	36 (6.8)	44 (4.4)
Grade 4	0	0	0
Arthralgia - N1	465	527	993
Any	105 (22.6)	221 (41.9)	326 (32.8)
Grade 1	69 (14.8)	86 (16.3)	155 (15.6)
Grade 2	32 (6.9)	110 (20.9)	142 (14.3)
Grade 3	4 (0.9)	25 (4.7)	29 (2.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Nausea/Vomiting - N1	465	527	993
Any	53 (11.4)	120 (22.8)	173 (17.4)
Grade 1	38 (8.2)	90 (17.1)	128 (12.9)
Grade 2	14 (3.0)	27 (5.1)	41 (4.1)
Grade 3	1 (0.2)	3 (0.6)	4 (0.4)
Grade 4	0	0	0
Chills - N1	465	527	993
Any	55 (11.8)	199 (37.8)	254 (25.6)
Grade 1	39 (8.4)	91 (17.3)	130 (13.1)
Grade 2	15 (3.2)	103 (19.5)	118 (11.9)
Grade 3	1 (0.2)	5 (0.9)	6 (0.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

In eDiary, only subject who has fever may report a grade 4 solicited adverse reaction.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15154) n (%)	mRNA-1273 (N=15167) n (%)	Total (N=30322) n (%)
Any Solicited Adverse Reactions - N1	15154	15167	30322
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1596 (10.5)	1572 (10.4)	3168 (10.4)
Day 1, after Vaccination (at Home)	2150 (14.2)	6769 (44.6)	8919 (29.4)
Day 2	1605 (10.6)	4490 (29.6)	6095 (20.1)
Day 3	745 (4.9)	290 (1.9)	1035 (3.4)
Day 4	417 (2.8)	74 (0.5)	491 (1.6)
Day 5	325 (2.1)	40 (0.3)	365 (1.2)
Day 6	243 (1.6)	45 (0.3)	288 (0.9)
Day 7	201 (1.3)	40 (0.3)	241 (0.8)
Solicited Local Adverse Reactions - N1	15150	15163	30314
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1139 (7.5)	1129 (7.4)	2268 (7.5)
Day 1, after Vaccination (at Home)	765 (5.0)	6386 (42.1)	7151 (23.6)
Day 2	582 (3.8)	4909 (32.4)	5491 (18.1)
Day 3	216 (1.4)	256 (1.7)	472 (1.6)
Day 4	117 (0.8)	43 (0.3)	160 (0.5)
Day 5	87 (0.6)	14 (<0.1)	101 (0.3)
Day 6	56 (0.4)	11 (<0.1)	67 (0.2)
Day 7	36 (0.2)	17 (0.1)	53 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15154) n (%)	mRNA-1273 (N=15167) n (%)	Total (N=30322) n (%)
Pain - N1	15150	15163	30314
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1100 (7.3)	1088 (7.2)	2188 (7.2)
Day 1, after Vaccination (at Home)	700 (4.6)	6353 (41.9)	7053 (23.3)
Day 2	493 (3.3)	4928 (32.5)	5421 (17.9)
Day 3	161 (1.1)	261 (1.7)	422 (1.4)
Day 4	83 (0.5)	37 (0.2)	120 (0.4)
Day 5	57 (0.4)	9 (<0.1)	66 (0.2)
Day 6	37 (0.2)	4 (<0.1)	41 (0.1)
Day 7	29 (0.2)	10 (<0.1)	39 (0.1)
Erythema (Redness) - N1	15150	15162	30313
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	10 (<0.1)	12 (<0.1)
Day 1, after Vaccination (at Home)	18 (0.1)	51 (0.3)	69 (0.2)
Day 2	18 (0.1)	229 (1.5)	247 (0.8)
Day 3	12 (<0.1)	113 (0.7)	125 (0.4)
Day 4	5 (<0.1)	15 (<0.1)	20 (<0.1)
Day 5	5 (<0.1)	7 (<0.1)	12 (<0.1)
Day 6	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15154) n (%)	mRNA-1273 (N=15167) n (%)	Total (N=30322) n (%)
Swelling (Hardness) - N1	15150	15162	30313
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	9 (<0.1)	189 (1.2)	198 (0.7)
Day 2	21 (0.1)	595 (3.9)	616 (2.0)
Day 3	5 (<0.1)	107 (0.7)	112 (0.4)
Day 4	2 (<0.1)	23 (0.2)	25 (<0.1)
Day 5	4 (<0.1)	2 (<0.1)	6 (<0.1)
Day 6	0	2 (<0.1)	2 (<0.1)
Day 7	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lymphadenopathy - N1 [1]	15150	15162	30313
Day 1, 30 Minutes after Vaccination (at Study Clinic)	97 (0.6)	97 (0.6)	194 (0.6)
Day 1, after Vaccination (at Home)	147 (1.0)	348 (2.3)	495 (1.6)
Day 2	162 (1.1)	489 (3.2)	651 (2.1)
Day 3	106 (0.7)	234 (1.5)	340 (1.1)
Day 4	64 (0.4)	97 (0.6)	161 (0.5)
Day 5	60 (0.4)	58 (0.4)	118 (0.4)
Day 6	51 (0.3)	89 (0.6)	140 (0.5)
Day 7	35 (0.2)	141 (0.9)	176 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15154) n (%)	mRNA-1273 (N=15167) n (%)	Total (N=30322) n (%)
Solicited Systemic Adverse Reactions - N1	15154	15166	30321
Day 1, 30 Minutes after Vaccination (at Study Clinic)	683 (4.5)	648 (4.3)	1331 (4.4)
Day 1, after Vaccination (at Home)	2007 (13.2)	2910 (19.2)	4917 (16.2)
Day 2	1621 (10.7)	2886 (19.0)	4507 (14.9)
Day 3	782 (5.2)	889 (5.9)	1671 (5.5)
Day 4	450 (3.0)	331 (2.2)	781 (2.6)
Day 5	356 (2.3)	244 (1.6)	600 (2.0)
Day 6	271 (1.8)	223 (1.5)	494 (1.6)
Day 7	228 (1.5)	190 (1.3)	418 (1.4)
Fever - N1	15152	15163	30316
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	15 (<0.1)	20 (<0.1)
Day 2	6 (<0.1)	56 (0.4)	62 (0.2)
Day 3	8 (<0.1)	26 (0.2)	34 (0.1)
Day 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Day 5	10 (<0.1)	7 (<0.1)	17 (<0.1)
Day 6	4 (<0.1)	3 (<0.1)	7 (<0.1)
Day 7	4 (<0.1)	2 (<0.1)	6 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15154) n (%)	mRNA-1273 (N=15167) n (%)	Total (N=30322) n (%)
Headache - N1	15149	15162	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	364 (2.4)	360 (2.4)	724 (2.4)
Day 1, after Vaccination (at Home)	982 (6.5)	1352 (8.9)	2334 (7.7)
Day 2	960 (6.3)	1546 (10.2)	2506 (8.3)
Day 3	551 (3.6)	711 (4.7)	1262 (4.2)
Day 4	363 (2.4)	286 (1.9)	649 (2.1)
Day 5	308 (2.0)	251 (1.7)	559 (1.8)
Day 6	271 (1.8)	232 (1.5)	503 (1.7)
Day 7	228 (1.5)	214 (1.4)	442 (1.5)
Fatigue - N1	15149	15162	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	236 (1.6)	248 (1.6)	484 (1.6)
Day 1, after Vaccination (at Home)	1373 (9.1)	1877 (12.4)	3250 (10.7)
Day 2	1093 (7.2)	2132 (14.1)	3225 (10.6)
Day 3	534 (3.5)	687 (4.5)	1221 (4.0)
Day 4	298 (2.0)	253 (1.7)	551 (1.8)
Day 5	246 (1.6)	159 (1.0)	405 (1.3)
Day 6	199 (1.3)	157 (1.0)	356 (1.2)
Day 7	154 (1.0)	122 (0.8)	276 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15154) n (%)	mRNA-1273 (N=15167) n (%)	Total (N=30322) n (%)
Myalgia - N1	15149	15162	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	123 (0.8)	130 (0.9)	253 (0.8)
Day 1, after Vaccination (at Home)	450 (3.0)	904 (6.0)	1354 (4.5)
Day 2	586 (3.9)	1472 (9.7)	2058 (6.8)
Day 3	292 (1.9)	486 (3.2)	778 (2.6)
Day 4	229 (1.5)	166 (1.1)	395 (1.3)
Day 5	157 (1.0)	107 (0.7)	264 (0.9)
Day 6	118 (0.8)	95 (0.6)	213 (0.7)
Day 7	114 (0.8)	81 (0.5)	195 (0.6)
Arthralgia - N1	15149	15162	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	99 (0.7)	106 (0.7)	205 (0.7)
Day 1, after Vaccination (at Home)	318 (2.1)	550 (3.6)	868 (2.9)
Day 2	495 (3.3)	941 (6.2)	1436 (4.7)
Day 3	292 (1.9)	439 (2.9)	731 (2.4)
Day 4	205 (1.4)	177 (1.2)	382 (1.3)
Day 5	146 (1.0)	111 (0.7)	257 (0.8)
Day 6	129 (0.9)	92 (0.6)	221 (0.7)
Day 7	99 (0.7)	94 (0.6)	193 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15154) n (%)	mRNA-1273 (N=15167) n (%)	Total (N=30322) n (%)
Nausea/Vomiting - N1	15149	15162	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	49 (0.3)	41 (0.3)	90 (0.3)
Day 1, after Vaccination (at Home)	175 (1.2)	216 (1.4)	391 (1.3)
Day 2	251 (1.7)	396 (2.6)	647 (2.1)
Day 3	168 (1.1)	248 (1.6)	416 (1.4)
Day 4	119 (0.8)	127 (0.8)	246 (0.8)
Day 5	107 (0.7)	81 (0.5)	188 (0.6)
Day 6	118 (0.8)	81 (0.5)	199 (0.7)
Day 7	87 (0.6)	73 (0.5)	160 (0.5)
Chills - N1	15149	15162	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	86 (0.6)	73 (0.5)	159 (0.5)
Day 1, after Vaccination (at Home)	196 (1.3)	272 (1.8)	468 (1.5)
Day 2	198 (1.3)	470 (3.1)	668 (2.2)
Day 3	131 (0.9)	241 (1.6)	372 (1.2)
Day 4	80 (0.5)	68 (0.4)	148 (0.5)
Day 5	79 (0.5)	60 (0.4)	139 (0.5)
Day 6	60 (0.4)	32 (0.2)	92 (0.3)
Day 7	48 (0.3)	37 (0.2)	85 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=13870) n (%)	mRNA-1273 (N=13947) n (%)	Total (N=27817) n (%)
Any Solicited Adverse Reactions - N1	13870	13947	27817
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1485 (10.7)	1373 (9.8)	2858 (10.3)
Day 1, after Vaccination (at Home)	1798 (13.0)	7840 (56.2)	9638 (34.6)
Day 2	1160 (8.4)	3472 (24.9)	4632 (16.7)
Day 3	541 (3.9)	133 (1.0)	674 (2.4)
Day 4	340 (2.5)	28 (0.2)	368 (1.3)
Day 5	262 (1.9)	10 (<0.1)	272 (1.0)
Day 6	199 (1.4)	12 (<0.1)	211 (0.8)
Day 7	157 (1.1)	9 (<0.1)	166 (0.6)
Solicited Local Adverse Reactions - N1	13866	13944	27810
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1139 (8.2)	1042 (7.5)	2181 (7.8)
Day 1, after Vaccination (at Home)	721 (5.2)	7625 (54.7)	8346 (30.0)
Day 2	388 (2.8)	3522 (25.3)	3910 (14.1)
Day 3	170 (1.2)	151 (1.1)	321 (1.2)
Day 4	78 (0.6)	24 (0.2)	102 (0.4)
Day 5	54 (0.4)	8 (<0.1)	62 (0.2)
Day 6	29 (0.2)	7 (<0.1)	36 (0.1)
Day 7	28 (0.2)	2 (<0.1)	30 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=13870) n (%)	mRNA-1273 (N=13947) n (%)	Total (N=27817) n (%)
Pain - N1	13866	13944	27810
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1108 (8.0)	1004 (7.2)	2112 (7.6)
Day 1, after Vaccination (at Home)	670 (4.8)	7604 (54.5)	8274 (29.8)
Day 2	318 (2.3)	3537 (25.4)	3855 (13.9)
Day 3	136 (1.0)	149 (1.1)	285 (1.0)
Day 4	55 (0.4)	20 (0.1)	75 (0.3)
Day 5	38 (0.3)	5 (<0.1)	43 (0.2)
Day 6	23 (0.2)	5 (<0.1)	28 (0.1)
Day 7	15 (0.1)	1 (<0.1)	16 (<0.1)
Erythema (Redness) - N1	13866	13944	27810
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	4 (<0.1)	12 (<0.1)
Day 1, after Vaccination (at Home)	19 (0.1)	109 (0.8)	128 (0.5)
Day 2	9 (<0.1)	483 (3.5)	492 (1.8)
Day 3	9 (<0.1)	470 (3.4)	479 (1.7)
Day 4	3 (<0.1)	109 (0.8)	112 (0.4)
Day 5	3 (<0.1)	14 (0.1)	17 (<0.1)
Day 6	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=13870) n (%)	mRNA-1273 (N=13947) n (%)	Total (N=27817) n (%)
Swelling (Hardness) - N1	13866	13944	27810
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (<0.1)	15 (0.1)	26 (<0.1)
Day 1, after Vaccination (at Home)	12 (<0.1)	442 (3.2)	454 (1.6)
Day 2	11 (<0.1)	880 (6.3)	891 (3.2)
Day 3	6 (<0.1)	281 (2.0)	287 (1.0)
Day 4	3 (<0.1)	63 (0.5)	66 (0.2)
Day 5	1 (<0.1)	9 (<0.1)	10 (<0.1)
Day 6	2 (<0.1)	3 (<0.1)	5 (<0.1)
Day 7	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lymphadenopathy - N1 [1]	13866	13944	27810
Day 1, 30 Minutes after Vaccination (at Study Clinic)	58 (0.4)	70 (0.5)	128 (0.5)
Day 1, after Vaccination (at Home)	135 (1.0)	464 (3.3)	599 (2.2)
Day 2	144 (1.0)	825 (5.9)	969 (3.5)
Day 3	81 (0.6)	378 (2.7)	459 (1.7)
Day 4	46 (0.3)	146 (1.0)	192 (0.7)
Day 5	38 (0.3)	38 (0.3)	76 (0.3)
Day 6	17 (0.1)	19 (0.1)	36 (0.1)
Day 7	15 (0.1)	16 (0.1)	31 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=13870) n (%)	mRNA-1273 (N=13947) n (%)	Total (N=27817) n (%)
Solicited Systemic Adverse Reactions - N1	13869	13947	27816
Day 1, 30 Minutes after Vaccination (at Study Clinic)	515 (3.7)	491 (3.5)	1006 (3.6)
Day 1, after Vaccination (at Home)	1669 (12.0)	3928 (28.2)	5597 (20.1)
Day 2	1217 (8.8)	6078 (43.6)	7295 (26.2)
Day 3	588 (4.2)	354 (2.5)	942 (3.4)
Day 4	373 (2.7)	92 (0.7)	465 (1.7)
Day 5	291 (2.1)	42 (0.3)	333 (1.2)
Day 6	235 (1.7)	48 (0.3)	283 (1.0)
Day 7	181 (1.3)	31 (0.2)	212 (0.8)
Fever - N1	13864	13939	27803
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	192 (1.4)	197 (0.7)
Day 2	9 (<0.1)	1806 (13.0)	1815 (6.5)
Day 3	7 (<0.1)	159 (1.1)	166 (0.6)
Day 4	3 (<0.1)	4 (<0.1)	7 (<0.1)
Day 5	5 (<0.1)	4 (<0.1)	9 (<0.1)
Day 6	8 (<0.1)	2 (<0.1)	10 (<0.1)
Day 7	5 (<0.1)	3 (<0.1)	8 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=13870) n (%)	mRNA-1273 (N=13947) n (%)	Total (N=27817) n (%)
Headache - N1	13866	13944	27810
Day 1, 30 Minutes after Vaccination (at Study Clinic)	255 (1.8)	252 (1.8)	507 (1.8)
Day 1, after Vaccination (at Home)	865 (6.2)	2011 (14.4)	2876 (10.3)
Day 2	744 (5.4)	5068 (36.3)	5812 (20.9)
Day 3	464 (3.3)	423 (3.0)	887 (3.2)
Day 4	310 (2.2)	151 (1.1)	461 (1.7)
Day 5	227 (1.6)	108 (0.8)	335 (1.2)
Day 6	201 (1.4)	91 (0.7)	292 (1.0)
Day 7	186 (1.3)	61 (0.4)	247 (0.9)
Fatigue - N1	13864	13944	27808
Day 1, 30 Minutes after Vaccination (at Study Clinic)	208 (1.5)	219 (1.6)	427 (1.5)
Day 1, after Vaccination (at Home)	1084 (7.8)	2701 (19.4)	3785 (13.6)
Day 2	850 (6.1)	5586 (40.1)	6436 (23.1)
Day 3	391 (2.8)	396 (2.8)	787 (2.8)
Day 4	236 (1.7)	82 (0.6)	318 (1.1)
Day 5	193 (1.4)	48 (0.3)	241 (0.9)
Day 6	167 (1.2)	37 (0.3)	204 (0.7)
Day 7	96 (0.7)	27 (0.2)	123 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=13870) n (%)	mRNA-1273 (N=13947) n (%)	Total (N=27817) n (%)
Myalgia - N1	13865	13944	27809
Day 1, 30 Minutes after Vaccination (at Study Clinic)	102 (0.7)	93 (0.7)	195 (0.7)
Day 1, after Vaccination (at Home)	408 (2.9)	1874 (13.4)	2282 (8.2)
Day 2	475 (3.4)	5603 (40.2)	6078 (21.9)
Day 3	237 (1.7)	326 (2.3)	563 (2.0)
Day 4	165 (1.2)	64 (0.5)	229 (0.8)
Day 5	117 (0.8)	28 (0.2)	145 (0.5)
Day 6	111 (0.8)	30 (0.2)	141 (0.5)
Day 7	82 (0.6)	18 (0.1)	100 (0.4)
Arthralgia - N1	13864	13944	27808
Day 1, 30 Minutes after Vaccination (at Study Clinic)	108 (0.8)	107 (0.8)	215 (0.8)
Day 1, after Vaccination (at Home)	340 (2.5)	1254 (9.0)	1594 (5.7)
Day 2	368 (2.7)	4087 (29.3)	4455 (16.0)
Day 3	208 (1.5)	316 (2.3)	524 (1.9)
Day 4	168 (1.2)	77 (0.6)	245 (0.9)
Day 5	95 (0.7)	36 (0.3)	131 (0.5)
Day 6	108 (0.8)	39 (0.3)	147 (0.5)
Day 7	73 (0.5)	21 (0.2)	94 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=13870) n (%)	mRNA-1273 (N=13947) n (%)	Total (N=27817) n (%)
Nausea/Vomiting - N1	13864	13944	27808
Day 1, 30 Minutes after Vaccination (at Study Clinic)	40 (0.3)	37 (0.3)	77 (0.3)
Day 1, after Vaccination (at Home)	203 (1.5)	457 (3.3)	660 (2.4)
Day 2	211 (1.5)	1682 (12.1)	1893 (6.8)
Day 3	128 (0.9)	244 (1.7)	372 (1.3)
Day 4	93 (0.7)	94 (0.7)	187 (0.7)
Day 5	69 (0.5)	47 (0.3)	116 (0.4)
Day 6	73 (0.5)	43 (0.3)	116 (0.4)
Day 7	66 (0.5)	30 (0.2)	96 (0.3)
Chills - N1	13864	13944	27808
Day 1, 30 Minutes after Vaccination (at Study Clinic)	55 (0.4)	45 (0.3)	100 (0.4)
Day 1, after Vaccination (at Home)	186 (1.3)	1031 (7.4)	1217 (4.4)
Day 2	191 (1.4)	4593 (32.9)	4784 (17.2)
Day 3	96 (0.7)	333 (2.4)	429 (1.5)
Day 4	67 (0.5)	44 (0.3)	111 (0.4)
Day 5	64 (0.5)	14 (0.1)	78 (0.3)
Day 6	54 (0.4)	23 (0.2)	77 (0.3)
Day 7	42 (0.3)	17 (0.1)	59 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Any Solicited Adverse Reactions - N1	15162	15176	30339
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2639 (17.4)	2573 (17.0)	5212 (17.2)
Day 1, after Vaccination (at Home)	2815 (18.6)	8764 (57.7)	11579 (38.2)
Day 2	1686 (11.1)	2808 (18.5)	4494 (14.8)
Day 3	740 (4.9)	115 (0.8)	855 (2.8)
Day 4	440 (2.9)	21 (0.1)	461 (1.5)
Day 5	313 (2.1)	22 (0.1)	335 (1.1)
Day 6	216 (1.4)	17 (0.1)	233 (0.8)
Day 7	178 (1.2)	18 (0.1)	196 (0.6)
Solicited Local Adverse Reactions - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1984 (13.1)	1941 (12.8)	3925 (12.9)
Day 1, after Vaccination (at Home)	1132 (7.5)	8735 (57.6)	9867 (32.5)
Day 2	662 (4.4)	3119 (20.6)	3781 (12.5)
Day 3	262 (1.7)	125 (0.8)	387 (1.3)
Day 4	141 (0.9)	15 (<0.1)	156 (0.5)
Day 5	96 (0.6)	11 (<0.1)	107 (0.4)
Day 6	59 (0.4)	9 (<0.1)	68 (0.2)
Day 7	45 (0.3)	7 (<0.1)	52 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Pain - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1922 (12.7)	1868 (12.3)	3790 (12.5)
Day 1, after Vaccination (at Home)	1050 (6.9)	8741 (57.6)	9791 (32.3)
Day 2	561 (3.7)	3148 (20.7)	3709 (12.2)
Day 3	203 (1.3)	117 (0.8)	320 (1.1)
Day 4	98 (0.6)	11 (<0.1)	109 (0.4)
Day 5	68 (0.4)	5 (<0.1)	73 (0.2)
Day 6	43 (0.3)	6 (<0.1)	49 (0.2)
Day 7	30 (0.2)	5 (<0.1)	35 (0.1)
Erythema (Redness) - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (<0.1)	14 (<0.1)	24 (<0.1)
Day 1, after Vaccination (at Home)	36 (0.2)	154 (1.0)	190 (0.6)
Day 2	25 (0.2)	640 (4.2)	665 (2.2)
Day 3	19 (0.1)	520 (3.4)	539 (1.8)
Day 4	8 (<0.1)	115 (0.8)	123 (0.4)
Day 5	8 (<0.1)	18 (0.1)	26 (<0.1)
Day 6	6 (<0.1)	6 (<0.1)	12 (<0.1)
Day 7	2 (<0.1)	3 (<0.1)	5 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Swelling (Hardness) - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	20 (0.1)	28 (0.2)	48 (0.2)
Day 1, after Vaccination (at Home)	21 (0.1)	566 (3.7)	587 (1.9)
Day 2	29 (0.2)	1189 (7.8)	1218 (4.0)
Day 3	9 (<0.1)	311 (2.0)	320 (1.1)
Day 4	5 (<0.1)	68 (0.4)	73 (0.2)
Day 5	5 (<0.1)	11 (<0.1)	16 (<0.1)
Day 6	2 (<0.1)	5 (<0.1)	7 (<0.1)
Day 7	4 (<0.1)	5 (<0.1)	9 (<0.1)
Lymphadenopathy - N1 [1]	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	150 (1.0)	163 (1.1)	313 (1.0)
Day 1, after Vaccination (at Home)	251 (1.7)	749 (4.9)	1000 (3.3)
Day 2	257 (1.7)	1089 (7.2)	1346 (4.4)
Day 3	147 (1.0)	487 (3.2)	634 (2.1)
Day 4	90 (0.6)	192 (1.3)	282 (0.9)
Day 5	83 (0.5)	67 (0.4)	150 (0.5)
Day 6	55 (0.4)	68 (0.4)	123 (0.4)
Day 7	41 (0.3)	99 (0.7)	140 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Solicited Systemic Adverse Reactions - N1	15162	15176	30339
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1085 (7.2)	1039 (6.8)	2124 (7.0)
Day 1, after Vaccination (at Home)	2881 (19.0)	5108 (33.7)	7989 (26.3)
Day 2	1884 (12.4)	5616 (37.0)	7500 (24.7)
Day 3	847 (5.6)	437 (2.9)	1284 (4.2)
Day 4	477 (3.1)	133 (0.9)	610 (2.0)
Day 5	361 (2.4)	91 (0.6)	452 (1.5)
Day 6	279 (1.8)	71 (0.5)	350 (1.2)
Day 7	218 (1.4)	58 (0.4)	276 (0.9)
Fever - N1	15161	15175	30337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 1, after Vaccination (at Home)	9 (<0.1)	205 (1.4)	214 (0.7)
Day 2	15 (<0.1)	1845 (12.2)	1860 (6.1)
Day 3	15 (<0.1)	172 (1.1)	187 (0.6)
Day 4	9 (<0.1)	7 (<0.1)	16 (<0.1)
Day 5	15 (<0.1)	11 (<0.1)	26 (<0.1)
Day 6	12 (<0.1)	3 (<0.1)	15 (<0.1)
Day 7	9 (<0.1)	5 (<0.1)	14 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Headache - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	578 (3.8)	576 (3.8)	1154 (3.8)
Day 1, after Vaccination (at Home)	1566 (10.3)	2799 (18.4)	4365 (14.4)
Day 2	1330 (8.8)	5003 (33.0)	6333 (20.9)
Day 3	729 (4.8)	540 (3.6)	1269 (4.2)
Day 4	444 (2.9)	220 (1.4)	664 (2.2)
Day 5	333 (2.2)	160 (1.1)	493 (1.6)
Day 6	290 (1.9)	153 (1.0)	443 (1.5)
Day 7	257 (1.7)	115 (0.8)	372 (1.2)
Fatigue - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	412 (2.7)	432 (2.8)	844 (2.8)
Day 1, after Vaccination (at Home)	2017 (13.3)	3670 (24.2)	5687 (18.7)
Day 2	1387 (9.1)	5454 (35.9)	6841 (22.5)
Day 3	641 (4.2)	482 (3.2)	1123 (3.7)
Day 4	349 (2.3)	131 (0.9)	480 (1.6)
Day 5	271 (1.8)	83 (0.5)	354 (1.2)
Day 6	243 (1.6)	79 (0.5)	322 (1.1)
Day 7	150 (1.0)	62 (0.4)	212 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Myalgia - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	215 (1.4)	207 (1.4)	422 (1.4)
Day 1, after Vaccination (at Home)	748 (4.9)	2433 (16.0)	3181 (10.5)
Day 2	854 (5.6)	5697 (37.5)	6551 (21.6)
Day 3	416 (2.7)	430 (2.8)	846 (2.8)
Day 4	300 (2.0)	111 (0.7)	411 (1.4)
Day 5	198 (1.3)	57 (0.4)	255 (0.8)
Day 6	175 (1.2)	64 (0.4)	239 (0.8)
Day 7	146 (1.0)	40 (0.3)	186 (0.6)
Arthralgia - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	201 (1.3)	201 (1.3)	402 (1.3)
Day 1, after Vaccination (at Home)	578 (3.8)	1594 (10.5)	2172 (7.2)
Day 2	704 (4.6)	4209 (27.7)	4913 (16.2)
Day 3	385 (2.5)	458 (3.0)	843 (2.8)
Day 4	270 (1.8)	141 (0.9)	411 (1.4)
Day 5	172 (1.1)	74 (0.5)	246 (0.8)
Day 6	176 (1.2)	70 (0.5)	246 (0.8)
Day 7	120 (0.8)	56 (0.4)	176 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15162) n (%)	mRNA-1273 (N=15176) n (%)	Total (N=30339) n (%)
Nausea/Vomiting - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	86 (0.6)	76 (0.5)	162 (0.5)
Day 1, after Vaccination (at Home)	342 (2.3)	631 (4.2)	973 (3.2)
Day 2	408 (2.7)	1863 (12.3)	2271 (7.5)
Day 3	244 (1.6)	368 (2.4)	612 (2.0)
Day 4	182 (1.2)	174 (1.1)	356 (1.2)
Day 5	145 (1.0)	91 (0.6)	236 (0.8)
Day 6	148 (1.0)	90 (0.6)	238 (0.8)
Day 7	124 (0.8)	73 (0.5)	197 (0.6)
Chills - N1	15161	15176	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	135 (0.9)	115 (0.8)	250 (0.8)
Day 1, after Vaccination (at Home)	349 (2.3)	1217 (8.0)	1566 (5.2)
Day 2	339 (2.2)	4639 (30.6)	4978 (16.4)
Day 3	197 (1.3)	417 (2.7)	614 (2.0)
Day 4	123 (0.8)	72 (0.5)	195 (0.6)
Day 5	122 (0.8)	42 (0.3)	164 (0.5)
Day 6	95 (0.6)	40 (0.3)	135 (0.4)
Day 7	79 (0.5)	38 (0.3)	117 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Any Solicited Adverse Reactions - N1	11406	11405	22812
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1341 (11.8)	1332 (11.7)	2673 (11.7)
Day 1, after Vaccination (at Home)	1712 (15.0)	5535 (48.5)	7247 (31.8)
Day 2	1223 (10.7)	3105 (27.2)	4328 (19.0)
Day 3	570 (5.0)	171 (1.5)	741 (3.2)
Day 4	308 (2.7)	39 (0.3)	347 (1.5)
Day 5	254 (2.2)	29 (0.3)	283 (1.2)
Day 6	176 (1.5)	26 (0.2)	202 (0.9)
Day 7	152 (1.3)	25 (0.2)	177 (0.8)
Solicited Local Adverse Reactions - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	977 (8.6)	974 (8.5)	1951 (8.6)
Day 1, after Vaccination (at Home)	628 (5.5)	5358 (47.0)	5986 (26.2)
Day 2	444 (3.9)	3406 (29.9)	3850 (16.9)
Day 3	162 (1.4)	160 (1.4)	322 (1.4)
Day 4	88 (0.8)	29 (0.3)	117 (0.5)
Day 5	68 (0.6)	12 (0.1)	80 (0.4)
Day 6	40 (0.4)	8 (<0.1)	48 (0.2)
Day 7	25 (0.2)	13 (0.1)	38 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Pain - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	945 (8.3)	939 (8.2)	1884 (8.3)
Day 1, after Vaccination (at Home)	577 (5.1)	5334 (46.8)	5911 (25.9)
Day 2	381 (3.3)	3427 (30.1)	3808 (16.7)
Day 3	127 (1.1)	166 (1.5)	293 (1.3)
Day 4	60 (0.5)	24 (0.2)	84 (0.4)
Day 5	42 (0.4)	8 (<0.1)	50 (0.2)
Day 6	28 (0.2)	3 (<0.1)	31 (0.1)
Day 7	19 (0.2)	7 (<0.1)	26 (0.1)
Erythema (Redness) - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	8 (<0.1)	10 (<0.1)
Day 1, after Vaccination (at Home)	17 (0.1)	42 (0.4)	59 (0.3)
Day 2	10 (<0.1)	187 (1.6)	197 (0.9)
Day 3	7 (<0.1)	85 (0.7)	92 (0.4)
Day 4	4 (<0.1)	14 (0.1)	18 (<0.1)
Day 5	1 (<0.1)	6 (<0.1)	7 (<0.1)
Day 6	4 (<0.1)	1 (<0.1)	5 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Swelling (Hardness) - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	10 (<0.1)	18 (<0.1)
Day 1, after Vaccination (at Home)	8 (<0.1)	170 (1.5)	178 (0.8)
Day 2	9 (<0.1)	488 (4.3)	497 (2.2)
Day 3	2 (<0.1)	77 (0.7)	79 (0.3)
Day 4	1 (<0.1)	17 (0.1)	18 (<0.1)
Day 5	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 6	0	2 (<0.1)	2 (<0.1)
Day 7	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lymphadenopathy - N1 [1]	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	74 (0.6)	71 (0.6)	145 (0.6)
Day 1, after Vaccination (at Home)	123 (1.1)	294 (2.6)	417 (1.8)
Day 2	122 (1.1)	415 (3.6)	537 (2.4)
Day 3	81 (0.7)	199 (1.7)	280 (1.2)
Day 4	49 (0.4)	81 (0.7)	130 (0.6)
Day 5	54 (0.5)	48 (0.4)	102 (0.4)
Day 6	37 (0.3)	82 (0.7)	119 (0.5)
Day 7	27 (0.2)	132 (1.2)	159 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Solicited Systemic Adverse Reactions - N1	11406	11405	22812
Day 1, 30 Minutes after Vaccination (at Study Clinic)	561 (4.9)	528 (4.6)	1089 (4.8)
Day 1, after Vaccination (at Home)	1629 (14.3)	2325 (20.4)	3954 (17.3)
Day 2	1269 (11.1)	2228 (19.5)	3497 (15.3)
Day 3	604 (5.3)	668 (5.9)	1272 (5.6)
Day 4	344 (3.0)	242 (2.1)	586 (2.6)
Day 5	280 (2.5)	193 (1.7)	473 (2.1)
Day 6	200 (1.8)	168 (1.5)	368 (1.6)
Day 7	176 (1.5)	151 (1.3)	327 (1.4)
Fever - N1	11404	11403	22808
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	2 (<0.1)	12 (0.1)	14 (<0.1)
Day 2	6 (<0.1)	55 (0.5)	61 (0.3)
Day 3	7 (<0.1)	25 (0.2)	32 (0.1)
Day 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Day 5	9 (<0.1)	4 (<0.1)	13 (<0.1)
Day 6	4 (<0.1)	1 (<0.1)	5 (<0.1)
Day 7	3 (<0.1)	2 (<0.1)	5 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Headache - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	297 (2.6)	294 (2.6)	591 (2.6)
Day 1, after Vaccination (at Home)	819 (7.2)	1093 (9.6)	1912 (8.4)
Day 2	787 (6.9)	1262 (11.1)	2049 (9.0)
Day 3	443 (3.9)	576 (5.1)	1019 (4.5)
Day 4	301 (2.6)	234 (2.1)	535 (2.3)
Day 5	245 (2.1)	207 (1.8)	452 (2.0)
Day 6	221 (1.9)	189 (1.7)	410 (1.8)
Day 7	190 (1.7)	176 (1.5)	366 (1.6)
Fatigue - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	197 (1.7)	206 (1.8)	403 (1.8)
Day 1, after Vaccination (at Home)	1113 (9.8)	1509 (13.2)	2622 (11.5)
Day 2	868 (7.6)	1644 (14.4)	2512 (11.0)
Day 3	422 (3.7)	513 (4.5)	935 (4.1)
Day 4	224 (2.0)	180 (1.6)	404 (1.8)
Day 5	195 (1.7)	125 (1.1)	320 (1.4)
Day 6	142 (1.2)	115 (1.0)	257 (1.1)
Day 7	121 (1.1)	92 (0.8)	213 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Myalgia - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	102 (0.9)	104 (0.9)	206 (0.9)
Day 1, after Vaccination (at Home)	359 (3.1)	726 (6.4)	1085 (4.8)
Day 2	466 (4.1)	1198 (10.5)	1664 (7.3)
Day 3	216 (1.9)	361 (3.2)	577 (2.5)
Day 4	181 (1.6)	108 (0.9)	289 (1.3)
Day 5	123 (1.1)	82 (0.7)	205 (0.9)
Day 6	93 (0.8)	59 (0.5)	152 (0.7)
Day 7	86 (0.8)	60 (0.5)	146 (0.6)
Arthralgia - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	76 (0.7)	77 (0.7)	153 (0.7)
Day 1, after Vaccination (at Home)	250 (2.2)	430 (3.8)	680 (3.0)
Day 2	369 (3.2)	745 (6.5)	1114 (4.9)
Day 3	214 (1.9)	328 (2.9)	542 (2.4)
Day 4	150 (1.3)	112 (1.0)	262 (1.1)
Day 5	101 (0.9)	74 (0.6)	175 (0.8)
Day 6	94 (0.8)	58 (0.5)	152 (0.7)
Day 7	73 (0.6)	68 (0.6)	141 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Nausea/Vomiting - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	44 (0.4)	33 (0.3)	77 (0.3)
Day 1, after Vaccination (at Home)	155 (1.4)	195 (1.7)	350 (1.5)
Day 2	205 (1.8)	341 (3.0)	546 (2.4)
Day 3	140 (1.2)	204 (1.8)	344 (1.5)
Day 4	105 (0.9)	110 (1.0)	215 (0.9)
Day 5	94 (0.8)	62 (0.5)	156 (0.7)
Day 6	94 (0.8)	66 (0.6)	160 (0.7)
Day 7	71 (0.6)	58 (0.5)	129 (0.6)
Chills - N1	11404	11401	22806
Day 1, 30 Minutes after Vaccination (at Study Clinic)	74 (0.6)	63 (0.6)	137 (0.6)
Day 1, after Vaccination (at Home)	162 (1.4)	225 (2.0)	387 (1.7)
Day 2	161 (1.4)	411 (3.6)	572 (2.5)
Day 3	108 (0.9)	198 (1.7)	306 (1.3)
Day 4	65 (0.6)	51 (0.4)	116 (0.5)
Day 5	70 (0.6)	46 (0.4)	116 (0.5)
Day 6	47 (0.4)	27 (0.2)	74 (0.3)
Day 7	43 (0.4)	30 (0.3)	73 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Any Solicited Adverse Reactions - N1	3748	3762	7510
Day 1, 30 Minutes after Vaccination (at Study Clinic)	255 (6.8)	240 (6.4)	495 (6.6)
Day 1, after Vaccination (at Home)	438 (11.7)	1234 (32.8)	1672 (22.3)
Day 2	382 (10.2)	1385 (36.8)	1767 (23.5)
Day 3	175 (4.7)	119 (3.2)	294 (3.9)
Day 4	109 (2.9)	35 (0.9)	144 (1.9)
Day 5	71 (1.9)	11 (0.3)	82 (1.1)
Day 6	67 (1.8)	19 (0.5)	86 (1.1)
Day 7	49 (1.3)	15 (0.4)	64 (0.9)
Solicited Local Adverse Reactions - N1	3746	3762	7508
Day 1, 30 Minutes after Vaccination (at Study Clinic)	162 (4.3)	155 (4.1)	317 (4.2)
Day 1, after Vaccination (at Home)	137 (3.7)	1028 (27.3)	1165 (15.5)
Day 2	138 (3.7)	1503 (40.0)	1641 (21.9)
Day 3	54 (1.4)	96 (2.6)	150 (2.0)
Day 4	29 (0.8)	14 (0.4)	43 (0.6)
Day 5	19 (0.5)	2 (<0.1)	21 (0.3)
Day 6	16 (0.4)	3 (<0.1)	19 (0.3)
Day 7	11 (0.3)	4 (0.1)	15 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Pain - N1	3746	3762	7508
Day 1, 30 Minutes after Vaccination (at Study Clinic)	155 (4.1)	149 (4.0)	304 (4.0)
Day 1, after Vaccination (at Home)	123 (3.3)	1019 (27.1)	1142 (15.2)
Day 2	112 (3.0)	1501 (39.9)	1613 (21.5)
Day 3	34 (0.9)	95 (2.5)	129 (1.7)
Day 4	23 (0.6)	13 (0.3)	36 (0.5)
Day 5	15 (0.4)	1 (<0.1)	16 (0.2)
Day 6	9 (0.2)	1 (<0.1)	10 (0.1)
Day 7	10 (0.3)	3 (<0.1)	13 (0.2)
Erythema (Redness) - N1	3746	3761	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	1 (<0.1)	9 (0.2)	10 (0.1)
Day 2	8 (0.2)	42 (1.1)	50 (0.7)
Day 3	5 (0.1)	28 (0.7)	33 (0.4)
Day 4	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 5	4 (0.1)	1 (<0.1)	5 (<0.1)
Day 6	0	3 (<0.1)	3 (<0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Swelling (Hardness) - N1	3746	3761	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	1 (<0.1)	19 (0.5)	20 (0.3)
Day 2	12 (0.3)	107 (2.8)	119 (1.6)
Day 3	3 (<0.1)	30 (0.8)	33 (0.4)
Day 4	1 (<0.1)	6 (0.2)	7 (<0.1)
Day 5	1 (<0.1)	0	1 (<0.1)
Day 6	0	0	0
Day 7	0	1 (<0.1)	1 (<0.1)
Lymphadenopathy - N1 [1]	3746	3761	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	23 (0.6)	26 (0.7)	49 (0.7)
Day 1, after Vaccination (at Home)	24 (0.6)	54 (1.4)	78 (1.0)
Day 2	40 (1.1)	74 (2.0)	114 (1.5)
Day 3	25 (0.7)	35 (0.9)	60 (0.8)
Day 4	15 (0.4)	16 (0.4)	31 (0.4)
Day 5	6 (0.2)	10 (0.3)	16 (0.2)
Day 6	14 (0.4)	7 (0.2)	21 (0.3)
Day 7	8 (0.2)	9 (0.2)	17 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Solicited Systemic Adverse Reactions - N1	3748	3761	7509
Day 1, 30 Minutes after Vaccination (at Study Clinic)	122 (3.3)	120 (3.2)	242 (3.2)
Day 1, after Vaccination (at Home)	378 (10.1)	585 (15.6)	963 (12.8)
Day 2	352 (9.4)	658 (17.5)	1010 (13.5)
Day 3	178 (4.7)	221 (5.9)	399 (5.3)
Day 4	106 (2.8)	89 (2.4)	195 (2.6)
Day 5	76 (2.0)	51 (1.4)	127 (1.7)
Day 6	71 (1.9)	55 (1.5)	126 (1.7)
Day 7	52 (1.4)	39 (1.0)	91 (1.2)
Fever - N1	3748	3760	7508
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	0	1 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 2	0	1 (<0.1)	1 (<0.1)
Day 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 4	0	0	0
Day 5	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 6	0	2 (<0.1)	2 (<0.1)
Day 7	1 (<0.1)	0	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Headache - N1	3745	3761	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	67 (1.8)	66 (1.8)	133 (1.8)
Day 1, after Vaccination (at Home)	163 (4.4)	259 (6.9)	422 (5.6)
Day 2	173 (4.6)	284 (7.6)	457 (6.1)
Day 3	108 (2.9)	135 (3.6)	243 (3.2)
Day 4	62 (1.7)	52 (1.4)	114 (1.5)
Day 5	63 (1.7)	44 (1.2)	107 (1.4)
Day 6	50 (1.3)	43 (1.1)	93 (1.2)
Day 7	38 (1.0)	38 (1.0)	76 (1.0)
Fatigue - N1	3745	3761	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	39 (1.0)	42 (1.1)	81 (1.1)
Day 1, after Vaccination (at Home)	260 (6.9)	368 (9.8)	628 (8.4)
Day 2	225 (6.0)	488 (13.0)	713 (9.5)
Day 3	112 (3.0)	174 (4.6)	286 (3.8)
Day 4	74 (2.0)	73 (1.9)	147 (2.0)
Day 5	51 (1.4)	34 (0.9)	85 (1.1)
Day 6	57 (1.5)	42 (1.1)	99 (1.3)
Day 7	33 (0.9)	30 (0.8)	63 (0.8)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Myalgia - N1	3745	3761	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	21 (0.6)	26 (0.7)	47 (0.6)
Day 1, after Vaccination (at Home)	91 (2.4)	178 (4.7)	269 (3.6)
Day 2	120 (3.2)	274 (7.3)	394 (5.2)
Day 3	76 (2.0)	125 (3.3)	201 (2.7)
Day 4	48 (1.3)	58 (1.5)	106 (1.4)
Day 5	34 (0.9)	25 (0.7)	59 (0.8)
Day 6	25 (0.7)	36 (1.0)	61 (0.8)
Day 7	28 (0.7)	21 (0.6)	49 (0.7)
Arthralgia - N1	3745	3761	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	23 (0.6)	29 (0.8)	52 (0.7)
Day 1, after Vaccination (at Home)	68 (1.8)	120 (3.2)	188 (2.5)
Day 2	126 (3.4)	196 (5.2)	322 (4.3)
Day 3	78 (2.1)	111 (3.0)	189 (2.5)
Day 4	55 (1.5)	65 (1.7)	120 (1.6)
Day 5	45 (1.2)	37 (1.0)	82 (1.1)
Day 6	35 (0.9)	34 (0.9)	69 (0.9)
Day 7	26 (0.7)	26 (0.7)	52 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.4

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Nausea/Vomiting - N1	3745	3761	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (0.1)	8 (0.2)	13 (0.2)
Day 1, after Vaccination (at Home)	20 (0.5)	21 (0.6)	41 (0.5)
Day 2	46 (1.2)	55 (1.5)	101 (1.3)
Day 3	28 (0.7)	44 (1.2)	72 (1.0)
Day 4	14 (0.4)	17 (0.5)	31 (0.4)
Day 5	13 (0.3)	19 (0.5)	32 (0.4)
Day 6	24 (0.6)	15 (0.4)	39 (0.5)
Day 7	16 (0.4)	15 (0.4)	31 (0.4)
Chills - N1	3745	3761	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (0.3)	10 (0.3)	22 (0.3)
Day 1, after Vaccination (at Home)	34 (0.9)	47 (1.2)	81 (1.1)
Day 2	37 (1.0)	59 (1.6)	96 (1.3)
Day 3	23 (0.6)	43 (1.1)	66 (0.9)
Day 4	15 (0.4)	17 (0.5)	32 (0.4)
Day 5	9 (0.2)	14 (0.4)	23 (0.3)
Day 6	13 (0.3)	5 (0.1)	18 (0.2)
Day 7	5 (0.1)	7 (0.2)	12 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Any Solicited Adverse Reactions - N1	10321	10358	20679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1253 (12.1)	1142 (11.0)	2395 (11.6)
Day 1, after Vaccination (at Home)	1391 (13.5)	6168 (59.5)	7559 (36.6)
Day 2	870 (8.4)	2235 (21.6)	3105 (15.0)
Day 3	417 (4.0)	83 (0.8)	500 (2.4)
Day 4	253 (2.5)	17 (0.2)	270 (1.3)
Day 5	200 (1.9)	4 (<0.1)	204 (1.0)
Day 6	151 (1.5)	8 (<0.1)	159 (0.8)
Day 7	113 (1.1)	7 (<0.1)	120 (0.6)
Solicited Local Adverse Reactions - N1	10317	10357	20674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1007 (9.8)	885 (8.5)	1892 (9.2)
Day 1, after Vaccination (at Home)	571 (5.5)	6080 (58.7)	6651 (32.2)
Day 2	279 (2.7)	2286 (22.1)	2565 (12.4)
Day 3	130 (1.3)	97 (0.9)	227 (1.1)
Day 4	54 (0.5)	15 (0.1)	69 (0.3)
Day 5	45 (0.4)	3 (<0.1)	48 (0.2)
Day 6	22 (0.2)	3 (<0.1)	25 (0.1)
Day 7	26 (0.3)	2 (<0.1)	28 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Pain - N1	10317	10357	20674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	984 (9.5)	855 (8.3)	1839 (8.9)
Day 1, after Vaccination (at Home)	530 (5.1)	6067 (58.6)	6597 (31.9)
Day 2	228 (2.2)	2299 (22.2)	2527 (12.2)
Day 3	104 (1.0)	95 (0.9)	199 (1.0)
Day 4	32 (0.3)	13 (0.1)	45 (0.2)
Day 5	32 (0.3)	2 (<0.1)	34 (0.2)
Day 6	19 (0.2)	3 (<0.1)	22 (0.1)
Day 7	13 (0.1)	1 (<0.1)	14 (<0.1)
Erythema (Redness) - N1	10317	10357	20674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (<0.1)	3 (<0.1)	10 (<0.1)
Day 1, after Vaccination (at Home)	13 (0.1)	90 (0.9)	103 (0.5)
Day 2	8 (<0.1)	367 (3.5)	375 (1.8)
Day 3	6 (<0.1)	376 (3.6)	382 (1.8)
Day 4	3 (<0.1)	81 (0.8)	84 (0.4)
Day 5	2 (<0.1)	9 (<0.1)	11 (<0.1)
Day 6	2 (<0.1)	1 (<0.1)	3 (<0.1)
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Swelling (Hardness) - N1	10317	10357	20674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	11 (0.1)	19 (<0.1)
Day 1, after Vaccination (at Home)	7 (<0.1)	363 (3.5)	370 (1.8)
Day 2	9 (<0.1)	658 (6.4)	667 (3.2)
Day 3	5 (<0.1)	220 (2.1)	225 (1.1)
Day 4	1 (<0.1)	47 (0.5)	48 (0.2)
Day 5	1 (<0.1)	5 (<0.1)	6 (<0.1)
Day 6	2 (<0.1)	3 (<0.1)	5 (<0.1)
Day 7	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lymphadenopathy - N1 [1]	10317	10357	20674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	46 (0.4)	55 (0.5)	101 (0.5)
Day 1, after Vaccination (at Home)	118 (1.1)	405 (3.9)	523 (2.5)
Day 2	114 (1.1)	686 (6.6)	800 (3.9)
Day 3	66 (0.6)	326 (3.1)	392 (1.9)
Day 4	43 (0.4)	122 (1.2)	165 (0.8)
Day 5	30 (0.3)	31 (0.3)	61 (0.3)
Day 6	13 (0.1)	14 (0.1)	27 (0.1)
Day 7	14 (0.1)	15 (0.1)	29 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Solicited Systemic Adverse Reactions - N1	10320	10358	20678
Day 1, 30 Minutes after Vaccination (at Study Clinic)	395 (3.8)	391 (3.8)	786 (3.8)
Day 1, after Vaccination (at Home)	1332 (12.9)	3141 (30.3)	4473 (21.6)
Day 2	945 (9.2)	4542 (43.9)	5487 (26.5)
Day 3	465 (4.5)	258 (2.5)	723 (3.5)
Day 4	287 (2.8)	67 (0.6)	354 (1.7)
Day 5	227 (2.2)	28 (0.3)	255 (1.2)
Day 6	180 (1.7)	34 (0.3)	214 (1.0)
Day 7	136 (1.3)	23 (0.2)	159 (0.8)
Fever - N1	10315	10352	20667
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	166 (1.6)	171 (0.8)
Day 2	7 (<0.1)	1490 (14.4)	1497 (7.2)
Day 3	7 (<0.1)	138 (1.3)	145 (0.7)
Day 4	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 5	3 (<0.1)	4 (<0.1)	7 (<0.1)
Day 6	7 (<0.1)	1 (<0.1)	8 (<0.1)
Day 7	5 (<0.1)	3 (<0.1)	8 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Headache - N1	10317	10357	20674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	199 (1.9)	208 (2.0)	407 (2.0)
Day 1, after Vaccination (at Home)	725 (7.0)	1640 (15.8)	2365 (11.4)
Day 2	574 (5.6)	3983 (38.5)	4557 (22.0)
Day 3	375 (3.6)	338 (3.3)	713 (3.4)
Day 4	257 (2.5)	123 (1.2)	380 (1.8)
Day 5	186 (1.8)	88 (0.8)	274 (1.3)
Day 6	158 (1.5)	69 (0.7)	227 (1.1)
Day 7	143 (1.4)	51 (0.5)	194 (0.9)
Fatigue - N1	10315	10357	20672
Day 1, 30 Minutes after Vaccination (at Study Clinic)	162 (1.6)	180 (1.7)	342 (1.7)
Day 1, after Vaccination (at Home)	866 (8.4)	2190 (21.1)	3056 (14.8)
Day 2	667 (6.5)	4195 (40.5)	4862 (23.5)
Day 3	307 (3.0)	300 (2.9)	607 (2.9)
Day 4	173 (1.7)	59 (0.6)	232 (1.1)
Day 5	157 (1.5)	33 (0.3)	190 (0.9)
Day 6	131 (1.3)	29 (0.3)	160 (0.8)
Day 7	67 (0.6)	16 (0.2)	83 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Myalgia - N1	10316	10357	20673
Day 1, 30 Minutes after Vaccination (at Study Clinic)	72 (0.7)	66 (0.6)	138 (0.7)
Day 1, after Vaccination (at Home)	337 (3.3)	1529 (14.8)	1866 (9.0)
Day 2	345 (3.3)	4411 (42.6)	4756 (23.0)
Day 3	183 (1.8)	251 (2.4)	434 (2.1)
Day 4	135 (1.3)	48 (0.5)	183 (0.9)
Day 5	87 (0.8)	19 (0.2)	106 (0.5)
Day 6	86 (0.8)	17 (0.2)	103 (0.5)
Day 7	67 (0.6)	12 (0.1)	79 (0.4)
Arthralgia - N1	10315	10357	20672
Day 1, 30 Minutes after Vaccination (at Study Clinic)	69 (0.7)	71 (0.7)	140 (0.7)
Day 1, after Vaccination (at Home)	269 (2.6)	999 (9.6)	1268 (6.1)
Day 2	261 (2.5)	3246 (31.3)	3507 (17.0)
Day 3	155 (1.5)	251 (2.4)	406 (2.0)
Day 4	125 (1.2)	53 (0.5)	178 (0.9)
Day 5	76 (0.7)	23 (0.2)	99 (0.5)
Day 6	76 (0.7)	27 (0.3)	103 (0.5)
Day 7	56 (0.5)	15 (0.1)	71 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Nausea/Vomiting - N1	10315	10357	20672
Day 1, 30 Minutes after Vaccination (at Study Clinic)	32 (0.3)	26 (0.3)	58 (0.3)
Day 1, after Vaccination (at Home)	182 (1.8)	388 (3.7)	570 (2.8)
Day 2	180 (1.7)	1409 (13.6)	1589 (7.7)
Day 3	110 (1.1)	205 (2.0)	315 (1.5)
Day 4	76 (0.7)	81 (0.8)	157 (0.8)
Day 5	61 (0.6)	41 (0.4)	102 (0.5)
Day 6	64 (0.6)	35 (0.3)	99 (0.5)
Day 7	49 (0.5)	24 (0.2)	73 (0.4)
Chills - N1	10315	10357	20672
Day 1, 30 Minutes after Vaccination (at Study Clinic)	45 (0.4)	32 (0.3)	77 (0.4)
Day 1, after Vaccination (at Home)	159 (1.5)	876 (8.5)	1035 (5.0)
Day 2	148 (1.4)	3753 (36.2)	3901 (18.9)
Day 3	77 (0.7)	264 (2.5)	341 (1.6)
Day 4	54 (0.5)	32 (0.3)	86 (0.4)
Day 5	50 (0.5)	12 (0.1)	62 (0.3)
Day 6	45 (0.4)	21 (0.2)	66 (0.3)
Day 7	33 (0.3)	11 (0.1)	44 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Any Solicited Adverse Reactions - N1	3549	3589	7138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	232 (6.5)	231 (6.4)	463 (6.5)
Day 1, after Vaccination (at Home)	407 (11.5)	1672 (46.6)	2079 (29.1)
Day 2	290 (8.2)	1237 (34.5)	1527 (21.4)
Day 3	124 (3.5)	50 (1.4)	174 (2.4)
Day 4	87 (2.5)	11 (0.3)	98 (1.4)
Day 5	62 (1.7)	6 (0.2)	68 (1.0)
Day 6	48 (1.4)	4 (0.1)	52 (0.7)
Day 7	44 (1.2)	2 (<0.1)	46 (0.6)
Solicited Local Adverse Reactions - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	132 (3.7)	157 (4.4)	289 (4.0)
Day 1, after Vaccination (at Home)	150 (4.2)	1545 (43.1)	1695 (23.8)
Day 2	109 (3.1)	1236 (34.5)	1345 (18.8)
Day 3	40 (1.1)	54 (1.5)	94 (1.3)
Day 4	24 (0.7)	9 (0.3)	33 (0.5)
Day 5	9 (0.3)	5 (0.1)	14 (0.2)
Day 6	7 (0.2)	4 (0.1)	11 (0.2)
Day 7	2 (<0.1)	0	2 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Pain - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	124 (3.5)	149 (4.2)	273 (3.8)
Day 1, after Vaccination (at Home)	140 (3.9)	1537 (42.8)	1677 (23.5)
Day 2	90 (2.5)	1238 (34.5)	1328 (18.6)
Day 3	32 (0.9)	54 (1.5)	86 (1.2)
Day 4	23 (0.6)	7 (0.2)	30 (0.4)
Day 5	6 (0.2)	3 (<0.1)	9 (0.1)
Day 6	4 (0.1)	2 (<0.1)	6 (<0.1)
Day 7	2 (<0.1)	0	2 (<0.1)
Erythema (Redness) - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	6 (0.2)	19 (0.5)	25 (0.4)
Day 2	1 (<0.1)	116 (3.2)	117 (1.6)
Day 3	3 (<0.1)	94 (2.6)	97 (1.4)
Day 4	0	28 (0.8)	28 (0.4)
Day 5	1 (<0.1)	5 (0.1)	6 (<0.1)
Day 6	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 7	0	1 (<0.1)	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Swelling (Hardness) - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	4 (0.1)	7 (<0.1)
Day 1, after Vaccination (at Home)	5 (0.1)	79 (2.2)	84 (1.2)
Day 2	2 (<0.1)	222 (6.2)	224 (3.1)
Day 3	1 (<0.1)	61 (1.7)	62 (0.9)
Day 4	2 (<0.1)	16 (0.4)	18 (0.3)
Day 5	0	4 (0.1)	4 (<0.1)
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (0.3)	15 (0.4)	27 (0.4)
Day 1, after Vaccination (at Home)	17 (0.5)	59 (1.6)	76 (1.1)
Day 2	30 (0.8)	139 (3.9)	169 (2.4)
Day 3	15 (0.4)	52 (1.4)	67 (0.9)
Day 4	3 (<0.1)	24 (0.7)	27 (0.4)
Day 5	8 (0.2)	7 (0.2)	15 (0.2)
Day 6	4 (0.1)	5 (0.1)	9 (0.1)
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Solicited Systemic Adverse Reactions - N1	3549	3589	7138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	120 (3.4)	100 (2.8)	220 (3.1)
Day 1, after Vaccination (at Home)	337 (9.5)	787 (21.9)	1124 (15.7)
Day 2	272 (7.7)	1536 (42.8)	1808 (25.3)
Day 3	123 (3.5)	96 (2.7)	219 (3.1)
Day 4	86 (2.4)	25 (0.7)	111 (1.6)
Day 5	64 (1.8)	14 (0.4)	78 (1.1)
Day 6	55 (1.5)	14 (0.4)	69 (1.0)
Day 7	45 (1.3)	8 (0.2)	53 (0.7)
Fever - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (<0.1)	1 (<0.1)
Day 1, after Vaccination (at Home)	0	26 (0.7)	26 (0.4)
Day 2	2 (<0.1)	316 (8.8)	318 (4.5)
Day 3	0	21 (0.6)	21 (0.3)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	2 (<0.1)	0	2 (<0.1)
Day 6	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Headache - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	56 (1.6)	44 (1.2)	100 (1.4)
Day 1, after Vaccination (at Home)	140 (3.9)	371 (10.3)	511 (7.2)
Day 2	170 (4.8)	1085 (30.2)	1255 (17.6)
Day 3	89 (2.5)	85 (2.4)	174 (2.4)
Day 4	53 (1.5)	28 (0.8)	81 (1.1)
Day 5	41 (1.2)	20 (0.6)	61 (0.9)
Day 6	43 (1.2)	22 (0.6)	65 (0.9)
Day 7	43 (1.2)	10 (0.3)	53 (0.7)
Fatigue - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	46 (1.3)	39 (1.1)	85 (1.2)
Day 1, after Vaccination (at Home)	218 (6.1)	511 (14.2)	729 (10.2)
Day 2	183 (5.2)	1391 (38.8)	1574 (22.1)
Day 3	84 (2.4)	96 (2.7)	180 (2.5)
Day 4	63 (1.8)	23 (0.6)	86 (1.2)
Day 5	36 (1.0)	15 (0.4)	51 (0.7)
Day 6	36 (1.0)	8 (0.2)	44 (0.6)
Day 7	29 (0.8)	11 (0.3)	40 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Myalgia - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	30 (0.8)	27 (0.8)	57 (0.8)
Day 1, after Vaccination (at Home)	71 (2.0)	345 (9.6)	416 (5.8)
Day 2	130 (3.7)	1192 (33.2)	1322 (18.5)
Day 3	54 (1.5)	75 (2.1)	129 (1.8)
Day 4	30 (0.8)	16 (0.4)	46 (0.6)
Day 5	30 (0.8)	9 (0.3)	39 (0.5)
Day 6	25 (0.7)	13 (0.4)	38 (0.5)
Day 7	15 (0.4)	6 (0.2)	21 (0.3)
Arthralgia - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	39 (1.1)	36 (1.0)	75 (1.1)
Day 1, after Vaccination (at Home)	71 (2.0)	255 (7.1)	326 (4.6)
Day 2	107 (3.0)	841 (23.4)	948 (13.3)
Day 3	53 (1.5)	65 (1.8)	118 (1.7)
Day 4	43 (1.2)	24 (0.7)	67 (0.9)
Day 5	19 (0.5)	13 (0.4)	32 (0.4)
Day 6	32 (0.9)	12 (0.3)	44 (0.6)
Day 7	17 (0.5)	6 (0.2)	23 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.5

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Nausea/Vomiting - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (0.2)	11 (0.3)	19 (0.3)
Day 1, after Vaccination (at Home)	21 (0.6)	69 (1.9)	90 (1.3)
Day 2	31 (0.9)	273 (7.6)	304 (4.3)
Day 3	18 (0.5)	39 (1.1)	57 (0.8)
Day 4	17 (0.5)	13 (0.4)	30 (0.4)
Day 5	8 (0.2)	6 (0.2)	14 (0.2)
Day 6	9 (0.3)	8 (0.2)	17 (0.2)
Day 7	17 (0.5)	6 (0.2)	23 (0.3)
Chills - N1	3549	3587	7136
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (0.3)	13 (0.4)	23 (0.3)
Day 1, after Vaccination (at Home)	27 (0.8)	155 (4.3)	182 (2.6)
Day 2	43 (1.2)	840 (23.4)	883 (12.4)
Day 3	19 (0.5)	69 (1.9)	88 (1.2)
Day 4	13 (0.4)	12 (0.3)	25 (0.4)
Day 5	14 (0.4)	2 (<0.1)	16 (0.2)
Day 6	9 (0.3)	2 (<0.1)	11 (0.2)
Day 7	9 (0.3)	6 (0.2)	15 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Any Solicited Adverse Reactions - N1	11412	11410	22823
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2188 (19.2)	2141 (18.8)	4329 (19.0)
Day 1, after Vaccination (at Home)	2179 (19.1)	6814 (59.7)	8993 (39.4)
Day 2	1239 (10.9)	1770 (15.5)	3009 (13.2)
Day 3	551 (4.8)	67 (0.6)	618 (2.7)
Day 4	323 (2.8)	12 (0.1)	335 (1.5)
Day 5	239 (2.1)	14 (0.1)	253 (1.1)
Day 6	159 (1.4)	10 (<0.1)	169 (0.7)
Day 7	139 (1.2)	13 (0.1)	152 (0.7)
Solicited Local Adverse Reactions - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1710 (15.0)	1649 (14.5)	3359 (14.7)
Day 1, after Vaccination (at Home)	898 (7.9)	6912 (60.6)	7810 (34.2)
Day 2	471 (4.1)	1958 (17.2)	2429 (10.6)
Day 3	194 (1.7)	78 (0.7)	272 (1.2)
Day 4	102 (0.9)	12 (0.1)	114 (0.5)
Day 5	72 (0.6)	6 (<0.1)	78 (0.3)
Day 6	41 (0.4)	4 (<0.1)	45 (0.2)
Day 7	34 (0.3)	6 (<0.1)	40 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Pain - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1662 (14.6)	1590 (13.9)	3252 (14.2)
Day 1, after Vaccination (at Home)	834 (7.3)	6926 (60.7)	7760 (34.0)
Day 2	405 (3.5)	1982 (17.4)	2387 (10.5)
Day 3	155 (1.4)	71 (0.6)	226 (1.0)
Day 4	64 (0.6)	10 (<0.1)	74 (0.3)
Day 5	50 (0.4)	3 (<0.1)	53 (0.2)
Day 6	33 (0.3)	3 (<0.1)	36 (0.2)
Day 7	21 (0.2)	5 (<0.1)	26 (0.1)
Erythema (Redness) - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	11 (<0.1)	20 (<0.1)
Day 1, after Vaccination (at Home)	29 (0.3)	126 (1.1)	155 (0.7)
Day 2	16 (0.1)	495 (4.3)	511 (2.2)
Day 3	11 (<0.1)	409 (3.6)	420 (1.8)
Day 4	7 (<0.1)	88 (0.8)	95 (0.4)
Day 5	3 (<0.1)	12 (0.1)	15 (<0.1)
Day 6	5 (<0.1)	2 (<0.1)	7 (<0.1)
Day 7	2 (<0.1)	2 (<0.1)	4 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Swelling (Hardness) - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	16 (0.1)	21 (0.2)	37 (0.2)
Day 1, after Vaccination (at Home)	15 (0.1)	473 (4.1)	488 (2.1)
Day 2	17 (0.1)	923 (8.1)	940 (4.1)
Day 3	5 (<0.1)	234 (2.1)	239 (1.0)
Day 4	2 (<0.1)	48 (0.4)	50 (0.2)
Day 5	4 (<0.1)	7 (<0.1)	11 (<0.1)
Day 6	2 (<0.1)	5 (<0.1)	7 (<0.1)
Day 7	4 (<0.1)	4 (<0.1)	8 (<0.1)
Lymphadenopathy - N1 [1]	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	117 (1.0)	122 (1.1)	239 (1.0)
Day 1, after Vaccination (at Home)	214 (1.9)	641 (5.6)	855 (3.7)
Day 2	193 (1.7)	907 (7.9)	1100 (4.8)
Day 3	117 (1.0)	413 (3.6)	530 (2.3)
Day 4	74 (0.6)	157 (1.4)	231 (1.0)
Day 5	72 (0.6)	56 (0.5)	128 (0.6)
Day 6	38 (0.3)	59 (0.5)	97 (0.4)
Day 7	33 (0.3)	92 (0.8)	125 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Solicited Systemic Adverse Reactions - N1	11412	11410	22823
Day 1, 30 Minutes after Vaccination (at Study Clinic)	853 (7.5)	835 (7.3)	1688 (7.4)
Day 1, after Vaccination (at Home)	2320 (20.3)	4035 (35.4)	6355 (27.8)
Day 2	1444 (12.7)	4190 (36.7)	5634 (24.7)
Day 3	644 (5.6)	308 (2.7)	952 (4.2)
Day 4	351 (3.1)	104 (0.9)	455 (2.0)
Day 5	282 (2.5)	64 (0.6)	346 (1.5)
Day 6	215 (1.9)	51 (0.4)	266 (1.2)
Day 7	169 (1.5)	44 (0.4)	213 (0.9)
Fever - N1	11411	11409	22821
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 1, after Vaccination (at Home)	6 (<0.1)	176 (1.5)	182 (0.8)
Day 2	13 (0.1)	1529 (13.4)	1542 (6.8)
Day 3	14 (0.1)	151 (1.3)	165 (0.7)
Day 4	9 (<0.1)	6 (<0.1)	15 (<0.1)
Day 5	12 (0.1)	8 (<0.1)	20 (<0.1)
Day 6	11 (<0.1)	2 (<0.1)	13 (<0.1)
Day 7	8 (<0.1)	5 (<0.1)	13 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Headache - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	456 (4.0)	470 (4.1)	926 (4.1)
Day 1, after Vaccination (at Home)	1306 (11.4)	2257 (19.8)	3563 (15.6)
Day 2	1057 (9.3)	3927 (34.4)	4984 (21.8)
Day 3	578 (5.1)	410 (3.6)	988 (4.3)
Day 4	356 (3.1)	182 (1.6)	538 (2.4)
Day 5	259 (2.3)	128 (1.1)	387 (1.7)
Day 6	234 (2.1)	122 (1.1)	356 (1.6)
Day 7	207 (1.8)	89 (0.8)	296 (1.3)
Fatigue - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	329 (2.9)	355 (3.1)	684 (3.0)
Day 1, after Vaccination (at Home)	1624 (14.2)	2922 (25.6)	4546 (19.9)
Day 2	1072 (9.4)	4089 (35.8)	5161 (22.6)
Day 3	501 (4.4)	362 (3.2)	863 (3.8)
Day 4	248 (2.2)	93 (0.8)	341 (1.5)
Day 5	216 (1.9)	61 (0.5)	277 (1.2)
Day 6	180 (1.6)	58 (0.5)	238 (1.0)
Day 7	109 (1.0)	46 (0.4)	155 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Myalgia - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	165 (1.4)	158 (1.4)	323 (1.4)
Day 1, after Vaccination (at Home)	605 (5.3)	1969 (17.3)	2574 (11.3)
Day 2	655 (5.7)	4492 (39.4)	5147 (22.6)
Day 3	309 (2.7)	323 (2.8)	632 (2.8)
Day 4	243 (2.1)	74 (0.6)	317 (1.4)
Day 5	151 (1.3)	40 (0.4)	191 (0.8)
Day 6	137 (1.2)	39 (0.3)	176 (0.8)
Day 7	113 (1.0)	30 (0.3)	143 (0.6)
Arthralgia - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	142 (1.2)	141 (1.2)	283 (1.2)
Day 1, after Vaccination (at Home)	455 (4.0)	1263 (11.1)	1718 (7.5)
Day 2	511 (4.5)	3337 (29.2)	3848 (16.9)
Day 3	280 (2.5)	345 (3.0)	625 (2.7)
Day 4	207 (1.8)	89 (0.8)	296 (1.3)
Day 5	125 (1.1)	49 (0.4)	174 (0.8)
Day 6	131 (1.1)	49 (0.4)	180 (0.8)
Day 7	94 (0.8)	42 (0.4)	136 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Nausea/Vomiting - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	74 (0.6)	57 (0.5)	131 (0.6)
Day 1, after Vaccination (at Home)	304 (2.7)	547 (4.8)	851 (3.7)
Day 2	338 (3.0)	1558 (13.7)	1896 (8.3)
Day 3	201 (1.8)	299 (2.6)	500 (2.2)
Day 4	154 (1.3)	151 (1.3)	305 (1.3)
Day 5	126 (1.1)	72 (0.6)	198 (0.9)
Day 6	118 (1.0)	71 (0.6)	189 (0.8)
Day 7	95 (0.8)	58 (0.5)	153 (0.7)
Chills - N1	11411	11410	22822
Day 1, 30 Minutes after Vaccination (at Study Clinic)	113 (1.0)	92 (0.8)	205 (0.9)
Day 1, after Vaccination (at Home)	290 (2.5)	1029 (9.0)	1319 (5.8)
Day 2	269 (2.4)	3792 (33.2)	4061 (17.8)
Day 3	161 (1.4)	326 (2.9)	487 (2.1)
Day 4	101 (0.9)	50 (0.4)	151 (0.7)
Day 5	101 (0.9)	35 (0.3)	136 (0.6)
Day 6	76 (0.7)	35 (0.3)	111 (0.5)
Day 7	66 (0.6)	29 (0.3)	95 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Any Solicited Adverse Reactions - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	451 (12.0)	432 (11.5)	883 (11.7)
Day 1, after Vaccination (at Home)	636 (17.0)	1950 (51.8)	2586 (34.4)
Day 2	447 (11.9)	1038 (27.6)	1485 (19.8)
Day 3	189 (5.0)	48 (1.3)	237 (3.2)
Day 4	117 (3.1)	9 (0.2)	126 (1.7)
Day 5	74 (2.0)	8 (0.2)	82 (1.1)
Day 6	57 (1.5)	7 (0.2)	64 (0.9)
Day 7	39 (1.0)	5 (0.1)	44 (0.6)
Solicited Local Adverse Reactions - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	274 (7.3)	292 (7.8)	566 (7.5)
Day 1, after Vaccination (at Home)	234 (6.2)	1823 (48.4)	2057 (27.4)
Day 2	191 (5.1)	1161 (30.8)	1352 (18.0)
Day 3	68 (1.8)	47 (1.2)	115 (1.5)
Day 4	39 (1.0)	3 (<0.1)	42 (0.6)
Day 5	24 (0.6)	5 (0.1)	29 (0.4)
Day 6	18 (0.5)	5 (0.1)	23 (0.3)
Day 7	11 (0.3)	1 (<0.1)	12 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Pain - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	260 (6.9)	278 (7.4)	538 (7.2)
Day 1, after Vaccination (at Home)	216 (5.8)	1815 (48.2)	2031 (27.0)
Day 2	156 (4.2)	1166 (31.0)	1322 (17.6)
Day 3	48 (1.3)	46 (1.2)	94 (1.3)
Day 4	34 (0.9)	1 (<0.1)	35 (0.5)
Day 5	18 (0.5)	2 (<0.1)	20 (0.3)
Day 6	10 (0.3)	3 (<0.1)	13 (0.2)
Day 7	9 (0.2)	0	9 (0.1)
Erythema (Redness) - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	7 (0.2)	28 (0.7)	35 (0.5)
Day 2	9 (0.2)	145 (3.9)	154 (2.0)
Day 3	8 (0.2)	111 (2.9)	119 (1.6)
Day 4	1 (<0.1)	27 (0.7)	28 (0.4)
Day 5	5 (0.1)	6 (0.2)	11 (0.1)
Day 6	1 (<0.1)	4 (0.1)	5 (<0.1)
Day 7	0	1 (<0.1)	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Swelling (Hardness) - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (0.1)	7 (0.2)	11 (0.1)
Day 1, after Vaccination (at Home)	6 (0.2)	93 (2.5)	99 (1.3)
Day 2	12 (0.3)	266 (7.1)	278 (3.7)
Day 3	4 (0.1)	77 (2.0)	81 (1.1)
Day 4	3 (<0.1)	20 (0.5)	23 (0.3)
Day 5	1 (<0.1)	4 (0.1)	5 (<0.1)
Day 6	0	0	0
Day 7	0	1 (<0.1)	1 (<0.1)
Lymphadenopathy - N1 [1]	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	33 (0.9)	41 (1.1)	74 (1.0)
Day 1, after Vaccination (at Home)	37 (1.0)	108 (2.9)	145 (1.9)
Day 2	64 (1.7)	182 (4.8)	246 (3.3)
Day 3	30 (0.8)	74 (2.0)	104 (1.4)
Day 4	16 (0.4)	35 (0.9)	51 (0.7)
Day 5	11 (0.3)	11 (0.3)	22 (0.3)
Day 6	17 (0.5)	9 (0.2)	26 (0.3)
Day 7	8 (0.2)	7 (0.2)	15 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Solicited Systemic Adverse Reactions - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	232 (6.2)	204 (5.4)	436 (5.8)
Day 1, after Vaccination (at Home)	561 (15.0)	1073 (28.5)	1634 (21.7)
Day 2	440 (11.7)	1426 (37.9)	1866 (24.8)
Day 3	203 (5.4)	129 (3.4)	332 (4.4)
Day 4	126 (3.4)	29 (0.8)	155 (2.1)
Day 5	79 (2.1)	27 (0.7)	106 (1.4)
Day 6	64 (1.7)	20 (0.5)	84 (1.1)
Day 7	49 (1.3)	14 (0.4)	63 (0.8)
Fever - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	29 (0.8)	32 (0.4)
Day 2	2 (<0.1)	316 (8.4)	318 (4.2)
Day 3	1 (<0.1)	21 (0.6)	22 (0.3)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 6	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 7	1 (<0.1)	0	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Headache - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	122 (3.3)	106 (2.8)	228 (3.0)
Day 1, after Vaccination (at Home)	260 (6.9)	542 (14.4)	802 (10.7)
Day 2	273 (7.3)	1076 (28.6)	1349 (17.9)
Day 3	151 (4.0)	130 (3.5)	281 (3.7)
Day 4	88 (2.3)	38 (1.0)	126 (1.7)
Day 5	74 (2.0)	32 (0.8)	106 (1.4)
Day 6	56 (1.5)	31 (0.8)	87 (1.2)
Day 7	50 (1.3)	26 (0.7)	76 (1.0)
Fatigue - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	83 (2.2)	77 (2.0)	160 (2.1)
Day 1, after Vaccination (at Home)	393 (10.5)	748 (19.9)	1141 (15.2)
Day 2	315 (8.4)	1365 (36.2)	1680 (22.4)
Day 3	140 (3.7)	120 (3.2)	260 (3.5)
Day 4	101 (2.7)	38 (1.0)	139 (1.8)
Day 5	55 (1.5)	22 (0.6)	77 (1.0)
Day 6	63 (1.7)	21 (0.6)	84 (1.1)
Day 7	41 (1.1)	16 (0.4)	57 (0.8)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Myalgia - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	50 (1.3)	49 (1.3)	99 (1.3)
Day 1, after Vaccination (at Home)	143 (3.8)	464 (12.3)	607 (8.1)
Day 2	199 (5.3)	1205 (32.0)	1404 (18.7)
Day 3	107 (2.9)	107 (2.8)	214 (2.8)
Day 4	57 (1.5)	37 (1.0)	94 (1.3)
Day 5	47 (1.3)	17 (0.5)	64 (0.9)
Day 6	38 (1.0)	25 (0.7)	63 (0.8)
Day 7	33 (0.9)	10 (0.3)	43 (0.6)
Arthralgia - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	59 (1.6)	60 (1.6)	119 (1.6)
Day 1, after Vaccination (at Home)	123 (3.3)	331 (8.8)	454 (6.0)
Day 2	193 (5.1)	872 (23.2)	1065 (14.2)
Day 3	105 (2.8)	113 (3.0)	218 (2.9)
Day 4	63 (1.7)	52 (1.4)	115 (1.5)
Day 5	47 (1.3)	25 (0.7)	72 (1.0)
Day 6	45 (1.2)	21 (0.6)	66 (0.9)
Day 7	26 (0.7)	14 (0.4)	40 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.6
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Nausea/Vomiting - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (0.3)	19 (0.5)	31 (0.4)
Day 1, after Vaccination (at Home)	38 (1.0)	84 (2.2)	122 (1.6)
Day 2	70 (1.9)	305 (8.1)	375 (5.0)
Day 3	43 (1.1)	69 (1.8)	112 (1.5)
Day 4	28 (0.7)	23 (0.6)	51 (0.7)
Day 5	19 (0.5)	19 (0.5)	38 (0.5)
Day 6	30 (0.8)	19 (0.5)	49 (0.7)
Day 7	29 (0.8)	15 (0.4)	44 (0.6)
Chills - N1	3750	3766	7516
Day 1, 30 Minutes after Vaccination (at Study Clinic)	22 (0.6)	23 (0.6)	45 (0.6)
Day 1, after Vaccination (at Home)	59 (1.6)	188 (5.0)	247 (3.3)
Day 2	70 (1.9)	847 (22.5)	917 (12.2)
Day 3	36 (1.0)	91 (2.4)	127 (1.7)
Day 4	22 (0.6)	22 (0.6)	44 (0.6)
Day 5	21 (0.6)	7 (0.2)	28 (0.4)
Day 6	19 (0.5)	5 (0.1)	24 (0.3)
Day 7	13 (0.3)	9 (0.2)	22 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Any Solicited Adverse Reactions - N1	14356	14301	28657
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1507 (10.5)	1486 (10.4)	2993 (10.4)
Day 1, after Vaccination (at Home)	2042 (14.2)	6415 (44.9)	8457 (29.5)
Day 2	1513 (10.5)	4236 (29.6)	5749 (20.1)
Day 3	715 (5.0)	271 (1.9)	986 (3.4)
Day 4	394 (2.7)	67 (0.5)	461 (1.6)
Day 5	300 (2.1)	37 (0.3)	337 (1.2)
Day 6	231 (1.6)	43 (0.3)	274 (1.0)
Day 7	186 (1.3)	36 (0.3)	222 (0.8)
Solicited Local Adverse Reactions - N1	14353	14297	28650
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1076 (7.5)	1075 (7.5)	2151 (7.5)
Day 1, after Vaccination (at Home)	721 (5.0)	6051 (42.3)	6772 (23.6)
Day 2	551 (3.8)	4641 (32.5)	5192 (18.1)
Day 3	205 (1.4)	235 (1.6)	440 (1.5)
Day 4	110 (0.8)	40 (0.3)	150 (0.5)
Day 5	81 (0.6)	13 (<0.1)	94 (0.3)
Day 6	53 (0.4)	10 (<0.1)	63 (0.2)
Day 7	33 (0.2)	15 (0.1)	48 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Pain - N1	14353	14297	28650
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1038 (7.2)	1036 (7.2)	2074 (7.2)
Day 1, after Vaccination (at Home)	658 (4.6)	6022 (42.1)	6680 (23.3)
Day 2	466 (3.2)	4661 (32.6)	5127 (17.9)
Day 3	155 (1.1)	239 (1.7)	394 (1.4)
Day 4	78 (0.5)	34 (0.2)	112 (0.4)
Day 5	51 (0.4)	9 (<0.1)	60 (0.2)
Day 6	36 (0.3)	3 (<0.1)	39 (0.1)
Day 7	25 (0.2)	9 (<0.1)	34 (0.1)
Erythema (Redness) - N1	14353	14296	28649
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	9 (<0.1)	11 (<0.1)
Day 1, after Vaccination (at Home)	18 (0.1)	48 (0.3)	66 (0.2)
Day 2	16 (0.1)	219 (1.5)	235 (0.8)
Day 3	11 (<0.1)	105 (0.7)	116 (0.4)
Day 4	4 (<0.1)	14 (<0.1)	18 (<0.1)
Day 5	5 (<0.1)	6 (<0.1)	11 (<0.1)
Day 6	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Swelling (Hardness) - N1	14353	14296	28649
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	8 (<0.1)	178 (1.2)	186 (0.6)
Day 2	19 (0.1)	570 (4.0)	589 (2.1)
Day 3	5 (<0.1)	96 (0.7)	101 (0.4)
Day 4	2 (<0.1)	22 (0.2)	24 (<0.1)
Day 5	4 (<0.1)	1 (<0.1)	5 (<0.1)
Day 6	0	1 (<0.1)	1 (<0.1)
Day 7	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lymphadenopathy - N1 [1]	14353	14296	28649
Day 1, 30 Minutes after Vaccination (at Study Clinic)	92 (0.6)	92 (0.6)	184 (0.6)
Day 1, after Vaccination (at Home)	140 (1.0)	330 (2.3)	470 (1.6)
Day 2	159 (1.1)	443 (3.1)	602 (2.1)
Day 3	94 (0.7)	215 (1.5)	309 (1.1)
Day 4	61 (0.4)	87 (0.6)	148 (0.5)
Day 5	55 (0.4)	53 (0.4)	108 (0.4)
Day 6	44 (0.3)	88 (0.6)	132 (0.5)
Day 7	32 (0.2)	137 (1.0)	169 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Solicited Systemic Adverse Reactions - N1	14356	14300	28656
Day 1, 30 Minutes after Vaccination (at Study Clinic)	645 (4.5)	604 (4.2)	1249 (4.4)
Day 1, after Vaccination (at Home)	1909 (13.3)	2762 (19.3)	4671 (16.3)
Day 2	1529 (10.7)	2667 (18.7)	4196 (14.6)
Day 3	745 (5.2)	848 (5.9)	1593 (5.6)
Day 4	422 (2.9)	309 (2.2)	731 (2.6)
Day 5	332 (2.3)	227 (1.6)	559 (2.0)
Day 6	259 (1.8)	212 (1.5)	471 (1.6)
Day 7	212 (1.5)	185 (1.3)	397 (1.4)
Fever - N1	14355	14298	28653
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	1 (<0.1)	3 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	13 (<0.1)	18 (<0.1)
Day 2	5 (<0.1)	29 (0.2)	34 (0.1)
Day 3	5 (<0.1)	22 (0.2)	27 (<0.1)
Day 4	6 (<0.1)	2 (<0.1)	8 (<0.1)
Day 5	7 (<0.1)	6 (<0.1)	13 (<0.1)
Day 6	4 (<0.1)	3 (<0.1)	7 (<0.1)
Day 7	4 (<0.1)	2 (<0.1)	6 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Headache - N1	14352	14296	28648
Day 1, 30 Minutes after Vaccination (at Study Clinic)	341 (2.4)	341 (2.4)	682 (2.4)
Day 1, after Vaccination (at Home)	934 (6.5)	1271 (8.9)	2205 (7.7)
Day 2	908 (6.3)	1429 (10.0)	2337 (8.2)
Day 3	523 (3.6)	669 (4.7)	1192 (4.2)
Day 4	337 (2.3)	267 (1.9)	604 (2.1)
Day 5	286 (2.0)	231 (1.6)	517 (1.8)
Day 6	255 (1.8)	219 (1.5)	474 (1.7)
Day 7	211 (1.5)	207 (1.4)	418 (1.5)
Fatigue - N1	14352	14296	28648
Day 1, 30 Minutes after Vaccination (at Study Clinic)	223 (1.6)	230 (1.6)	453 (1.6)
Day 1, after Vaccination (at Home)	1315 (9.2)	1791 (12.5)	3106 (10.8)
Day 2	1034 (7.2)	1976 (13.8)	3010 (10.5)
Day 3	503 (3.5)	656 (4.6)	1159 (4.0)
Day 4	277 (1.9)	239 (1.7)	516 (1.8)
Day 5	221 (1.5)	145 (1.0)	366 (1.3)
Day 6	188 (1.3)	148 (1.0)	336 (1.2)
Day 7	142 (1.0)	118 (0.8)	260 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Myalgia - N1	14352	14296	28648
Day 1, 30 Minutes after Vaccination (at Study Clinic)	112 (0.8)	124 (0.9)	236 (0.8)
Day 1, after Vaccination (at Home)	426 (3.0)	846 (5.9)	1272 (4.4)
Day 2	553 (3.9)	1343 (9.4)	1896 (6.6)
Day 3	274 (1.9)	463 (3.2)	737 (2.6)
Day 4	214 (1.5)	157 (1.1)	371 (1.3)
Day 5	144 (1.0)	96 (0.7)	240 (0.8)
Day 6	108 (0.8)	89 (0.6)	197 (0.7)
Day 7	106 (0.7)	76 (0.5)	182 (0.6)
Arthralgia - N1	14352	14296	28648
Day 1, 30 Minutes after Vaccination (at Study Clinic)	90 (0.6)	99 (0.7)	189 (0.7)
Day 1, after Vaccination (at Home)	305 (2.1)	518 (3.6)	823 (2.9)
Day 2	463 (3.2)	866 (6.1)	1329 (4.6)
Day 3	270 (1.9)	414 (2.9)	684 (2.4)
Day 4	191 (1.3)	164 (1.1)	355 (1.2)
Day 5	140 (1.0)	98 (0.7)	238 (0.8)
Day 6	122 (0.9)	87 (0.6)	209 (0.7)
Day 7	90 (0.6)	91 (0.6)	181 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Nausea/Vomiting - N1	14352	14296	28648
Day 1, 30 Minutes after Vaccination (at Study Clinic)	47 (0.3)	39 (0.3)	86 (0.3)
Day 1, after Vaccination (at Home)	166 (1.2)	209 (1.5)	375 (1.3)
Day 2	240 (1.7)	362 (2.5)	602 (2.1)
Day 3	162 (1.1)	229 (1.6)	391 (1.4)
Day 4	111 (0.8)	117 (0.8)	228 (0.8)
Day 5	99 (0.7)	70 (0.5)	169 (0.6)
Day 6	108 (0.8)	76 (0.5)	184 (0.6)
Day 7	79 (0.6)	68 (0.5)	147 (0.5)
Chills - N1	14352	14296	28648
Day 1, 30 Minutes after Vaccination (at Study Clinic)	81 (0.6)	67 (0.5)	148 (0.5)
Day 1, after Vaccination (at Home)	186 (1.3)	251 (1.8)	437 (1.5)
Day 2	186 (1.3)	398 (2.8)	584 (2.0)
Day 3	125 (0.9)	223 (1.6)	348 (1.2)
Day 4	73 (0.5)	66 (0.5)	139 (0.5)
Day 5	74 (0.5)	55 (0.4)	129 (0.5)
Day 6	56 (0.4)	30 (0.2)	86 (0.3)
Day 7	41 (0.3)	34 (0.2)	75 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Any Solicited Adverse Reactions - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	26 (7.8)	26 (7.6)	52 (7.7)
Day 1, after Vaccination (at Home)	34 (10.2)	117 (34.4)	151 (22.4)
Day 2	36 (10.8)	103 (30.3)	139 (20.6)
Day 3	12 (3.6)	9 (2.6)	21 (3.1)
Day 4	9 (2.7)	2 (0.6)	11 (1.6)
Day 5	6 (1.8)	1 (0.3)	7 (1.0)
Day 6	3 (0.9)	0	3 (0.4)
Day 7	8 (2.4)	1 (0.3)	9 (1.3)
Solicited Local Adverse Reactions - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	18 (5.4)	15 (4.4)	33 (4.9)
Day 1, after Vaccination (at Home)	16 (4.8)	105 (30.9)	121 (18.0)
Day 2	10 (3.0)	110 (32.4)	120 (17.8)
Day 3	5 (1.5)	11 (3.2)	16 (2.4)
Day 4	3 (0.9)	1 (0.3)	4 (0.6)
Day 5	3 (0.9)	1 (0.3)	4 (0.6)
Day 6	0	0	0
Day 7	3 (0.9)	1 (0.3)	4 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Pain - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	18 (5.4)	15 (4.4)	33 (4.9)
Day 1, after Vaccination (at Home)	15 (4.5)	105 (30.9)	120 (17.8)
Day 2	9 (2.7)	107 (31.5)	116 (17.2)
Day 3	4 (1.2)	13 (3.8)	17 (2.5)
Day 4	2 (0.6)	1 (0.3)	3 (0.4)
Day 5	3 (0.9)	0	3 (0.4)
Day 6	0	0	0
Day 7	3 (0.9)	1 (0.3)	4 (0.6)
Erythema (Redness) - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (0.3)	1 (0.1)
Day 2	1 (0.3)	3 (0.9)	4 (0.6)
Day 3	1 (0.3)	2 (0.6)	3 (0.4)
Day 4	1 (0.3)	1 (0.3)	2 (0.3)
Day 5	0	1 (0.3)	1 (0.1)
Day 6	0	1 (0.3)	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Swelling (Hardness) - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	1 (0.3)	4 (1.2)	5 (0.7)
Day 2	1 (0.3)	13 (3.8)	14 (2.1)
Day 3	0	1 (0.3)	1 (0.1)
Day 4	0	0	0
Day 5	0	1 (0.3)	1 (0.1)
Day 6	0	1 (0.3)	1 (0.1)
Day 7	0	0	0
Lymphadenopathy - N1 [1]	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (0.6)	2 (0.3)
Day 1, after Vaccination (at Home)	2 (0.6)	6 (1.8)	8 (1.2)
Day 2	1 (0.3)	21 (6.2)	22 (3.3)
Day 3	4 (1.2)	15 (4.4)	19 (2.8)
Day 4	1 (0.3)	4 (1.2)	5 (0.7)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	2 (0.6)	0	2 (0.3)
Day 7	2 (0.6)	2 (0.6)	4 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Solicited Systemic Adverse Reactions - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (3.0)	16 (4.7)	26 (3.9)
Day 1, after Vaccination (at Home)	27 (8.1)	56 (16.5)	83 (12.3)
Day 2	37 (11.1)	112 (32.9)	149 (22.1)
Day 3	16 (4.8)	13 (3.8)	29 (4.3)
Day 4	12 (3.6)	6 (1.8)	18 (2.7)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	3 (0.9)	1 (0.3)	4 (0.6)
Day 7	9 (2.7)	2 (0.6)	11 (1.6)
Fever - N1	333	340	673
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.3)	1 (0.1)
Day 1, after Vaccination (at Home)	0	1 (0.3)	1 (0.1)
Day 2	1 (0.3)	24 (7.1)	25 (3.7)
Day 3	3 (0.9)	2 (0.6)	5 (0.7)
Day 4	0	2 (0.6)	2 (0.3)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Headache - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (1.5)	6 (1.8)	11 (1.6)
Day 1, after Vaccination (at Home)	13 (3.9)	32 (9.4)	45 (6.7)
Day 2	23 (6.9)	61 (17.9)	84 (12.5)
Day 3	9 (2.7)	13 (3.8)	22 (3.3)
Day 4	10 (3.0)	8 (2.4)	18 (2.7)
Day 5	7 (2.1)	8 (2.4)	15 (2.2)
Day 6	4 (1.2)	0	4 (0.6)
Day 7	8 (2.4)	1 (0.3)	9 (1.3)
Fatigue - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (0.9)	8 (2.4)	11 (1.6)
Day 1, after Vaccination (at Home)	16 (4.8)	31 (9.1)	47 (7.0)
Day 2	21 (6.3)	74 (21.8)	95 (14.1)
Day 3	12 (3.6)	9 (2.6)	21 (3.1)
Day 4	8 (2.4)	2 (0.6)	10 (1.5)
Day 5	3 (0.9)	3 (0.9)	6 (0.9)
Day 6	2 (0.6)	3 (0.9)	5 (0.7)
Day 7	5 (1.5)	2 (0.6)	7 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Myalgia - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	2 (0.6)	3 (0.4)
Day 1, after Vaccination (at Home)	4 (1.2)	26 (7.6)	30 (4.5)
Day 2	17 (5.1)	76 (22.4)	93 (13.8)
Day 3	7 (2.1)	11 (3.2)	18 (2.7)
Day 4	7 (2.1)	2 (0.6)	9 (1.3)
Day 5	3 (0.9)	2 (0.6)	5 (0.7)
Day 6	2 (0.6)	1 (0.3)	3 (0.4)
Day 7	5 (1.5)	2 (0.6)	7 (1.0)
Arthralgia - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	3 (0.9)	4 (0.6)
Day 1, after Vaccination (at Home)	3 (0.9)	18 (5.3)	21 (3.1)
Day 2	12 (3.6)	45 (13.2)	57 (8.5)
Day 3	9 (2.7)	11 (3.2)	20 (3.0)
Day 4	5 (1.5)	3 (0.9)	8 (1.2)
Day 5	0	3 (0.9)	3 (0.4)
Day 6	2 (0.6)	0	2 (0.3)
Day 7	6 (1.8)	2 (0.6)	8 (1.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Nausea/Vomiting - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	4 (1.2)	3 (0.9)	7 (1.0)
Day 2	4 (1.2)	20 (5.9)	24 (3.6)
Day 3	3 (0.9)	8 (2.4)	11 (1.6)
Day 4	2 (0.6)	5 (1.5)	7 (1.0)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	3 (0.9)	0	3 (0.4)
Day 7	5 (1.5)	2 (0.6)	7 (1.0)
Chills - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	2 (0.6)	3 (0.4)
Day 1, after Vaccination (at Home)	4 (1.2)	12 (3.5)	16 (2.4)
Day 2	7 (2.1)	53 (15.6)	60 (8.9)
Day 3	6 (1.8)	8 (2.4)	14 (2.1)
Day 4	4 (1.2)	1 (0.3)	5 (0.7)
Day 5	1 (0.3)	2 (0.6)	3 (0.4)
Day 6	0	0	0
Day 7	3 (0.9)	2 (0.6)	5 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Any Solicited Adverse Reactions - N1	464	526	991
Day 1, 30 Minutes after Vaccination (at Study Clinic)	63 (13.6)	60 (11.4)	123 (12.4)
Day 1, after Vaccination (at Home)	74 (15.9)	237 (45.1)	311 (31.4)
Day 2	56 (12.1)	151 (28.7)	207 (20.9)
Day 3	18 (3.9)	10 (1.9)	28 (2.8)
Day 4	14 (3.0)	5 (1.0)	19 (1.9)
Day 5	19 (4.1)	2 (0.4)	21 (2.1)
Day 6	9 (1.9)	2 (0.4)	11 (1.1)
Day 7	7 (1.5)	3 (0.6)	10 (1.0)
Solicited Local Adverse Reactions - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	45 (9.7)	39 (7.4)	84 (8.5)
Day 1, after Vaccination (at Home)	28 (6.0)	230 (43.7)	258 (26.1)
Day 2	21 (4.5)	158 (30.0)	179 (18.1)
Day 3	6 (1.3)	10 (1.9)	16 (1.6)
Day 4	4 (0.9)	2 (0.4)	6 (0.6)
Day 5	3 (0.6)	0	3 (0.3)
Day 6	3 (0.6)	1 (0.2)	4 (0.4)
Day 7	0	1 (0.2)	1 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Pain - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	44 (9.5)	37 (7.0)	81 (8.2)
Day 1, after Vaccination (at Home)	27 (5.8)	226 (43.0)	253 (25.6)
Day 2	18 (3.9)	160 (30.4)	178 (18.0)
Day 3	2 (0.4)	9 (1.7)	11 (1.1)
Day 4	3 (0.6)	2 (0.4)	5 (0.5)
Day 5	3 (0.6)	0	3 (0.3)
Day 6	1 (0.2)	1 (0.2)	2 (0.2)
Day 7	1 (0.2)	0	1 (0.1)
Erythema (Redness) - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.2)	1 (0.1)
Day 1, after Vaccination (at Home)	0	2 (0.4)	2 (0.2)
Day 2	1 (0.2)	7 (1.3)	8 (0.8)
Day 3	0	6 (1.1)	6 (0.6)
Day 4	0	0	0
Day 5	0	0	0
Day 6	1 (0.2)	0	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Swelling (Hardness) - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	7 (1.3)	7 (0.7)
Day 2	1 (0.2)	12 (2.3)	13 (1.3)
Day 3	0	10 (1.9)	10 (1.0)
Day 4	0	1 (0.2)	1 (0.1)
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (1.1)	3 (0.6)	8 (0.8)
Day 1, after Vaccination (at Home)	5 (1.1)	12 (2.3)	17 (1.7)
Day 2	2 (0.4)	25 (4.8)	27 (2.7)
Day 3	8 (1.7)	4 (0.8)	12 (1.2)
Day 4	2 (0.4)	6 (1.1)	8 (0.8)
Day 5	1 (0.2)	3 (0.6)	4 (0.4)
Day 6	5 (1.1)	1 (0.2)	6 (0.6)
Day 7	1 (0.2)	2 (0.4)	3 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Solicited Systemic Adverse Reactions - N1	464	526	991
Day 1, 30 Minutes after Vaccination (at Study Clinic)	28 (6.0)	28 (5.3)	56 (5.7)
Day 1, after Vaccination (at Home)	71 (15.3)	92 (17.5)	163 (16.4)
Day 2	55 (11.9)	107 (20.3)	162 (16.3)
Day 3	21 (4.5)	28 (5.3)	49 (4.9)
Day 4	16 (3.4)	16 (3.0)	32 (3.2)
Day 5	20 (4.3)	15 (2.9)	35 (3.5)
Day 6	9 (1.9)	10 (1.9)	19 (1.9)
Day 7	7 (1.5)	3 (0.6)	10 (1.0)
Fever - N1	464	525	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.2)	0	1 (0.1)
Day 1, after Vaccination (at Home)	0	1 (0.2)	1 (0.1)
Day 2	0	3 (0.6)	3 (0.3)
Day 3	0	2 (0.4)	2 (0.2)
Day 4	0	0	0
Day 5	1 (0.2)	0	1 (0.1)
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Headache - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	18 (3.9)	13 (2.5)	31 (3.1)
Day 1, after Vaccination (at Home)	35 (7.6)	49 (9.3)	84 (8.5)
Day 2	29 (6.3)	56 (10.6)	85 (8.6)
Day 3	19 (4.1)	29 (5.5)	48 (4.8)
Day 4	16 (3.5)	11 (2.1)	27 (2.7)
Day 5	15 (3.2)	12 (2.3)	27 (2.7)
Day 6	12 (2.6)	13 (2.5)	25 (2.5)
Day 7	9 (1.9)	6 (1.1)	15 (1.5)
Fatigue - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (2.2)	10 (1.9)	20 (2.0)
Day 1, after Vaccination (at Home)	42 (9.1)	55 (10.5)	97 (9.8)
Day 2	38 (8.2)	82 (15.6)	120 (12.1)
Day 3	19 (4.1)	22 (4.2)	41 (4.1)
Day 4	13 (2.8)	12 (2.3)	25 (2.5)
Day 5	22 (4.8)	11 (2.1)	33 (3.3)
Day 6	9 (1.9)	6 (1.1)	15 (1.5)
Day 7	7 (1.5)	2 (0.4)	9 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Myalgia - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (2.2)	4 (0.8)	14 (1.4)
Day 1, after Vaccination (at Home)	20 (4.3)	32 (6.1)	52 (5.3)
Day 2	16 (3.5)	53 (10.1)	69 (7.0)
Day 3	11 (2.4)	12 (2.3)	23 (2.3)
Day 4	8 (1.7)	7 (1.3)	15 (1.5)
Day 5	10 (2.2)	9 (1.7)	19 (1.9)
Day 6	8 (1.7)	5 (1.0)	13 (1.3)
Day 7	3 (0.6)	3 (0.6)	6 (0.6)
Arthralgia - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (1.7)	4 (0.8)	12 (1.2)
Day 1, after Vaccination (at Home)	10 (2.2)	14 (2.7)	24 (2.4)
Day 2	20 (4.3)	30 (5.7)	50 (5.1)
Day 3	13 (2.8)	14 (2.7)	27 (2.7)
Day 4	9 (1.9)	10 (1.9)	19 (1.9)
Day 5	6 (1.3)	10 (1.9)	16 (1.6)
Day 6	5 (1.1)	5 (1.0)	10 (1.0)
Day 7	3 (0.6)	1 (0.2)	4 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.7

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Nausea/Vomiting - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.4)	2 (0.4)	4 (0.4)
Day 1, after Vaccination (at Home)	5 (1.1)	4 (0.8)	9 (0.9)
Day 2	7 (1.5)	14 (2.7)	21 (2.1)
Day 3	3 (0.6)	11 (2.1)	14 (1.4)
Day 4	6 (1.3)	5 (1.0)	11 (1.1)
Day 5	4 (0.9)	9 (1.7)	13 (1.3)
Day 6	7 (1.5)	5 (1.0)	12 (1.2)
Day 7	3 (0.6)	3 (0.6)	6 (0.6)
Chills - N1	463	526	990
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (0.9)	4 (0.8)	8 (0.8)
Day 1, after Vaccination (at Home)	6 (1.3)	9 (1.7)	15 (1.5)
Day 2	5 (1.1)	19 (3.6)	24 (2.4)
Day 3	0	10 (1.9)	10 (1.0)
Day 4	3 (0.6)	1 (0.2)	4 (0.4)
Day 5	4 (0.9)	3 (0.6)	7 (0.7)
Day 6	4 (0.9)	2 (0.4)	6 (0.6)
Day 7	4 (0.9)	1 (0.2)	5 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Any Solicited Adverse Reactions - N1	13252	13286	26538
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1410 (10.6)	1304 (9.8)	2714 (10.2)
Day 1, after Vaccination (at Home)	1723 (13.0)	7497 (56.4)	9220 (34.7)
Day 2	1111 (8.4)	3306 (24.9)	4417 (16.6)
Day 3	516 (3.9)	127 (1.0)	643 (2.4)
Day 4	324 (2.4)	26 (0.2)	350 (1.3)
Day 5	247 (1.9)	10 (<0.1)	257 (1.0)
Day 6	190 (1.4)	12 (<0.1)	202 (0.8)
Day 7	153 (1.2)	9 (<0.1)	162 (0.6)
Solicited Local Adverse Reactions - N1	13249	13283	26532
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1079 (8.1)	992 (7.5)	2071 (7.8)
Day 1, after Vaccination (at Home)	682 (5.1)	7291 (54.9)	7973 (30.1)
Day 2	371 (2.8)	3354 (25.3)	3725 (14.0)
Day 3	162 (1.2)	145 (1.1)	307 (1.2)
Day 4	77 (0.6)	22 (0.2)	99 (0.4)
Day 5	48 (0.4)	8 (<0.1)	56 (0.2)
Day 6	26 (0.2)	7 (<0.1)	33 (0.1)
Day 7	28 (0.2)	2 (<0.1)	30 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Pain - N1	13249	13283	26532
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1048 (7.9)	956 (7.2)	2004 (7.6)
Day 1, after Vaccination (at Home)	635 (4.8)	7272 (54.7)	7907 (29.8)
Day 2	304 (2.3)	3368 (25.4)	3672 (13.8)
Day 3	131 (1.0)	144 (1.1)	275 (1.0)
Day 4	54 (0.4)	19 (0.1)	73 (0.3)
Day 5	34 (0.3)	5 (<0.1)	39 (0.1)
Day 6	21 (0.2)	5 (<0.1)	26 (<0.1)
Day 7	15 (0.1)	1 (<0.1)	16 (<0.1)
Erythema (Redness) - N1	13249	13283	26532
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (<0.1)	4 (<0.1)	11 (<0.1)
Day 1, after Vaccination (at Home)	18 (0.1)	105 (0.8)	123 (0.5)
Day 2	9 (<0.1)	469 (3.5)	478 (1.8)
Day 3	8 (<0.1)	456 (3.4)	464 (1.7)
Day 4	3 (<0.1)	100 (0.8)	103 (0.4)
Day 5	3 (<0.1)	14 (0.1)	17 (<0.1)
Day 6	2 (<0.1)	2 (<0.1)	4 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Swelling (Hardness) - N1	13249	13283	26532
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (<0.1)	15 (0.1)	26 (<0.1)
Day 1, after Vaccination (at Home)	12 (<0.1)	425 (3.2)	437 (1.6)
Day 2	11 (<0.1)	852 (6.4)	863 (3.3)
Day 3	6 (<0.1)	274 (2.1)	280 (1.1)
Day 4	3 (<0.1)	61 (0.5)	64 (0.2)
Day 5	0	7 (<0.1)	7 (<0.1)
Day 6	2 (<0.1)	3 (<0.1)	5 (<0.1)
Day 7	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lymphadenopathy - N1 [1]	13249	13283	26532
Day 1, 30 Minutes after Vaccination (at Study Clinic)	53 (0.4)	67 (0.5)	120 (0.5)
Day 1, after Vaccination (at Home)	128 (1.0)	438 (3.3)	566 (2.1)
Day 2	137 (1.0)	785 (5.9)	922 (3.5)
Day 3	75 (0.6)	367 (2.8)	442 (1.7)
Day 4	44 (0.3)	139 (1.0)	183 (0.7)
Day 5	35 (0.3)	38 (0.3)	73 (0.3)
Day 6	15 (0.1)	19 (0.1)	34 (0.1)
Day 7	15 (0.1)	16 (0.1)	31 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Solicited Systemic Adverse Reactions - N1	13251	13286	26537
Day 1, 30 Minutes after Vaccination (at Study Clinic)	485 (3.7)	461 (3.5)	946 (3.6)
Day 1, after Vaccination (at Home)	1598 (12.1)	3750 (28.2)	5348 (20.2)
Day 2	1162 (8.8)	5820 (43.8)	6982 (26.3)
Day 3	561 (4.2)	340 (2.6)	901 (3.4)
Day 4	353 (2.7)	83 (0.6)	436 (1.6)
Day 5	273 (2.1)	39 (0.3)	312 (1.2)
Day 6	226 (1.7)	44 (0.3)	270 (1.0)
Day 7	175 (1.3)	31 (0.2)	206 (0.8)
Fever - N1	13247	13279	26526
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	182 (1.4)	187 (0.7)
Day 2	9 (<0.1)	1745 (13.1)	1754 (6.6)
Day 3	7 (<0.1)	153 (1.2)	160 (0.6)
Day 4	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 5	5 (<0.1)	4 (<0.1)	9 (<0.1)
Day 6	7 (<0.1)	2 (<0.1)	9 (<0.1)
Day 7	5 (<0.1)	3 (<0.1)	8 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Headache - N1	13249	13283	26532
Day 1, 30 Minutes after Vaccination (at Study Clinic)	239 (1.8)	240 (1.8)	479 (1.8)
Day 1, after Vaccination (at Home)	826 (6.2)	1919 (14.4)	2745 (10.3)
Day 2	713 (5.4)	4872 (36.7)	5585 (21.1)
Day 3	443 (3.3)	410 (3.1)	853 (3.2)
Day 4	294 (2.2)	141 (1.1)	435 (1.6)
Day 5	216 (1.6)	104 (0.8)	320 (1.2)
Day 6	193 (1.5)	87 (0.7)	280 (1.1)
Day 7	179 (1.4)	61 (0.5)	240 (0.9)
Fatigue - N1	13247	13283	26530
Day 1, 30 Minutes after Vaccination (at Study Clinic)	196 (1.5)	204 (1.5)	400 (1.5)
Day 1, after Vaccination (at Home)	1029 (7.8)	2590 (19.5)	3619 (13.6)
Day 2	808 (6.1)	5364 (40.4)	6172 (23.3)
Day 3	374 (2.8)	381 (2.9)	755 (2.8)
Day 4	226 (1.7)	73 (0.5)	299 (1.1)
Day 5	176 (1.3)	46 (0.3)	222 (0.8)
Day 6	159 (1.2)	35 (0.3)	194 (0.7)
Day 7	94 (0.7)	26 (0.2)	120 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Myalgia - N1	13248	13283	26531
Day 1, 30 Minutes after Vaccination (at Study Clinic)	97 (0.7)	87 (0.7)	184 (0.7)
Day 1, after Vaccination (at Home)	383 (2.9)	1779 (13.4)	2162 (8.1)
Day 2	442 (3.3)	5362 (40.4)	5804 (21.9)
Day 3	219 (1.7)	313 (2.4)	532 (2.0)
Day 4	154 (1.2)	60 (0.5)	214 (0.8)
Day 5	110 (0.8)	28 (0.2)	138 (0.5)
Day 6	108 (0.8)	27 (0.2)	135 (0.5)
Day 7	76 (0.6)	17 (0.1)	93 (0.4)
Arthralgia - N1	13247	13283	26530
Day 1, 30 Minutes after Vaccination (at Study Clinic)	104 (0.8)	99 (0.7)	203 (0.8)
Day 1, after Vaccination (at Home)	318 (2.4)	1192 (9.0)	1510 (5.7)
Day 2	342 (2.6)	3915 (29.5)	4257 (16.0)
Day 3	193 (1.5)	305 (2.3)	498 (1.9)
Day 4	158 (1.2)	76 (0.6)	234 (0.9)
Day 5	92 (0.7)	36 (0.3)	128 (0.5)
Day 6	103 (0.8)	36 (0.3)	139 (0.5)
Day 7	72 (0.5)	21 (0.2)	93 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Nausea/Vomiting - N1	13247	13283	26530
Day 1, 30 Minutes after Vaccination (at Study Clinic)	40 (0.3)	36 (0.3)	76 (0.3)
Day 1, after Vaccination (at Home)	198 (1.5)	433 (3.3)	631 (2.4)
Day 2	197 (1.5)	1609 (12.1)	1806 (6.8)
Day 3	121 (0.9)	234 (1.8)	355 (1.3)
Day 4	86 (0.6)	91 (0.7)	177 (0.7)
Day 5	66 (0.5)	46 (0.3)	112 (0.4)
Day 6	69 (0.5)	39 (0.3)	108 (0.4)
Day 7	64 (0.5)	30 (0.2)	94 (0.4)
Chills - N1	13247	13283	26530
Day 1, 30 Minutes after Vaccination (at Study Clinic)	52 (0.4)	42 (0.3)	94 (0.4)
Day 1, after Vaccination (at Home)	178 (1.3)	982 (7.4)	1160 (4.4)
Day 2	179 (1.4)	4407 (33.2)	4586 (17.3)
Day 3	93 (0.7)	324 (2.4)	417 (1.6)
Day 4	61 (0.5)	42 (0.3)	103 (0.4)
Day 5	58 (0.4)	14 (0.1)	72 (0.3)
Day 6	53 (0.4)	22 (0.2)	75 (0.3)
Day 7	38 (0.3)	17 (0.1)	55 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Any Solicited Adverse Reactions - N1	213	203	416
Day 1, 30 Minutes after Vaccination (at Study Clinic)	18 (8.5)	13 (6.4)	31 (7.5)
Day 1, after Vaccination (at Home)	23 (10.8)	97 (47.8)	120 (28.8)
Day 2	17 (8.0)	51 (25.1)	68 (16.3)
Day 3	5 (2.3)	2 (1.0)	7 (1.7)
Day 4	4 (1.9)	1 (0.5)	5 (1.2)
Day 5	3 (1.4)	0	3 (0.7)
Day 6	3 (1.4)	0	3 (0.7)
Day 7	1 (0.5)	0	1 (0.2)
Solicited Local Adverse Reactions - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	13 (6.1)	7 (3.4)	20 (4.8)
Day 1, after Vaccination (at Home)	13 (6.1)	93 (45.8)	106 (25.5)
Day 2	7 (3.3)	46 (22.7)	53 (12.8)
Day 3	1 (0.5)	3 (1.5)	4 (1.0)
Day 4	1 (0.5)	2 (1.0)	3 (0.7)
Day 5	1 (0.5)	0	1 (0.2)
Day 6	1 (0.5)	0	1 (0.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Pain - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	13 (6.1)	7 (3.4)	20 (4.8)
Day 1, after Vaccination (at Home)	12 (5.7)	92 (45.3)	104 (25.1)
Day 2	4 (1.9)	46 (22.7)	50 (12.0)
Day 3	0	2 (1.0)	2 (0.5)
Day 4	1 (0.5)	1 (0.5)	2 (0.5)
Day 5	1 (0.5)	0	1 (0.2)
Day 6	0	0	0
Day 7	0	0	0
Erythema (Redness) - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	3 (1.5)	3 (0.7)
Day 3	1 (0.5)	2 (1.0)	3 (0.7)
Day 4	0	3 (1.5)	3 (0.7)
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Swelling (Hardness) - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	3 (1.5)	3 (0.7)
Day 2	0	3 (1.5)	3 (0.7)
Day 3	0	2 (1.0)	2 (0.5)
Day 4	0	1 (0.5)	1 (0.2)
Day 5	1 (0.5)	1 (0.5)	2 (0.5)
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	2 (0.9)	10 (4.9)	12 (2.9)
Day 2	5 (2.4)	9 (4.4)	14 (3.4)
Day 3	1 (0.5)	3 (1.5)	4 (1.0)
Day 4	0	5 (2.5)	5 (1.2)
Day 5	0	0	0
Day 6	2 (0.9)	0	2 (0.5)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Solicited Systemic Adverse Reactions - N1	213	203	416
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (3.8)	7 (3.4)	15 (3.6)
Day 1, after Vaccination (at Home)	19 (8.9)	56 (27.6)	75 (18.0)
Day 2	21 (9.9)	65 (32.0)	86 (20.7)
Day 3	7 (3.3)	2 (1.0)	9 (2.2)
Day 4	4 (1.9)	2 (1.0)	6 (1.4)
Day 5	3 (1.4)	1 (0.5)	4 (1.0)
Day 6	3 (1.4)	2 (1.0)	5 (1.2)
Day 7	1 (0.5)	0	1 (0.2)
Fever - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.5)	1 (0.2)
Day 1, after Vaccination (at Home)	0	3 (1.5)	3 (0.7)
Day 2	0	20 (9.9)	20 (4.8)
Day 3	0	2 (1.0)	2 (0.5)
Day 4	0	1 (0.5)	1 (0.2)
Day 5	0	0	0
Day 6	1 (0.5)	0	1 (0.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Headache - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (1.9)	2 (1.0)	6 (1.4)
Day 1, after Vaccination (at Home)	10 (4.7)	28 (13.8)	38 (9.2)
Day 2	9 (4.2)	50 (24.6)	59 (14.2)
Day 3	6 (2.8)	2 (1.0)	8 (1.9)
Day 4	3 (1.4)	2 (1.0)	5 (1.2)
Day 5	3 (1.4)	1 (0.5)	4 (1.0)
Day 6	3 (1.4)	3 (1.5)	6 (1.4)
Day 7	2 (0.9)	0	2 (0.5)
Fatigue - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (2.4)	4 (2.0)	9 (2.2)
Day 1, after Vaccination (at Home)	14 (6.6)	30 (14.8)	44 (10.6)
Day 2	11 (5.2)	55 (27.1)	66 (15.9)
Day 3	8 (3.8)	3 (1.5)	11 (2.7)
Day 4	6 (2.8)	0	6 (1.4)
Day 5	4 (1.9)	0	4 (1.0)
Day 6	1 (0.5)	0	1 (0.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Myalgia - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (1.0)	2 (0.5)
Day 1, after Vaccination (at Home)	7 (3.3)	29 (14.3)	36 (8.7)
Day 2	8 (3.8)	65 (32.0)	73 (17.6)
Day 3	3 (1.4)	2 (1.0)	5 (1.2)
Day 4	5 (2.4)	1 (0.5)	6 (1.4)
Day 5	2 (0.9)	0	2 (0.5)
Day 6	1 (0.5)	2 (1.0)	3 (0.7)
Day 7	3 (1.4)	0	3 (0.7)
Arthralgia - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.5)	3 (1.5)	4 (1.0)
Day 1, after Vaccination (at Home)	6 (2.8)	17 (8.4)	23 (5.5)
Day 2	6 (2.8)	40 (19.7)	46 (11.1)
Day 3	3 (1.4)	4 (2.0)	7 (1.7)
Day 4	3 (1.4)	0	3 (0.7)
Day 5	0	0	0
Day 6	1 (0.5)	2 (1.0)	3 (0.7)
Day 7	1 (0.5)	0	1 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Nausea/Vomiting - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	11 (5.4)	11 (2.7)
Day 2	2 (0.9)	16 (7.9)	18 (4.3)
Day 3	3 (1.4)	3 (1.5)	6 (1.4)
Day 4	4 (1.9)	1 (0.5)	5 (1.2)
Day 5	0	0	0
Day 6	1 (0.5)	1 (0.5)	2 (0.5)
Day 7	1 (0.5)	0	1 (0.2)
Chills - N1	212	203	415
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.5)	0	1 (0.2)
Day 1, after Vaccination (at Home)	3 (1.4)	16 (7.9)	19 (4.6)
Day 2	2 (0.9)	48 (23.6)	50 (12.0)
Day 3	2 (0.9)	3 (1.5)	5 (1.2)
Day 4	2 (0.9)	1 (0.5)	3 (0.7)
Day 5	2 (0.9)	0	2 (0.5)
Day 6	0	1 (0.5)	1 (0.2)
Day 7	2 (0.9)	0	2 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Any Solicited Adverse Reactions - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	57 (14.1)	56 (12.2)	113 (13.1)
Day 1, after Vaccination (at Home)	52 (12.8)	246 (53.7)	298 (34.5)
Day 2	32 (7.9)	115 (25.1)	147 (17.0)
Day 3	20 (4.9)	4 (0.9)	24 (2.8)
Day 4	12 (3.0)	1 (0.2)	13 (1.5)
Day 5	12 (3.0)	0	12 (1.4)
Day 6	6 (1.5)	0	6 (0.7)
Day 7	3 (0.7)	0	3 (0.3)
Solicited Local Adverse Reactions - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	47 (11.6)	43 (9.4)	90 (10.4)
Day 1, after Vaccination (at Home)	26 (6.4)	241 (52.6)	267 (30.9)
Day 2	10 (2.5)	122 (26.6)	132 (15.3)
Day 3	7 (1.7)	3 (0.7)	10 (1.2)
Day 4	0	0	0
Day 5	5 (1.2)	0	5 (0.6)
Day 6	2 (0.5)	0	2 (0.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Pain - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	47 (11.6)	41 (9.0)	88 (10.2)
Day 1, after Vaccination (at Home)	23 (5.7)	240 (52.4)	263 (30.5)
Day 2	10 (2.5)	123 (26.9)	133 (15.4)
Day 3	5 (1.2)	3 (0.7)	8 (0.9)
Day 4	0	0	0
Day 5	3 (0.7)	0	3 (0.3)
Day 6	2 (0.5)	0	2 (0.2)
Day 7	0	0	0
Erythema (Redness) - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.2)	0	1 (0.1)
Day 1, after Vaccination (at Home)	1 (0.2)	4 (0.9)	5 (0.6)
Day 2	0	11 (2.4)	11 (1.3)
Day 3	0	12 (2.6)	12 (1.4)
Day 4	0	6 (1.3)	6 (0.7)
Day 5	0	0	0
Day 6	1 (0.2)	0	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Swelling (Hardness) - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	14 (3.1)	14 (1.6)
Day 2	0	25 (5.5)	25 (2.9)
Day 3	0	5 (1.1)	5 (0.6)
Day 4	0	1 (0.2)	1 (0.1)
Day 5	0	1 (0.2)	1 (0.1)
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (1.2)	3 (0.7)	8 (0.9)
Day 1, after Vaccination (at Home)	5 (1.2)	16 (3.5)	21 (2.4)
Day 2	2 (0.5)	31 (6.8)	33 (3.8)
Day 3	5 (1.2)	8 (1.7)	13 (1.5)
Day 4	2 (0.5)	2 (0.4)	4 (0.5)
Day 5	3 (0.7)	0	3 (0.3)
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Solicited Systemic Adverse Reactions - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	22 (5.4)	23 (5.0)	45 (5.2)
Day 1, after Vaccination (at Home)	52 (12.8)	122 (26.6)	174 (20.2)
Day 2	34 (8.4)	193 (42.1)	227 (26.3)
Day 3	20 (4.9)	12 (2.6)	32 (3.7)
Day 4	16 (4.0)	7 (1.5)	23 (2.7)
Day 5	15 (3.7)	2 (0.4)	17 (2.0)
Day 6	6 (1.5)	2 (0.4)	8 (0.9)
Day 7	5 (1.2)	0	5 (0.6)
Fever - N1	405	457	862
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	7 (1.5)	7 (0.8)
Day 2	0	41 (9.0)	41 (4.8)
Day 3	0	4 (0.9)	4 (0.5)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Headache - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (3.0)	10 (2.2)	22 (2.5)
Day 1, after Vaccination (at Home)	29 (7.2)	64 (14.0)	93 (10.8)
Day 2	22 (5.4)	146 (31.9)	168 (19.5)
Day 3	15 (3.7)	11 (2.4)	26 (3.0)
Day 4	13 (3.2)	8 (1.7)	21 (2.4)
Day 5	8 (2.0)	3 (0.7)	11 (1.3)
Day 6	5 (1.2)	1 (0.2)	6 (0.7)
Day 7	5 (1.2)	0	5 (0.6)
Fatigue - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (1.7)	11 (2.4)	18 (2.1)
Day 1, after Vaccination (at Home)	41 (10.1)	81 (17.7)	122 (14.1)
Day 2	31 (7.7)	167 (36.5)	198 (22.9)
Day 3	9 (2.2)	12 (2.6)	21 (2.4)
Day 4	4 (1.0)	9 (2.0)	13 (1.5)
Day 5	13 (3.2)	2 (0.4)	15 (1.7)
Day 6	7 (1.7)	2 (0.4)	9 (1.0)
Day 7	2 (0.5)	1 (0.2)	3 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Myalgia - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (1.2)	4 (0.9)	9 (1.0)
Day 1, after Vaccination (at Home)	18 (4.4)	66 (14.4)	84 (9.7)
Day 2	25 (6.2)	176 (38.4)	201 (23.3)
Day 3	15 (3.7)	11 (2.4)	26 (3.0)
Day 4	6 (1.5)	3 (0.7)	9 (1.0)
Day 5	5 (1.2)	0	5 (0.6)
Day 6	2 (0.5)	1 (0.2)	3 (0.3)
Day 7	3 (0.7)	1 (0.2)	4 (0.5)
Arthralgia - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (0.7)	5 (1.1)	8 (0.9)
Day 1, after Vaccination (at Home)	16 (4.0)	45 (9.8)	61 (7.1)
Day 2	20 (4.9)	132 (28.8)	152 (17.6)
Day 3	12 (3.0)	7 (1.5)	19 (2.2)
Day 4	7 (1.7)	1 (0.2)	8 (0.9)
Day 5	3 (0.7)	0	3 (0.3)
Day 6	4 (1.0)	1 (0.2)	5 (0.6)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.8
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Nausea/Vomiting - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.2)	1 (0.1)
Day 1, after Vaccination (at Home)	5 (1.2)	13 (2.8)	18 (2.1)
Day 2	12 (3.0)	57 (12.4)	69 (8.0)
Day 3	4 (1.0)	7 (1.5)	11 (1.3)
Day 4	3 (0.7)	2 (0.4)	5 (0.6)
Day 5	3 (0.7)	1 (0.2)	4 (0.5)
Day 6	3 (0.7)	3 (0.7)	6 (0.7)
Day 7	1 (0.2)	0	1 (0.1)
Chills - N1	405	458	863
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.5)	3 (0.7)	5 (0.6)
Day 1, after Vaccination (at Home)	5 (1.2)	33 (7.2)	38 (4.4)
Day 2	10 (2.5)	138 (30.1)	148 (17.1)
Day 3	1 (0.2)	6 (1.3)	7 (0.8)
Day 4	4 (1.0)	1 (0.2)	5 (0.6)
Day 5	4 (1.0)	0	4 (0.5)
Day 6	1 (0.2)	0	1 (0.1)
Day 7	2 (0.5)	0	2 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Any Solicited Adverse Reactions - N1	14363	14309	28672
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2500 (17.4)	2435 (17.0)	4935 (17.2)
Day 1, after Vaccination (at Home)	2686 (18.7)	8315 (58.1)	11001 (38.4)
Day 2	1593 (11.1)	2638 (18.4)	4231 (14.8)
Day 3	706 (4.9)	104 (0.7)	810 (2.8)
Day 4	423 (2.9)	20 (0.1)	443 (1.5)
Day 5	294 (2.0)	21 (0.1)	315 (1.1)
Day 6	209 (1.5)	17 (0.1)	226 (0.8)
Day 7	165 (1.1)	16 (0.1)	181 (0.6)
Solicited Local Adverse Reactions - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1880 (13.1)	1847 (12.9)	3727 (13.0)
Day 1, after Vaccination (at Home)	1072 (7.5)	8290 (57.9)	9362 (32.7)
Day 2	627 (4.4)	2927 (20.5)	3554 (12.4)
Day 3	248 (1.7)	111 (0.8)	359 (1.3)
Day 4	135 (0.9)	12 (<0.1)	147 (0.5)
Day 5	88 (0.6)	10 (<0.1)	98 (0.3)
Day 6	54 (0.4)	9 (<0.1)	63 (0.2)
Day 7	43 (0.3)	5 (<0.1)	48 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Pain - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1819 (12.7)	1777 (12.4)	3596 (12.5)
Day 1, after Vaccination (at Home)	995 (6.9)	8296 (58.0)	9291 (32.4)
Day 2	532 (3.7)	2954 (20.6)	3486 (12.2)
Day 3	193 (1.3)	105 (0.7)	298 (1.0)
Day 4	94 (0.7)	9 (<0.1)	103 (0.4)
Day 5	60 (0.4)	5 (<0.1)	65 (0.2)
Day 6	41 (0.3)	6 (<0.1)	47 (0.2)
Day 7	28 (0.2)	4 (<0.1)	32 (0.1)
Erythema (Redness) - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	35 (0.2)	148 (1.0)	183 (0.6)
Day 2	23 (0.2)	618 (4.3)	641 (2.2)
Day 3	17 (0.1)	501 (3.5)	518 (1.8)
Day 4	7 (<0.1)	105 (0.7)	112 (0.4)
Day 5	8 (<0.1)	17 (0.1)	25 (<0.1)
Day 6	4 (<0.1)	5 (<0.1)	9 (<0.1)
Day 7	2 (<0.1)	3 (<0.1)	5 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Swelling (Hardness) - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	20 (0.1)	28 (0.2)	48 (0.2)
Day 1, after Vaccination (at Home)	20 (0.1)	542 (3.8)	562 (2.0)
Day 2	27 (0.2)	1144 (8.0)	1171 (4.1)
Day 3	9 (<0.1)	300 (2.1)	309 (1.1)
Day 4	5 (<0.1)	65 (0.5)	70 (0.2)
Day 5	4 (<0.1)	8 (<0.1)	12 (<0.1)
Day 6	2 (<0.1)	4 (<0.1)	6 (<0.1)
Day 7	4 (<0.1)	5 (<0.1)	9 (<0.1)
Lymphadenopathy - N1 [1]	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	141 (1.0)	155 (1.1)	296 (1.0)
Day 1, after Vaccination (at Home)	238 (1.7)	709 (5.0)	947 (3.3)
Day 2	248 (1.7)	1020 (7.1)	1268 (4.4)
Day 3	132 (0.9)	467 (3.3)	599 (2.1)
Day 4	86 (0.6)	178 (1.2)	264 (0.9)
Day 5	78 (0.5)	62 (0.4)	140 (0.5)
Day 6	49 (0.3)	67 (0.5)	116 (0.4)
Day 7	38 (0.3)	96 (0.7)	134 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Solicited Systemic Adverse Reactions - N1	14363	14309	28672
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1022 (7.1)	970 (6.8)	1992 (6.9)
Day 1, after Vaccination (at Home)	2751 (19.2)	4858 (34.0)	7609 (26.5)
Day 2	1781 (12.4)	5317 (37.2)	7098 (24.8)
Day 3	805 (5.6)	416 (2.9)	1221 (4.3)
Day 4	453 (3.2)	122 (0.9)	575 (2.0)
Day 5	341 (2.4)	86 (0.6)	427 (1.5)
Day 6	272 (1.9)	68 (0.5)	340 (1.2)
Day 7	203 (1.4)	56 (0.4)	259 (0.9)
Fever - N1	14363	14309	28672
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 1, after Vaccination (at Home)	9 (<0.1)	193 (1.3)	202 (0.7)
Day 2	14 (<0.1)	1765 (12.3)	1779 (6.2)
Day 3	12 (<0.1)	163 (1.1)	175 (0.6)
Day 4	9 (<0.1)	4 (<0.1)	13 (<0.1)
Day 5	12 (<0.1)	10 (<0.1)	22 (<0.1)
Day 6	11 (<0.1)	3 (<0.1)	14 (<0.1)
Day 7	9 (<0.1)	5 (<0.1)	14 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Headache - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	541 (3.8)	545 (3.8)	1086 (3.8)
Day 1, after Vaccination (at Home)	1496 (10.4)	2654 (18.5)	4150 (14.5)
Day 2	1264 (8.8)	4778 (33.4)	6042 (21.1)
Day 3	691 (4.8)	511 (3.6)	1202 (4.2)
Day 4	418 (2.9)	206 (1.4)	624 (2.2)
Day 5	311 (2.2)	151 (1.1)	462 (1.6)
Day 6	277 (1.9)	142 (1.0)	419 (1.5)
Day 7	238 (1.7)	112 (0.8)	350 (1.2)
Fatigue - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	389 (2.7)	400 (2.8)	789 (2.8)
Day 1, after Vaccination (at Home)	1923 (13.4)	3511 (24.5)	5434 (19.0)
Day 2	1310 (9.1)	5192 (36.3)	6502 (22.7)
Day 3	606 (4.2)	461 (3.2)	1067 (3.7)
Day 4	332 (2.3)	119 (0.8)	451 (1.6)
Day 5	244 (1.7)	76 (0.5)	320 (1.1)
Day 6	232 (1.6)	74 (0.5)	306 (1.1)
Day 7	142 (1.0)	57 (0.4)	199 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Myalgia - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	199 (1.4)	197 (1.4)	396 (1.4)
Day 1, after Vaccination (at Home)	703 (4.9)	2298 (16.1)	3001 (10.5)
Day 2	805 (5.6)	5412 (37.8)	6217 (21.7)
Day 3	391 (2.7)	406 (2.8)	797 (2.8)
Day 4	280 (1.9)	103 (0.7)	383 (1.3)
Day 5	186 (1.3)	53 (0.4)	239 (0.8)
Day 6	166 (1.2)	58 (0.4)	224 (0.8)
Day 7	136 (0.9)	34 (0.2)	170 (0.6)
Arthralgia - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	188 (1.3)	188 (1.3)	376 (1.3)
Day 1, after Vaccination (at Home)	546 (3.8)	1506 (10.5)	2052 (7.2)
Day 2	657 (4.6)	4007 (28.0)	4664 (16.3)
Day 3	358 (2.5)	437 (3.1)	795 (2.8)
Day 4	253 (1.8)	133 (0.9)	386 (1.3)
Day 5	168 (1.2)	68 (0.5)	236 (0.8)
Day 6	169 (1.2)	66 (0.5)	235 (0.8)
Day 7	112 (0.8)	54 (0.4)	166 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Nausea/Vomiting - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	84 (0.6)	73 (0.5)	157 (0.5)
Day 1, after Vaccination (at Home)	328 (2.3)	600 (4.2)	928 (3.2)
Day 2	384 (2.7)	1766 (12.3)	2150 (7.5)
Day 3	234 (1.6)	347 (2.4)	581 (2.0)
Day 4	172 (1.2)	164 (1.1)	336 (1.2)
Day 5	137 (1.0)	82 (0.6)	219 (0.8)
Day 6	138 (1.0)	84 (0.6)	222 (0.8)
Day 7	115 (0.8)	68 (0.5)	183 (0.6)
Chills - N1	14362	14309	28671
Day 1, 30 Minutes after Vaccination (at Study Clinic)	127 (0.9)	106 (0.7)	233 (0.8)
Day 1, after Vaccination (at Home)	331 (2.3)	1149 (8.0)	1480 (5.2)
Day 2	316 (2.2)	4423 (30.9)	4739 (16.5)
Day 3	189 (1.3)	399 (2.8)	588 (2.1)
Day 4	113 (0.8)	70 (0.5)	183 (0.6)
Day 5	113 (0.8)	40 (0.3)	153 (0.5)
Day 6	90 (0.6)	39 (0.3)	129 (0.4)
Day 7	69 (0.5)	36 (0.3)	105 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Any Solicited Adverse Reactions - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	39 (11.7)	38 (11.2)	77 (11.4)
Day 1, after Vaccination (at Home)	42 (12.6)	153 (45.0)	195 (28.9)
Day 2	33 (9.9)	81 (23.8)	114 (16.9)
Day 3	14 (4.2)	5 (1.5)	19 (2.8)
Day 4	9 (2.7)	1 (0.3)	10 (1.5)
Day 5	3 (0.9)	0	3 (0.4)
Day 6	2 (0.6)	0	2 (0.3)
Day 7	9 (2.7)	1 (0.3)	10 (1.5)
Solicited Local Adverse Reactions - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	27 (8.1)	22 (6.5)	49 (7.3)
Day 1, after Vaccination (at Home)	22 (6.6)	149 (43.8)	171 (25.4)
Day 2	12 (3.6)	85 (25.0)	97 (14.4)
Day 3	5 (1.5)	7 (2.1)	12 (1.8)
Day 4	3 (0.9)	3 (0.9)	6 (0.9)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	1 (0.3)	0	1 (0.1)
Day 7	2 (0.6)	1 (0.3)	3 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Pain - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	27 (8.1)	22 (6.5)	49 (7.3)
Day 1, after Vaccination (at Home)	20 (6.0)	149 (43.8)	169 (25.1)
Day 2	9 (2.7)	85 (25.0)	94 (13.9)
Day 3	4 (1.2)	6 (1.8)	10 (1.5)
Day 4	2 (0.6)	2 (0.6)	4 (0.6)
Day 5	3 (0.9)	0	3 (0.4)
Day 6	0	0	0
Day 7	2 (0.6)	1 (0.3)	3 (0.4)
Erythema (Redness) - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (0.3)	1 (0.1)
Day 2	1 (0.3)	5 (1.5)	6 (0.9)
Day 3	2 (0.6)	4 (1.2)	6 (0.9)
Day 4	1 (0.3)	4 (1.2)	5 (0.7)
Day 5	0	1 (0.3)	1 (0.1)
Day 6	0	1 (0.3)	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Swelling (Hardness) - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	1 (0.3)	6 (1.8)	7 (1.0)
Day 2	1 (0.3)	14 (4.1)	15 (2.2)
Day 3	0	2 (0.6)	2 (0.3)
Day 4	0	1 (0.3)	1 (0.1)
Day 5	1 (0.3)	2 (0.6)	3 (0.4)
Day 6	0	1 (0.3)	1 (0.1)
Day 7	0	0	0
Lymphadenopathy - N1 [1]	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (0.6)	2 (0.3)
Day 1, after Vaccination (at Home)	4 (1.2)	15 (4.4)	19 (2.8)
Day 2	5 (1.5)	25 (7.4)	30 (4.5)
Day 3	4 (1.2)	13 (3.8)	17 (2.5)
Day 4	0	9 (2.6)	9 (1.3)
Day 5	3 (0.9)	2 (0.6)	5 (0.7)
Day 6	2 (0.6)	0	2 (0.3)
Day 7	2 (0.6)	1 (0.3)	3 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Solicited Systemic Adverse Reactions - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	17 (5.1)	22 (6.5)	39 (5.8)
Day 1, after Vaccination (at Home)	39 (11.7)	90 (26.5)	129 (19.1)
Day 2	38 (11.4)	109 (32.1)	147 (21.8)
Day 3	17 (5.1)	8 (2.4)	25 (3.7)
Day 4	11 (3.3)	5 (1.5)	16 (2.4)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	3 (0.9)	1 (0.3)	4 (0.6)
Day 7	10 (3.0)	1 (0.3)	11 (1.6)
Fever - N1	333	340	673
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (0.6)	2 (0.3)
Day 1, after Vaccination (at Home)	0	4 (1.2)	4 (0.6)
Day 2	1 (0.3)	38 (11.2)	39 (5.8)
Day 3	3 (0.9)	4 (1.2)	7 (1.0)
Day 4	0	3 (0.9)	3 (0.4)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	1 (0.3)	0	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Headache - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (2.7)	8 (2.4)	17 (2.5)
Day 1, after Vaccination (at Home)	20 (6.0)	52 (15.3)	72 (10.7)
Day 2	26 (7.8)	78 (22.9)	104 (15.4)
Day 3	12 (3.6)	8 (2.4)	20 (3.0)
Day 4	9 (2.7)	6 (1.8)	15 (2.2)
Day 5	6 (1.8)	5 (1.5)	11 (1.6)
Day 6	4 (1.2)	3 (0.9)	7 (1.0)
Day 7	9 (2.7)	1 (0.3)	10 (1.5)
Fatigue - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (2.1)	12 (3.5)	19 (2.8)
Day 1, after Vaccination (at Home)	25 (7.5)	51 (15.0)	76 (11.3)
Day 2	24 (7.2)	87 (25.6)	111 (16.5)
Day 3	17 (5.1)	9 (2.6)	26 (3.9)
Day 4	9 (2.7)	1 (0.3)	10 (1.5)
Day 5	5 (1.5)	2 (0.6)	7 (1.0)
Day 6	2 (0.6)	1 (0.3)	3 (0.4)
Day 7	4 (1.2)	2 (0.6)	6 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Myalgia - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	4 (1.2)	5 (0.7)
Day 1, after Vaccination (at Home)	11 (3.3)	51 (15.0)	62 (9.2)
Day 2	20 (6.0)	100 (29.4)	120 (17.8)
Day 3	7 (2.1)	10 (2.9)	17 (2.5)
Day 4	10 (3.0)	3 (0.9)	13 (1.9)
Day 5	4 (1.2)	1 (0.3)	5 (0.7)
Day 6	2 (0.6)	2 (0.6)	4 (0.6)
Day 7	6 (1.8)	2 (0.6)	8 (1.2)
Arthralgia - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.6)	6 (1.8)	8 (1.2)
Day 1, after Vaccination (at Home)	9 (2.7)	34 (10.0)	43 (6.4)
Day 2	16 (4.8)	66 (19.4)	82 (12.2)
Day 3	8 (2.4)	11 (3.2)	19 (2.8)
Day 4	6 (1.8)	2 (0.6)	8 (1.2)
Day 5	0	2 (0.6)	2 (0.3)
Day 6	2 (0.6)	1 (0.3)	3 (0.4)
Day 7	7 (2.1)	1 (0.3)	8 (1.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Nausea/Vomiting - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	4 (1.2)	14 (4.1)	18 (2.7)
Day 2	6 (1.8)	30 (8.8)	36 (5.3)
Day 3	6 (1.8)	9 (2.6)	15 (2.2)
Day 4	4 (1.2)	4 (1.2)	8 (1.2)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	4 (1.2)	1 (0.3)	5 (0.7)
Day 7	6 (1.8)	2 (0.6)	8 (1.2)
Chills - N1	334	340	674
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.6)	2 (0.6)	4 (0.6)
Day 1, after Vaccination (at Home)	7 (2.1)	26 (7.6)	33 (4.9)
Day 2	9 (2.7)	78 (22.9)	87 (12.9)
Day 3	7 (2.1)	9 (2.6)	16 (2.4)
Day 4	4 (1.2)	1 (0.3)	5 (0.7)
Day 5	3 (0.9)	1 (0.3)	4 (0.6)
Day 6	0	1 (0.3)	1 (0.1)
Day 7	4 (1.2)	1 (0.3)	5 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Any Solicited Adverse Reactions - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	100 (21.5)	100 (19.0)	200 (20.1)
Day 1, after Vaccination (at Home)	87 (18.7)	296 (56.2)	383 (38.6)
Day 2	60 (12.9)	89 (16.9)	149 (15.0)
Day 3	20 (4.3)	6 (1.1)	26 (2.6)
Day 4	8 (1.7)	0	8 (0.8)
Day 5	16 (3.4)	1 (0.2)	17 (1.7)
Day 6	5 (1.1)	0	5 (0.5)
Day 7	4 (0.9)	1 (0.2)	5 (0.5)
Solicited Local Adverse Reactions - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	77 (16.6)	72 (13.7)	149 (15.0)
Day 1, after Vaccination (at Home)	38 (8.2)	296 (56.2)	334 (33.6)
Day 2	23 (4.9)	107 (20.3)	130 (13.1)
Day 3	9 (1.9)	7 (1.3)	16 (1.6)
Day 4	3 (0.6)	0	3 (0.3)
Day 5	6 (1.3)	0	6 (0.6)
Day 6	4 (0.9)	0	4 (0.4)
Day 7	0	1 (0.2)	1 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Pain - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	76 (16.3)	69 (13.1)	145 (14.6)
Day 1, after Vaccination (at Home)	35 (7.5)	296 (56.2)	331 (33.3)
Day 2	20 (4.3)	109 (20.7)	129 (13.0)
Day 3	6 (1.3)	6 (1.1)	12 (1.2)
Day 4	2 (0.4)	0	2 (0.2)
Day 5	5 (1.1)	0	5 (0.5)
Day 6	2 (0.4)	0	2 (0.2)
Day 7	0	0	0
Erythema (Redness) - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.2)	1 (0.2)	2 (0.2)
Day 1, after Vaccination (at Home)	1 (0.2)	5 (0.9)	6 (0.6)
Day 2	1 (0.2)	17 (3.2)	18 (1.8)
Day 3	0	15 (2.8)	15 (1.5)
Day 4	0	6 (1.1)	6 (0.6)
Day 5	0	0	0
Day 6	2 (0.4)	0	2 (0.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Swelling (Hardness) - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	18 (3.4)	18 (1.8)
Day 2	1 (0.2)	31 (5.9)	32 (3.2)
Day 3	0	9 (1.7)	9 (0.9)
Day 4	0	2 (0.4)	2 (0.2)
Day 5	0	1 (0.2)	1 (0.1)
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (1.9)	6 (1.1)	15 (1.5)
Day 1, after Vaccination (at Home)	9 (1.9)	25 (4.7)	34 (3.4)
Day 2	4 (0.9)	44 (8.3)	48 (4.8)
Day 3	11 (2.4)	7 (1.3)	18 (1.8)
Day 4	4 (0.9)	5 (0.9)	9 (0.9)
Day 5	2 (0.4)	3 (0.6)	5 (0.5)
Day 6	4 (0.9)	1 (0.2)	5 (0.5)
Day 7	1 (0.2)	2 (0.4)	3 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9

Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Solicited Systemic Adverse Reactions - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	46 (9.9)	47 (8.9)	93 (9.4)
Day 1, after Vaccination (at Home)	91 (19.6)	160 (30.4)	251 (25.3)
Day 2	65 (14.0)	190 (36.1)	255 (25.7)
Day 3	25 (5.4)	13 (2.5)	38 (3.8)
Day 4	13 (2.8)	6 (1.1)	19 (1.9)
Day 5	18 (3.9)	4 (0.8)	22 (2.2)
Day 6	4 (0.9)	2 (0.4)	6 (0.6)
Day 7	5 (1.1)	1 (0.2)	6 (0.6)
Fever - N1	465	526	992
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.2)	0	1 (0.1)
Day 1, after Vaccination (at Home)	0	8 (1.5)	8 (0.8)
Day 2	0	42 (8.0)	42 (4.2)
Day 3	0	5 (1.0)	5 (0.5)
Day 4	0	0	0
Day 5	1 (0.2)	0	1 (0.1)
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Headache - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	28 (6.0)	23 (4.4)	51 (5.1)
Day 1, after Vaccination (at Home)	50 (10.8)	93 (17.6)	143 (14.4)
Day 2	40 (8.6)	147 (27.9)	187 (18.8)
Day 3	26 (5.6)	21 (4.0)	47 (4.7)
Day 4	17 (3.7)	8 (1.5)	25 (2.5)
Day 5	16 (3.4)	4 (0.8)	20 (2.0)
Day 6	9 (1.9)	8 (1.5)	17 (1.7)
Day 7	10 (2.2)	2 (0.4)	12 (1.2)
Fatigue - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	16 (3.4)	20 (3.8)	36 (3.6)
Day 1, after Vaccination (at Home)	69 (14.8)	108 (20.5)	177 (17.8)
Day 2	53 (11.4)	175 (33.2)	228 (23.0)
Day 3	18 (3.9)	12 (2.3)	30 (3.0)
Day 4	8 (1.7)	11 (2.1)	19 (1.9)
Day 5	22 (4.7)	5 (0.9)	27 (2.7)
Day 6	9 (1.9)	4 (0.8)	13 (1.3)
Day 7	4 (0.9)	3 (0.6)	7 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Myalgia - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	15 (3.2)	6 (1.1)	21 (2.1)
Day 1, after Vaccination (at Home)	34 (7.3)	84 (15.9)	118 (11.9)
Day 2	29 (6.2)	185 (35.1)	214 (21.6)
Day 3	18 (3.9)	14 (2.7)	32 (3.2)
Day 4	10 (2.2)	5 (0.9)	15 (1.5)
Day 5	8 (1.7)	3 (0.6)	11 (1.1)
Day 6	7 (1.5)	4 (0.8)	11 (1.1)
Day 7	4 (0.9)	4 (0.8)	8 (0.8)
Arthralgia - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (2.4)	7 (1.3)	18 (1.8)
Day 1, after Vaccination (at Home)	23 (4.9)	54 (10.2)	77 (7.8)
Day 2	31 (6.7)	136 (25.8)	167 (16.8)
Day 3	19 (4.1)	10 (1.9)	29 (2.9)
Day 4	11 (2.4)	6 (1.1)	17 (1.7)
Day 5	4 (0.9)	4 (0.8)	8 (0.8)
Day 6	5 (1.1)	3 (0.6)	8 (0.8)
Day 7	1 (0.2)	1 (0.2)	2 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.9
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Nausea/Vomiting - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.4)	3 (0.6)	5 (0.5)
Day 1, after Vaccination (at Home)	10 (2.2)	17 (3.2)	27 (2.7)
Day 2	18 (3.9)	67 (12.7)	85 (8.6)
Day 3	4 (0.9)	12 (2.3)	16 (1.6)
Day 4	6 (1.3)	6 (1.1)	12 (1.2)
Day 5	4 (0.9)	7 (1.3)	11 (1.1)
Day 6	6 (1.3)	5 (0.9)	11 (1.1)
Day 7	3 (0.6)	3 (0.6)	6 (0.6)
Chills - N1	465	527	993
Day 1, 30 Minutes after Vaccination (at Study Clinic)	6 (1.3)	7 (1.3)	13 (1.3)
Day 1, after Vaccination (at Home)	11 (2.4)	42 (8.0)	53 (5.3)
Day 2	14 (3.0)	138 (26.2)	152 (15.3)
Day 3	1 (0.2)	9 (1.7)	10 (1.0)
Day 4	6 (1.3)	1 (0.2)	7 (0.7)
Day 5	6 (1.3)	1 (0.2)	7 (0.7)
Day 6	5 (1.1)	0	5 (0.5)
Day 7	6 (1.3)	1 (0.2)	7 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11406)	mRNA-1273 (N=11405)	Total (N=22812)
Solicited Adverse Reactions			
n	5736	10262	15998
Mean (SD)	3.1 (3.58)	3.5 (3.09)	3.3 (3.28)
Median	2.0	3.0	3.0
Min, Max	1, 60	1, 43	1, 60
Solicited Local Adverse Reactions			
n	2432	9960	12392
Mean (SD)	1.9 (2.16)	2.7 (1.94)	2.5 (2.01)
Median	1.0	2.0	2.0
Min, Max	1, 34	1, 35	1, 35
Pain			
n	2179	9908	12087
Mean (SD)	1.6 (1.77)	2.5 (1.49)	2.4 (1.58)
Median	1.0	2.0	2.0
Min, Max	1, 34	1, 35	1, 35
Erythema (Redness)			
n	46	345	391
Mean (SD)	1.8 (2.44)	2.3 (2.75)	2.2 (2.71)
Median	1.0	2.0	1.0
Min, Max	1, 13	1, 29	1, 29

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11406)	mRNA-1273 (N=11405)	Total (N=22812)
Swelling (Hardness)			
n	33	768	801
Mean (SD)	3.0 (4.82)	2.1 (2.03)	2.1 (2.21)
Median	1.0	2.0	2.0
Min, Max	1, 27	1, 25	1, 27
Lymphadenopathy [1]			
n	567	1322	1889
Mean (SD)	2.2 (2.89)	2.3 (2.86)	2.3 (2.87)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 31	1, 33
Solicited Systemic Adverse Reactions			
n	5063	6503	11566
Mean (SD)	3.0 (3.62)	2.9 (3.37)	3.0 (3.48)
Median	2.0	2.0	2.0
Min, Max	1, 59	1, 43	1, 59
Fever			
n	39	105	144
Mean (SD)	1.4 (0.59)	1.3 (0.73)	1.3 (0.69)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 6	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11406)	mRNA-1273 (N=11405)	Total (N=22812)
Headache			
n	3303	4031	7334
Mean (SD)	2.1 (2.36)	2.1 (2.14)	2.1 (2.24)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 35	1, 35
Fatigue			
n	3282	4384	7666
Mean (SD)	2.7 (3.25)	2.6 (3.25)	2.7 (3.25)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 43	1, 43
Myalgia			
n	1626	2698	4324
Mean (SD)	2.5 (3.32)	2.2 (2.81)	2.3 (3.02)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 42	1, 42
Arthralgia			
n	1327	1892	3219
Mean (SD)	3.0 (4.29)	2.5 (3.43)	2.7 (3.82)
Median	2.0	1.0	1.0
Min, Max	1, 59	1, 40	1, 59

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11406)	mRNA-1273 (N=11405)	Total (N=22812)
Nausea/Vomiting			
n	908	1069	1977
Mean (SD)	1.8 (2.28)	1.7 (1.64)	1.7 (1.96)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 25	1, 33
Chills			
n	730	1051	1781
Mean (SD)	1.7 (1.78)	1.5 (1.63)	1.6 (1.70)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 28	1, 33

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3748)	mRNA-1273 (N=3762)	Total (N=7510)
Solicited Adverse Reactions			
n	1546	3058	4604
Mean (SD)	3.3 (4.98)	3.1 (3.42)	3.2 (4.01)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 70	1, 74
Solicited Local Adverse Reactions			
n	566	2805	3371
Mean (SD)	2.1 (3.51)	2.3 (1.64)	2.2 (2.08)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 36	1, 51
Pain			
n	481	2782	3263
Mean (SD)	1.8 (3.01)	2.2 (1.21)	2.1 (1.61)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 29	1, 51
Erythema (Redness)			
n	19	86	105
Mean (SD)	2.8 (5.75)	2.7 (4.54)	2.7 (4.75)
Median	1.0	2.0	1.0
Min, Max	1, 26	1, 35	1, 35

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3748)	mRNA-1273 (N=3762)	Total (N=7510)
Swelling (Hardness)			
n	19	166	185
Mean (SD)	6.5 (9.56)	1.9 (1.94)	2.4 (3.78)
Median	2.0	1.0	1.0
Min, Max	1, 27	1, 22	1, 27
Lymphadenopathy [1]			
n	155	231	386
Mean (SD)	1.8 (2.08)	1.8 (2.61)	1.8 (2.41)
Median	1.0	1.0	1.0
Min, Max	1, 16	1, 24	1, 24
Solicited Systemic Adverse Reactions			
n	1335	1818	3153
Mean (SD)	3.3 (4.94)	3.0 (4.12)	3.1 (4.49)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Fever			
n	7	10	17
Mean (SD)	1.4 (0.79)	1.1 (0.32)	1.2 (0.56)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 2	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3748)	mRNA-1273 (N=3762)	Total (N=7510)
Headache			
n	724	921	1645
Mean (SD)	2.0 (2.33)	2.0 (2.35)	2.0 (2.34)
Median	1.0	1.0	1.0
Min, Max	1, 26	1, 42	1, 42
Fatigue			
n	851	1251	2102
Mean (SD)	3.1 (4.94)	2.7 (4.05)	2.9 (4.43)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Myalgia			
n	443	743	1186
Mean (SD)	3.2 (4.94)	2.5 (3.63)	2.7 (4.18)
Median	1.0	1.0	1.0
Min, Max	1, 44	1, 59	1, 59
Arthralgia			
n	456	618	1074
Mean (SD)	3.5 (4.94)	3.0 (4.80)	3.2 (4.86)
Median	2.0	1.0	1.0
Min, Max	1, 34	1, 59	1, 59

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.4
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3748)	mRNA-1273 (N=3762)	Total (N=7510)
Nausea/Vomiting			
n	166	194	360
Mean (SD)	1.6 (1.43)	1.6 (1.27)	1.6 (1.35)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 10	1, 11
Chills			
n	148	202	350
Mean (SD)	1.5 (1.28)	1.6 (1.94)	1.6 (1.69)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 19	1, 19

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=10321)	mRNA-1273 (N=10358)	Total (N=20679)
Solicited Adverse Reactions			
n	4648	9664	14312
Mean (SD)	3.2 (4.42)	4.0 (4.00)	3.7 (4.16)
Median	2.0	3.0	3.0
Min, Max	1, 76	1, 72	1, 76
Solicited Local Adverse Reactions			
n	2134	9371	11505
Mean (SD)	2.0 (3.24)	3.2 (2.54)	3.0 (2.73)
Median	1.0	3.0	3.0
Min, Max	1, 76	1, 59	1, 76
Pain			
n	1942	9335	11277
Mean (SD)	1.8 (2.66)	3.0 (2.01)	2.8 (2.19)
Median	1.0	3.0	3.0
Min, Max	1, 58	1, 59	1, 59
Erythema (Redness)			
n	42	928	970
Mean (SD)	2.0 (1.85)	2.5 (2.76)	2.4 (2.73)
Median	1.0	2.0	2.0
Min, Max	1, 8	1, 48	1, 48

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=10321)	mRNA-1273 (N=10358)	Total (N=20679)
Swelling (Hardness)			
n	35	1309	1344
Mean (SD)	2.7 (3.05)	2.5 (3.19)	2.5 (3.19)
Median	1.0	2.0	2.0
Min, Max	1, 13	1, 58	1, 58
Lymphadenopathy [1]			
n	444	1654	2098
Mean (SD)	2.6 (5.01)	2.5 (3.04)	2.5 (3.55)
Median	1.0	2.0	2.0
Min, Max	1, 76	1, 54	1, 76
Solicited Systemic Adverse Reactions			
n	3967	8484	12451
Mean (SD)	3.2 (4.34)	3.1 (3.85)	3.1 (4.01)
Median	2.0	2.0	2.0
Min, Max	1, 70	1, 72	1, 72
Fever			
n	38	1806	1844
Mean (SD)	1.2 (0.53)	1.2 (1.99)	1.2 (1.97)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 58	1, 58

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=10321)	mRNA-1273 (N=10358)	Total (N=20679)
Headache			
n	2617	6500	9117
Mean (SD)	2.3 (2.57)	2.3 (2.80)	2.3 (2.73)
Median	1.0	2.0	2.0
Min, Max	1, 58	1, 65	1, 65
Fatigue			
n	2530	7002	9532
Mean (SD)	2.9 (4.12)	2.6 (3.27)	2.6 (3.52)
Median	2.0	2.0	2.0
Min, Max	1, 69	1, 64	1, 69
Myalgia			
n	1312	6353	7665
Mean (SD)	2.9 (4.49)	2.1 (2.84)	2.2 (3.20)
Median	2.0	2.0	2.0
Min, Max	1, 58	1, 65	1, 65
Arthralgia			
n	1087	4685	5772
Mean (SD)	3.3 (5.15)	2.2 (2.82)	2.4 (3.42)
Median	2.0	1.0	1.0
Min, Max	1, 58	1, 70	1, 70

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=10321)	mRNA-1273 (N=10358)	Total (N=20679)
Nausea/Vomiting			
n	754	2209	2963
Mean (SD)	2.0 (3.48)	1.7 (2.06)	1.8 (2.50)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64
Chills			
n	611	5001	5612
Mean (SD)	1.9 (2.85)	1.5 (1.97)	1.5 (2.09)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3549)	mRNA-1273 (N=3589)	Total (N=7138)
Solicited Adverse Reactions			
n	1294	3213	4507
Mean (SD)	3.5 (6.00)	3.8 (4.57)	3.7 (5.02)
Median	2.0	3.0	3.0
Min, Max	1, 64	1, 65	1, 65
Solicited Local Adverse Reactions			
n	473	3010	3483
Mean (SD)	2.1 (3.66)	3.0 (2.54)	2.9 (2.74)
Median	1.0	3.0	2.0
Min, Max	1, 55	1, 64	1, 64
Pain			
n	421	2990	3411
Mean (SD)	1.8 (2.94)	2.8 (1.93)	2.7 (2.10)
Median	1.0	3.0	2.0
Min, Max	1, 55	1, 64	1, 64
Erythema (Redness)			
n	13	265	278
Mean (SD)	3.8 (10.26)	3.2 (4.69)	3.2 (5.05)
Median	1.0	2.0	2.0
Min, Max	1, 38	1, 57	1, 57

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3549)	mRNA-1273 (N=3589)	Total (N=7138)
Swelling (Hardness)			
n	13	386	399
Mean (SD)	4.8 (9.02)	2.6 (3.98)	2.7 (4.23)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 56	1, 56
Lymphadenopathy [1]			
n	90	302	392
Mean (SD)	2.3 (2.05)	1.8 (1.36)	1.9 (1.56)
Median	1.0	1.0	1.0
Min, Max	1, 14	1, 9	1, 14
Solicited Systemic Adverse Reactions			
n	1102	2580	3682
Mean (SD)	3.6 (6.07)	3.0 (4.58)	3.2 (5.08)
Median	2.0	2.0	2.0
Min, Max	1, 64	1, 65	1, 65
Fever			
n	5	366	371
Mean (SD)	1.6 (0.55)	1.1 (0.28)	1.1 (0.29)
Median	2.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3549)	mRNA-1273 (N=3589)	Total (N=7138)
Headache			
n	635	1665	2300
Mean (SD)	2.3 (3.50)	2.0 (2.80)	2.1 (3.01)
Median	1.0	1.0	1.0
Min, Max	1, 49	1, 63	1, 63
Fatigue			
n	695	2094	2789
Mean (SD)	3.1 (4.87)	2.6 (3.85)	2.7 (4.13)
Median	2.0	2.0	2.0
Min, Max	1, 62	1, 65	1, 65
Myalgia			
n	385	1683	2068
Mean (SD)	3.7 (7.50)	2.1 (3.33)	2.4 (4.46)
Median	2.0	1.0	1.0
Min, Max	1, 64	1, 63	1, 64
Arthralgia			
n	381	1252	1633
Mean (SD)	4.3 (8.07)	2.4 (3.72)	2.9 (5.14)
Median	2.0	1.0	1.0
Min, Max	1, 64	1, 60	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.5
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3549)	mRNA-1273 (N=3589)	Total (N=7138)
Nausea/Vomiting			
n	129	425	554
Mean (SD)	1.5 (1.25)	1.6 (2.16)	1.6 (1.98)
Median	1.0	1.0	1.0
Min, Max	1, 9	1, 31	1, 31
Chills			
n	144	1099	1243
Mean (SD)	1.8 (2.27)	1.4 (1.20)	1.4 (1.38)
Median	1.0	1.0	1.0
Min, Max	1, 24	1, 27	1, 27

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11412)	mRNA-1273 (N=11410)	Total (N=22823)
Solicited Adverse Reactions			
n	7017	10841	17858
Mean (SD)	3.5 (4.49)	4.5 (4.38)	4.1 (4.45)
Median	2.0	4.0	3.0
Min, Max	1, 76	1, 72	1, 76
Solicited Local Adverse Reactions			
n	3522	10625	14147
Mean (SD)	2.0 (2.92)	3.5 (2.75)	3.1 (2.86)
Median	1.0	3.0	3.0
Min, Max	1, 76	1, 59	1, 76
Pain			
n	3224	10590	13814
Mean (SD)	1.8 (2.37)	3.2 (2.12)	2.9 (2.26)
Median	1.0	3.0	3.0
Min, Max	1, 58	1, 59	1, 59
Erythema (Redness)			
n	82	1145	1227
Mean (SD)	1.8 (2.06)	2.5 (2.85)	2.4 (2.81)
Median	1.0	2.0	2.0
Min, Max	1, 13	1, 48	1, 48

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11412)	mRNA-1273 (N=11410)	Total (N=22823)
Swelling (Hardness)			
n	65	1715	1780
Mean (SD)	2.8 (4.03)	2.5 (3.06)	2.5 (3.10)
Median	1.0	2.0	2.0
Min, Max	1, 27	1, 58	1, 58
Lymphadenopathy [1]			
n	858	2447	3305
Mean (SD)	2.4 (4.05)	2.5 (3.08)	2.4 (3.36)
Median	1.0	2.0	1.0
Min, Max	1, 76	1, 54	1, 76
Solicited Systemic Adverse Reactions			
n	6278	9631	15909
Mean (SD)	3.4 (4.41)	3.5 (4.23)	3.4 (4.30)
Median	2.0	2.0	2.0
Min, Max	1, 70	1, 72	1, 72
Fever			
n	76	1880	1956
Mean (SD)	1.3 (0.57)	1.2 (1.96)	1.2 (1.92)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 58	1, 58

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11412)	mRNA-1273 (N=11410)	Total (N=22823)
Headache			
n	4453	7585	12038
Mean (SD)	2.4 (2.68)	2.5 (2.88)	2.4 (2.81)
Median	2.0	2.0	2.0
Min, Max	1, 58	1, 65	1, 65
Fatigue			
n	4279	7986	12265
Mean (SD)	3.0 (4.01)	2.8 (3.65)	2.9 (3.78)
Median	2.0	2.0	2.0
Min, Max	1, 69	1, 64	1, 69
Myalgia			
n	2378	7125	9503
Mean (SD)	2.8 (4.03)	2.2 (3.08)	2.4 (3.35)
Median	2.0	2.0	2.0
Min, Max	1, 58	1, 65	1, 65
Arthralgia			
n	1945	5315	7260
Mean (SD)	3.2 (4.93)	2.3 (3.15)	2.6 (3.73)
Median	2.0	1.0	2.0
Min, Max	1, 59	1, 70	1, 70

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11412)	mRNA-1273 (N=11410)	Total (N=22823)
Nausea/Vomiting			
n	1410	2813	4223
Mean (SD)	1.9 (2.97)	1.7 (2.04)	1.8 (2.39)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64
Chills			
n	1177	5388	6565
Mean (SD)	1.8 (2.26)	1.5 (2.00)	1.6 (2.05)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3750)	mRNA-1273 (N=3766)	Total (N=7516)
Solicited Adverse Reactions			
n	2010	3497	5507
Mean (SD)	3.8 (6.10)	4.3 (5.02)	4.1 (5.44)
Median	2.0	3.0	3.0
Min, Max	1, 74	1, 70	1, 74
Solicited Local Adverse Reactions			
n	859	3337	4196
Mean (SD)	2.2 (3.83)	3.1 (2.65)	2.9 (2.96)
Median	1.0	3.0	2.0
Min, Max	1, 55	1, 64	1, 64
Pain			
n	751	3311	4062
Mean (SD)	1.9 (3.20)	2.9 (1.92)	2.7 (2.25)
Median	1.0	3.0	2.0
Min, Max	1, 55	1, 64	1, 64
Erythema (Redness)			
n	32	325	357
Mean (SD)	3.2 (7.76)	3.2 (4.81)	3.2 (5.13)
Median	1.0	2.0	2.0
Min, Max	1, 38	1, 57	1, 57

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3750)	mRNA-1273 (N=3766)	Total (N=7516)
Swelling (Hardness)			
n	30	468	498
Mean (SD)	5.6 (9.32)	2.6 (3.77)	2.7 (4.36)
Median	2.0	2.0	2.0
Min, Max	1, 32	1, 56	1, 56
Lymphadenopathy [1]			
n	216	467	683
Mean (SD)	2.0 (2.06)	1.8 (2.09)	1.9 (2.08)
Median	1.0	1.0	1.0
Min, Max	1, 16	1, 24	1, 24
Solicited Systemic Adverse Reactions			
n	1754	2922	4676
Mean (SD)	3.8 (6.04)	3.4 (5.09)	3.6 (5.47)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Fever			
n	12	372	384
Mean (SD)	1.5 (0.67)	1.1 (0.28)	1.1 (0.31)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3750)	mRNA-1273 (N=3766)	Total (N=7516)
Headache			
n	1074	1981	3055
Mean (SD)	2.3 (3.18)	2.1 (2.92)	2.2 (3.01)
Median	1.0	1.0	1.0
Min, Max	1, 49	1, 63	1, 63
Fatigue			
n	1191	2407	3598
Mean (SD)	3.2 (5.31)	2.9 (4.43)	3.0 (4.74)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Myalgia			
n	674	1914	2588
Mean (SD)	3.4 (6.49)	2.3 (3.75)	2.6 (4.65)
Median	1.0	1.0	1.0
Min, Max	1, 64	1, 63	1, 64
Arthralgia			
n	661	1488	2149
Mean (SD)	4.0 (6.89)	2.7 (4.40)	3.1 (5.32)
Median	2.0	1.0	1.0
Min, Max	1, 64	1, 60	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.6
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3750)	mRNA-1273 (N=3766)	Total (N=7516)
Nausea/Vomiting			
n	269	553	822
Mean (SD)	1.6 (1.37)	1.7 (2.02)	1.6 (1.83)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 31	1, 31
Chills			
n	262	1192	1454
Mean (SD)	1.6 (1.88)	1.4 (1.39)	1.4 (1.49)
Median	1.0	1.0	1.0
Min, Max	1, 24	1, 27	1, 27

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14356)	mRNA-1273 (N=14301)	Total (N=28657)
Solicited Adverse Reactions			
n	6888	12591	19479
Mean (SD)	3.1 (3.87)	3.4 (3.17)	3.3 (3.44)
Median	2.0	3.0	3.0
Min, Max	1, 74	1, 70	1, 74
Solicited Local Adverse Reactions			
n	2830	12080	14910
Mean (SD)	1.9 (2.48)	2.6 (1.89)	2.5 (2.03)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 36	1, 51
Pain			
n	2507	12013	14520
Mean (SD)	1.7 (2.03)	2.5 (1.42)	2.3 (1.57)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 34	1, 51
Erythema (Redness)			
n	60	406	466
Mean (SD)	2.2 (3.84)	2.4 (3.26)	2.4 (3.34)
Median	1.0	2.0	1.0
Min, Max	1, 26	1, 35	1, 35

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14356)	mRNA-1273 (N=14301)	Total (N=28657)
Swelling (Hardness)			
n	49	884	933
Mean (SD)	4.4 (7.24)	2.0 (2.00)	2.2 (2.60)
Median	2.0	2.0	2.0
Min, Max	1, 27	1, 25	1, 27
Lymphadenopathy [1]			
n	677	1445	2122
Mean (SD)	2.1 (2.80)	2.3 (2.90)	2.2 (2.87)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 31	1, 33
Solicited Systemic Adverse Reactions			
n	6053	7814	13867
Mean (SD)	3.1 (3.87)	2.9 (3.55)	3.0 (3.70)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Fever			
n	38	78	116
Mean (SD)	1.4 (0.64)	1.3 (0.79)	1.3 (0.74)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 6	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14356)	mRNA-1273 (N=14301)	Total (N=28657)
Headache			
n	3795	4634	8429
Mean (SD)	2.1 (2.37)	2.1 (2.18)	2.1 (2.26)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 42	1, 42
Fatigue			
n	3903	5303	9206
Mean (SD)	2.7 (3.65)	2.7 (3.45)	2.7 (3.54)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Myalgia			
n	1937	3194	5131
Mean (SD)	2.6 (3.53)	2.3 (3.04)	2.4 (3.24)
Median	1.0	1.0	1.0
Min, Max	1, 44	1, 59	1, 59
Arthralgia			
n	1671	2337	4008
Mean (SD)	3.0 (4.37)	2.6 (3.90)	2.8 (4.11)
Median	2.0	1.0	1.0
Min, Max	1, 59	1, 59	1, 59

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14356)	mRNA-1273 (N=14301)	Total (N=28657)
Nausea/Vomiting			
n	1012	1170	2182
Mean (SD)	1.8 (2.18)	1.7 (1.60)	1.7 (1.89)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 25	1, 33
Chills			
n	822	1124	1946
Mean (SD)	1.7 (1.74)	1.6 (1.74)	1.6 (1.74)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 28	1, 33

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Solicited Adverse Reactions			
n	134	259	393
Mean (SD)	3.3 (3.25)	3.7 (4.03)	3.6 (3.78)
Median	2.0	3.0	3.0
Min, Max	1, 19	1, 35	1, 35
Solicited Local Adverse Reactions			
n	58	244	302
Mean (SD)	1.9 (1.55)	2.7 (2.62)	2.5 (2.47)
Median	1.0	2.0	2.0
Min, Max	1, 10	1, 35	1, 35
Pain			
n	54	242	296
Mean (SD)	1.6 (1.24)	2.5 (2.44)	2.4 (2.30)
Median	1.0	2.0	2.0
Min, Max	1, 8	1, 35	1, 35
Erythema (Redness)			
n	3	9	12
Mean (SD)	1.0 (0.00)	1.9 (1.45)	1.7 (1.30)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 5	1, 5

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Swelling (Hardness)			
n	2	20	22
Mean (SD)	1.5 (0.71)	2.5 (3.15)	2.4 (3.02)
Median	1.5	1.0	1.0
Min, Max	1, 2	1, 15	1, 15
Lymphadenopathy [1]			
n	16	52	68
Mean (SD)	2.3 (2.32)	1.9 (1.31)	2.0 (1.59)
Median	1.5	1.0	1.0
Min, Max	1, 10	1, 6	1, 10
Solicited Systemic Adverse Reactions			
n	118	208	326
Mean (SD)	3.3 (3.32)	3.0 (3.77)	3.1 (3.61)
Median	2.0	2.0	2.0
Min, Max	1, 18	1, 30	1, 30
Fever			
n	6	31	37
Mean (SD)	1.3 (0.52)	1.2 (0.50)	1.2 (0.49)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Headache			
n	79	129	208
Mean (SD)	2.3 (2.30)	2.5 (2.98)	2.4 (2.74)
Median	1.0	1.0	1.0
Min, Max	1, 15	1, 22	1, 22
Fatigue			
n	70	132	202
Mean (SD)	3.2 (3.20)	2.6 (3.37)	2.8 (3.32)
Median	2.0	2.0	2.0
Min, Max	1, 15	1, 29	1, 29
Myalgia			
n	46	122	168
Mean (SD)	3.6 (3.97)	2.2 (2.75)	2.6 (3.18)
Median	2.0	1.0	2.0
Min, Max	1, 18	1, 27	1, 27
Arthralgia			
n	38	85	123
Mean (SD)	3.5 (3.92)	1.8 (1.38)	2.3 (2.56)
Median	2.0	1.0	1.0
Min, Max	1, 17	1, 7	1, 17

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Nausea/Vomiting			
n	25	40	65
Mean (SD)	1.6 (1.29)	1.8 (1.98)	1.7 (1.73)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 13	1, 13
Chills			
n	26	80	106
Mean (SD)	2.0 (1.37)	1.6 (1.39)	1.7 (1.39)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 10	1, 10

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=464)	mRNA-1273 (N=526)	Total (N=991)
Solicited Adverse Reactions			
n	260	470	730
Mean (SD)	3.8 (5.27)	3.3 (2.67)	3.4 (3.81)
Median	2.0	3.0	3.0
Min, Max	1, 41	1, 31	1, 41
Solicited Local Adverse Reactions			
n	110	441	551
Mean (SD)	1.9 (2.78)	2.5 (1.31)	2.4 (1.72)
Median	1.0	2.0	2.0
Min, Max	1, 28	1, 10	1, 28
Pain			
n	99	435	534
Mean (SD)	1.8 (2.87)	2.4 (1.11)	2.3 (1.60)
Median	1.0	2.0	2.0
Min, Max	1, 28	1, 10	1, 28
Erythema (Redness)			
n	2	16	18
Mean (SD)	1.0 (0.00)	2.0 (1.21)	1.9 (1.18)
Median	1.0	2.0	1.5
Min, Max	1, 1	1, 5	1, 5

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=464)	mRNA-1273 (N=526)	Total (N=991)
Swelling (Hardness)			
n	1	30	31
Mean (SD)	1.0 (NA)	1.8 (1.37)	1.8 (1.35)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 7	1, 7
Lymphadenopathy [1]			
n	29	56	85
Mean (SD)	1.5 (0.91)	1.8 (1.70)	1.7 (1.48)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 9	1, 9
Solicited Systemic Adverse Reactions			
n	227	299	526
Mean (SD)	3.9 (5.52)	2.8 (3.12)	3.3 (4.35)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 31	1, 41
Fever			
n	2	6	8
Mean (SD)	1.0 (0.00)	1.2 (0.41)	1.1 (0.35)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 2

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=464)	mRNA-1273 (N=526)	Total (N=991)
Headache			
n	153	189	342
Mean (SD)	2.1 (1.88)	2.0 (1.56)	2.0 (1.71)
Median	2.0	1.0	1.0
Min, Max	1, 13	1, 10	1, 13
Fatigue			
n	160	200	360
Mean (SD)	2.9 (4.18)	2.6 (3.16)	2.7 (3.64)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 31	1, 41
Myalgia			
n	86	125	211
Mean (SD)	4.0 (6.67)	2.2 (2.32)	2.9 (4.69)
Median	1.0	1.0	1.0
Min, Max	1, 30	1, 17	1, 30
Arthralgia			
n	74	88	162
Mean (SD)	4.1 (6.47)	2.5 (3.26)	3.2 (5.04)
Median	2.0	1.0	1.5
Min, Max	1, 32	1, 24	1, 32

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.7

Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=464)	mRNA-1273 (N=526)	Total (N=991)
Nausea/Vomiting			
n	37	53	90
Mean (SD)	2.1 (2.34)	1.5 (0.89)	1.7 (1.66)
Median	1.0	1.0	1.0
Min, Max	1, 14	1, 5	1, 14
Chills			
n	30	49	79
Mean (SD)	1.4 (0.76)	1.2 (0.46)	1.3 (0.59)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 3	1, 4

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=13252)	mRNA-1273 (N=13286)	Total (N=26538)
Solicited Adverse Reactions			
n	5674	12291	17965
Mean (SD)	3.2 (4.79)	4.0 (4.10)	3.7 (4.34)
Median	2.0	3.0	3.0
Min, Max	1, 76	1, 65	1, 76
Solicited Local Adverse Reactions			
n	2473	11821	14294
Mean (SD)	2.0 (3.29)	3.2 (2.52)	3.0 (2.71)
Median	1.0	3.0	3.0
Min, Max	1, 76	1, 64	1, 76
Pain			
n	2242	11770	14012
Mean (SD)	1.8 (2.76)	3.0 (1.94)	2.8 (2.14)
Median	1.0	3.0	3.0
Min, Max	1, 58	1, 64	1, 64
Erythema (Redness)			
n	51	1152	1203
Mean (SD)	1.8 (1.72)	2.6 (3.33)	2.6 (3.28)
Median	1.0	2.0	2.0
Min, Max	1, 8	1, 57	1, 57

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=13252)	mRNA-1273 (N=13286)	Total (N=26538)
Swelling (Hardness)			
n	47	1639	1686
Mean (SD)	3.3 (5.37)	2.5 (3.41)	2.5 (3.48)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 58	1, 58
Lymphadenopathy [1]			
n	502	1869	2371
Mean (SD)	2.5 (4.73)	2.4 (2.90)	2.4 (3.37)
Median	1.0	2.0	2.0
Min, Max	1, 76	1, 54	1, 76
Solicited Systemic Adverse Reactions			
n	4833	10568	15401
Mean (SD)	3.2 (4.75)	3.1 (3.96)	3.1 (4.23)
Median	2.0	2.0	2.0
Min, Max	1, 70	1, 65	1, 70
Fever			
n	42	2093	2135
Mean (SD)	1.3 (0.54)	1.2 (1.37)	1.2 (1.36)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 44	1, 44

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=13252)	mRNA-1273 (N=13286)	Total (N=26538)
Headache			
n	3103	7834	10937
Mean (SD)	2.3 (2.78)	2.3 (2.76)	2.3 (2.76)
Median	1.0	2.0	2.0
Min, Max	1, 58	1, 65	1, 65
Fatigue			
n	3062	8719	11781
Mean (SD)	2.9 (4.35)	2.6 (3.34)	2.7 (3.63)
Median	2.0	2.0	2.0
Min, Max	1, 69	1, 65	1, 69
Myalgia			
n	1589	7673	9262
Mean (SD)	3.1 (5.29)	2.1 (2.85)	2.3 (3.42)
Median	2.0	1.0	1.0
Min, Max	1, 64	1, 65	1, 65
Arthralgia			
n	1382	5680	7062
Mean (SD)	3.6 (6.01)	2.2 (2.94)	2.5 (3.78)
Median	2.0	1.0	1.0
Min, Max	1, 64	1, 60	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=13252)	mRNA-1273 (N=13286)	Total (N=26538)
Nausea/Vomiting			
n	841	2518	3359
Mean (SD)	1.9 (3.27)	1.7 (2.10)	1.7 (2.45)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64
Chills			
n	712	5850	6562
Mean (SD)	1.9 (2.78)	1.5 (1.72)	1.5 (1.87)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=213)	mRNA-1273 (N=203)	Total (N=416)
Solicited Adverse Reactions			
n	74	164	238
Mean (SD)	3.4 (3.45)	3.2 (2.55)	3.2 (2.86)
Median	2.0	3.0	3.0
Min, Max	1, 20	1, 20	1, 20
Solicited Local Adverse Reactions			
n	37	151	188
Mean (SD)	2.5 (3.08)	2.7 (1.99)	2.6 (2.24)
Median	1.0	2.0	2.0
Min, Max	1, 18	1, 20	1, 20
Pain			
n	31	148	179
Mean (SD)	1.6 (1.02)	2.6 (1.98)	2.4 (1.88)
Median	1.0	2.0	2.0
Min, Max	1, 5	1, 20	1, 20
Erythema (Redness)			
n	1	8	9
Mean (SD)	2.0 (NA)	2.5 (1.20)	2.4 (1.13)
Median	2.0	2.5	2.0
Min, Max	2, 2	1, 4	1, 4

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=213)	mRNA-1273 (N=203)	Total (N=416)
Swelling (Hardness)			
n	1	10	11
Mean (SD)	1.0 (NA)	3.9 (5.40)	3.6 (5.20)
Median	1.0	2.5	2.0
Min, Max	1, 1	1, 19	1, 19
Lymphadenopathy [1]			
n	10	27	37
Mean (SD)	4.6 (4.79)	2.3 (1.78)	2.9 (3.01)
Median	3.5	2.0	2.0
Min, Max	1, 17	1, 7	1, 17
Solicited Systemic Adverse Reactions			
n	66	135	201
Mean (SD)	3.4 (3.48)	2.6 (2.29)	2.9 (2.75)
Median	2.0	2.0	2.0
Min, Max	1, 20	1, 16	1, 20
Fever			
n	1	27	28
Mean (SD)	1.0 (NA)	1.0 (0.00)	1.0 (0.00)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 1	1, 1

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=213)	mRNA-1273 (N=203)	Total (N=416)
Headache			
n	40	88	128
Mean (SD)	2.4 (2.22)	2.4 (2.33)	2.4 (2.29)
Median	2.0	1.5	2.0
Min, Max	1, 12	1, 15	1, 15
Fatigue			
n	49	92	141
Mean (SD)	2.8 (3.09)	2.4 (2.04)	2.5 (2.46)
Median	2.0	2.0	2.0
Min, Max	1, 19	1, 12	1, 19
Myalgia			
n	29	101	130
Mean (SD)	3.4 (4.37)	2.0 (1.57)	2.3 (2.54)
Median	2.0	1.0	2.0
Min, Max	1, 20	1, 11	1, 20
Arthralgia			
n	21	66	87
Mean (SD)	4.4 (5.03)	2.1 (1.72)	2.7 (3.01)
Median	2.0	2.0	2.0
Min, Max	1, 20	1, 11	1, 20

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=213)	mRNA-1273 (N=203)	Total (N=416)
Nausea/Vomiting			
n	11	32	43
Mean (SD)	1.4 (0.67)	1.7 (1.22)	1.6 (1.11)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 6	1, 6
Chills			
n	14	69	83
Mean (SD)	2.7 (3.15)	1.7 (0.98)	1.9 (1.59)
Median	1.0	1.0	1.0
Min, Max	1, 10	1, 5	1, 10

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=405)	mRNA-1273 (N=458)	Total (N=863)
Solicited Adverse Reactions			
n	194	422	616
Mean (SD)	3.9 (5.90)	4.0 (5.63)	4.0 (5.71)
Median	2.0	3.0	3.0
Min, Max	1, 50	1, 72	1, 72
Solicited Local Adverse Reactions			
n	97	409	506
Mean (SD)	2.2 (4.05)	3.0 (3.24)	2.9 (3.42)
Median	1.0	3.0	2.0
Min, Max	1, 38	1, 59	1, 59
Pain			
n	90	407	497
Mean (SD)	1.7 (1.66)	2.9 (3.16)	2.7 (2.98)
Median	1.0	3.0	2.0
Min, Max	1, 13	1, 59	1, 59
Erythema (Redness)			
n	3	33	36
Mean (SD)	13.3 (21.36)	2.4 (2.19)	3.3 (6.32)
Median	1.0	2.0	2.0
Min, Max	1, 38	1, 13	1, 38

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=405)	mRNA-1273 (N=458)	Total (N=863)
Swelling (Hardness)			
n	0	46	46
Mean (SD)		2.3 (1.40)	2.3 (1.40)
Median		2.0	2.0
Min, Max		1, 6	1, 6
Lymphadenopathy [1]			
n	22	60	82
Mean (SD)	2.1 (1.52)	2.1 (1.77)	2.1 (1.70)
Median	1.5	1.0	1.0
Min, Max	1, 6	1, 9	1, 9
Solicited Systemic Adverse Reactions			
n	170	361	531
Mean (SD)	3.9 (5.64)	3.3 (6.10)	3.5 (5.96)
Median	2.0	2.0	2.0
Min, Max	1, 49	1, 72	1, 72
Fever			
n	0	52	52
Mean (SD)		2.2 (7.90)	2.2 (7.90)
Median		1.0	1.0
Min, Max		1, 58	1, 58

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=405)	mRNA-1273 (N=458)	Total (N=863)
Headache			
n	109	243	352
Mean (SD)	2.4 (2.92)	2.4 (4.06)	2.4 (3.74)
Median	1.0	2.0	2.0
Min, Max	1, 24	1, 59	1, 59
Fatigue			
n	114	285	399
Mean (SD)	3.2 (3.25)	2.8 (5.36)	2.9 (4.85)
Median	2.0	2.0	2.0
Min, Max	1, 22	1, 60	1, 60
Myalgia			
n	79	262	341
Mean (SD)	3.8 (6.41)	2.5 (5.24)	2.8 (5.55)
Median	2.0	1.0	2.0
Min, Max	1, 48	1, 58	1, 58
Arthralgia			
n	65	191	256
Mean (SD)	4.3 (7.33)	2.5 (5.29)	2.9 (5.91)
Median	2.0	1.0	2.0
Min, Max	1, 48	1, 70	1, 70

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.8

Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=405)	mRNA-1273 (N=458)	Total (N=863)
Nausea/Vomiting			
n	31	84	115
Mean (SD)	2.1 (3.27)	1.7 (1.62)	1.8 (2.18)
Median	1.0	1.0	1.0
Min, Max	1, 19	1, 13	1, 19
Chills			
n	29	181	210
Mean (SD)	2.0 (1.30)	1.8 (4.42)	1.8 (4.13)
Median	2.0	1.0	1.0
Min, Max	1, 6	1, 58	1, 58

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14363)	mRNA-1273 (N=14309)	Total (N=28672)
Solicited Adverse Reactions			
n	8576	13566	22142
Mean (SD)	3.5 (4.87)	4.4 (4.52)	4.1 (4.68)
Median	2.0	4.0	3.0
Min, Max	1, 76	1, 70	1, 76
Solicited Local Adverse Reactions			
n	4147	13211	17358
Mean (SD)	2.1 (3.11)	3.4 (2.71)	3.1 (2.87)
Median	1.0	3.0	3.0
Min, Max	1, 76	1, 64	1, 76
Pain			
n	3762	13156	16918
Mean (SD)	1.8 (2.57)	3.1 (2.02)	2.8 (2.23)
Median	1.0	3.0	3.0
Min, Max	1, 58	1, 64	1, 64
Erythema (Redness)			
n	105	1410	1515
Mean (SD)	1.9 (3.03)	2.6 (3.44)	2.6 (3.42)
Median	1.0	2.0	2.0
Min, Max	1, 26	1, 57	1, 57

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14363)	mRNA-1273 (N=14309)	Total (N=28672)
Swelling (Hardness)			
n	91	2096	2187
Mean (SD)	3.8 (6.41)	2.5 (3.25)	2.5 (3.45)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 58	1, 58
Lymphadenopathy [1]			
n	1010	2754	3764
Mean (SD)	2.3 (3.81)	2.4 (3.01)	2.4 (3.24)
Median	1.0	1.0	1.0
Min, Max	1, 76	1, 54	1, 76
Solicited Systemic Adverse Reactions			
n	7628	11893	19521
Mean (SD)	3.5 (4.79)	3.5 (4.40)	3.5 (4.56)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Fever			
n	79	2145	2224
Mean (SD)	1.3 (0.60)	1.2 (1.36)	1.2 (1.34)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 44	1, 44

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14363)	mRNA-1273 (N=14309)	Total (N=28672)
Headache			
n	5236	9099	14335
Mean (SD)	2.3 (2.80)	2.4 (2.86)	2.4 (2.84)
Median	2.0	2.0	2.0
Min, Max	1, 58	1, 65	1, 65
Fatigue			
n	5178	9890	15068
Mean (SD)	3.0 (4.35)	2.9 (3.80)	2.9 (4.00)
Median	2.0	2.0	2.0
Min, Max	1, 74	1, 69	1, 74
Myalgia			
n	2866	8561	11427
Mean (SD)	2.9 (4.59)	2.3 (3.16)	2.4 (3.59)
Median	2.0	2.0	2.0
Min, Max	1, 64	1, 65	1, 65
Arthralgia			
n	2451	6459	8910
Mean (SD)	3.4 (5.46)	2.4 (3.41)	2.7 (4.10)
Median	2.0	1.0	2.0
Min, Max	1, 64	1, 60	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14363)	mRNA-1273 (N=14309)	Total (N=28672)
Nausea/Vomiting			
n	1592	3184	4776
Mean (SD)	1.9 (2.79)	1.7 (2.06)	1.8 (2.33)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64
Chills			
n	1348	6262	7610
Mean (SD)	1.8 (2.23)	1.5 (1.80)	1.5 (1.88)
Median	1.0	1.0	1.0
Min, Max	1, 58	1, 64	1, 64

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Solicited Adverse Reactions			
n	151	279	430
Mean (SD)	3.7 (3.52)	4.0 (4.12)	3.9 (3.92)
Median	2.0	3.0	3.0
Min, Max	1, 20	1, 35	1, 35
Solicited Local Adverse Reactions			
n	74	268	342
Mean (SD)	2.2 (2.49)	3.0 (2.77)	2.8 (2.73)
Median	1.0	3.0	2.0
Min, Max	1, 18	1, 35	1, 35
Pain			
n	67	265	332
Mean (SD)	1.7 (1.23)	2.8 (2.63)	2.6 (2.45)
Median	1.0	3.0	2.0
Min, Max	1, 8	1, 35	1, 35
Erythema (Redness)			
n	4	16	20
Mean (SD)	1.3 (0.50)	2.3 (1.34)	2.1 (1.28)
Median	1.0	2.0	1.5
Min, Max	1, 2	1, 5	1, 5

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Swelling (Hardness)			
n	3	26	29
Mean (SD)	1.3 (0.58)	3.1 (4.29)	2.9 (4.09)
Median	1.0	1.5	1.0
Min, Max	1, 2	1, 19	1, 19
Lymphadenopathy [1]			
n	20	67	87
Mean (SD)	3.5 (3.97)	2.1 (1.52)	2.4 (2.37)
Median	2.0	1.0	2.0
Min, Max	1, 17	1, 7	1, 17
Solicited Systemic Adverse Reactions			
n	137	237	374
Mean (SD)	3.6 (3.58)	3.2 (3.71)	3.4 (3.66)
Median	2.0	2.0	2.0
Min, Max	1, 20	1, 30	1, 30
Fever			
n	7	52	59
Mean (SD)	1.3 (0.49)	1.1 (0.40)	1.2 (0.41)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Headache			
n	95	161	256
Mean (SD)	2.4 (2.47)	2.7 (2.96)	2.6 (2.78)
Median	2.0	2.0	2.0
Min, Max	1, 15	1, 22	1, 22
Fatigue			
n	93	165	258
Mean (SD)	3.4 (3.43)	2.8 (3.19)	3.0 (3.28)
Median	2.0	2.0	2.0
Min, Max	1, 19	1, 29	1, 29
Myalgia			
n	61	173	234
Mean (SD)	3.7 (4.15)	2.2 (2.54)	2.6 (3.09)
Median	2.0	2.0	2.0
Min, Max	1, 20	1, 27	1, 27
Arthralgia			
n	50	123	173
Mean (SD)	3.8 (4.33)	2.1 (1.65)	2.6 (2.80)
Median	2.0	2.0	2.0
Min, Max	1, 20	1, 11	1, 20

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=334)	mRNA-1273 (N=340)	Total (N=674)
Nausea/Vomiting			
n	34	62	96
Mean (SD)	1.6 (1.16)	1.7 (1.68)	1.7 (1.51)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 13	1, 13
Chills			
n	36	119	155
Mean (SD)	2.4 (2.23)	1.7 (1.32)	1.9 (1.59)
Median	1.0	1.0	1.0
Min, Max	1, 10	1, 10	1, 10

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=465)	mRNA-1273 (N=527)	Total (N=993)
Solicited Adverse Reactions			
n	300	493	793
Mean (SD)	4.2 (6.03)	4.4 (5.40)	4.3 (5.65)
Median	2.0	3.0	3.0
Min, Max	1, 50	1, 72	1, 72
Solicited Local Adverse Reactions			
n	160	483	643
Mean (SD)	2.1 (3.76)	3.2 (3.05)	2.9 (3.27)
Median	1.0	3.0	2.0
Min, Max	1, 38	1, 59	1, 59
Pain			
n	146	480	626
Mean (SD)	1.8 (2.50)	3.0 (2.94)	2.8 (2.89)
Median	1.0	3.0	2.0
Min, Max	1, 28	1, 59	1, 59
Erythema (Redness)			
n	5	44	49
Mean (SD)	8.4 (16.55)	2.3 (2.01)	2.9 (5.47)
Median	1.0	2.0	2.0
Min, Max	1, 38	1, 13	1, 38

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=465)	mRNA-1273 (N=527)	Total (N=993)
Swelling (Hardness)			
n	1	61	62
Mean (SD)	1.0 (NA)	2.2 (1.44)	2.1 (1.44)
Median	1.0	2.0	2.0
Min, Max	1, 1	1, 7	1, 7
Lymphadenopathy [1]			
n	44	93	137
Mean (SD)	1.8 (1.22)	2.1 (1.88)	2.0 (1.70)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 9	1, 9
Solicited Systemic Adverse Reactions			
n	267	423	690
Mean (SD)	4.3 (5.93)	3.5 (5.86)	3.8 (5.89)
Median	2.0	2.0	2.0
Min, Max	1, 49	1, 72	1, 72
Fever			
n	2	55	57
Mean (SD)	1.0 (0.00)	2.1 (7.68)	2.1 (7.54)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 58	1, 58

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=465)	mRNA-1273 (N=527)	Total (N=993)
Headache			
n	196	306	502
Mean (SD)	2.4 (2.51)	2.4 (3.72)	2.4 (3.29)
Median	2.0	2.0	2.0
Min, Max	1, 24	1, 59	1, 59
Fatigue			
n	199	338	537
Mean (SD)	3.2 (4.25)	3.0 (5.13)	3.1 (4.82)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 60	1, 60
Myalgia			
n	125	305	430
Mean (SD)	4.0 (6.73)	2.6 (5.00)	3.0 (5.59)
Median	2.0	2.0	2.0
Min, Max	1, 48	1, 58	1, 58
Arthralgia			
n	105	221	326
Mean (SD)	4.2 (6.77)	2.6 (5.23)	3.1 (5.81)
Median	2.0	2.0	2.0
Min, Max	1, 48	1, 70	1, 70

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.9
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=465)	mRNA-1273 (N=527)	Total (N=993)
Nausea/Vomiting			
n	53	120	173
Mean (SD)	2.3 (3.09)	1.7 (1.45)	1.9 (2.11)
Median	1.0	1.0	1.0
Min, Max	1, 19	1, 13	1, 19
Chills			
n	55	199	254
Mean (SD)	1.7 (1.12)	1.7 (4.22)	1.7 (3.77)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 58	1, 58

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Solicited Adverse Reactions - N1	11406	11405	22812
Any Solicited Adverse Reactions	712 (6.2)	888 (7.8)	1600 (7.0)
95% CI	5.8, 6.7	7.3, 8.3	6.7, 7.4
Grade 1	301 (2.6)	403 (3.5)	704 (3.1)
Grade 2	330 (2.9)	395 (3.5)	725 (3.2)
Grade 3	81 (0.7)	90 (0.8)	171 (0.7)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	11404	11401	22806
Any Solicited Local Adverse Reactions	85 (0.7)	303 (2.7)	388 (1.7)
95% CI	0.6, 0.9	2.4, 3.0	1.5, 1.9
Grade 1	68 (0.6)	212 (1.9)	280 (1.2)
Grade 2	14 (0.1)	74 (0.6)	88 (0.4)
Grade 3	3 (<0.1)	17 (0.1)	20 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Pain - N1	11404	11401	22806
Any	38 (0.3)	81 (0.7)	119 (0.5)
Grade 1	31 (0.3)	44 (0.4)	75 (0.3)
Grade 2	5 (<0.1)	29 (0.3)	34 (0.1)
Grade 3	2 (<0.1)	8 (<0.1)	10 (<0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	11404	11401	22806
Any	3 (<0.1)	13 (0.1)	16 (<0.1)
Grade 1	2 (<0.1)	6 (<0.1)	8 (<0.1)
Grade 2	0	5 (<0.1)	5 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	11404	11401	22806
Any	4 (<0.1)	19 (0.2)	23 (0.1)
Grade 1	2 (<0.1)	12 (0.1)	14 (<0.1)
Grade 2	1 (<0.1)	7 (<0.1)	8 (<0.1)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Lymphadenopathy - N1 [1]	11404	11401	22806
Any	49 (0.4)	223 (2.0)	272 (1.2)
Grade 1	40 (0.4)	172 (1.5)	212 (0.9)
Grade 2	9 (<0.1)	43 (0.4)	52 (0.2)
Grade 3	0	8 (<0.1)	8 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	11406	11405	22812
Any Solicited Systemic Adverse Reactions	661 (5.8)	671 (5.9)	1332 (5.8)
95% CI	5.4, 6.2	5.5, 6.3	5.5, 6.2
Grade 1	257 (2.3)	244 (2.1)	501 (2.2)
Grade 2	325 (2.8)	349 (3.1)	674 (3.0)
Grade 3	79 (0.7)	78 (0.7)	157 (0.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Fever - N1	11404	11403	22808
Any	3 (<0.1)	3 (<0.1)	6 (<0.1)
Grade 1	3 (<0.1)	1 (<0.1)	4 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Headache - N1	11404	11401	22806
Any	256 (2.2)	284 (2.5)	540 (2.4)
Grade 1	122 (1.1)	144 (1.3)	266 (1.2)
Grade 2	95 (0.8)	112 (1.0)	207 (0.9)
Grade 3	39 (0.3)	28 (0.2)	67 (0.3)
Grade 4	0	0	0
Fatigue - N1	11404	11401	22806
Any	367 (3.2)	391 (3.4)	758 (3.3)
Grade 1	113 (1.0)	108 (0.9)	221 (1.0)
Grade 2	218 (1.9)	242 (2.1)	460 (2.0)
Grade 3	36 (0.3)	41 (0.4)	77 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1). 95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Myalgia - N1	11404	11401	22806
Any	174 (1.5)	163 (1.4)	337 (1.5)
Grade 1	64 (0.6)	53 (0.5)	117 (0.5)
Grade 2	91 (0.8)	84 (0.7)	175 (0.8)
Grade 3	19 (0.2)	26 (0.2)	45 (0.2)
Grade 4	0	0	0
Arthralgia - N1	11404	11401	22806
Any	191 (1.7)	167 (1.5)	358 (1.6)
Grade 1	82 (0.7)	68 (0.6)	150 (0.7)
Grade 2	95 (0.8)	80 (0.7)	175 (0.8)
Grade 3	14 (0.1)	19 (0.2)	33 (0.1)
Grade 4	0	0	0
Nausea/Vomiting - N1	11404	11401	22806
Any	56 (0.5)	55 (0.5)	111 (0.5)
Grade 1	32 (0.3)	30 (0.3)	62 (0.3)
Grade 2	23 (0.2)	25 (0.2)	48 (0.2)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11406) n (%)	mRNA-1273 (N=11405) n (%)	Total (N=22812) n (%)
Chills - N1	11404	11401	22806
Any	39 (0.3)	29 (0.3)	68 (0.3)
Grade 1	21 (0.2)	8 (<0.1)	29 (0.1)
Grade 2	17 (0.1)	18 (0.2)	35 (0.2)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Solicited Adverse Reactions - N1	3748	3762	7510
Any Solicited Adverse Reactions	214 (5.7)	225 (6.0)	439 (5.8)
95% CI	5.0, 6.5	5.2, 6.8	5.3, 6.4
Grade 1	112 (3.0)	103 (2.7)	215 (2.9)
Grade 2	85 (2.3)	101 (2.7)	186 (2.5)
Grade 3	17 (0.5)	21 (0.6)	38 (0.5)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	3746	3762	7508
Any Solicited Local Adverse Reactions	24 (0.6)	25 (0.7)	49 (0.7)
95% CI	0.4, 1.0	0.4, 1.0	0.5, 0.9
Grade 1	14 (0.4)	16 (0.4)	30 (0.4)
Grade 2	9 (0.2)	6 (0.2)	15 (0.2)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Pain - N1	3746	3762	7508
Any	11 (0.3)	8 (0.2)	19 (0.3)
Grade 1	8 (0.2)	4 (0.1)	12 (0.2)
Grade 2	3 (<0.1)	3 (<0.1)	6 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	3746	3761	7507
Any	2 (<0.1)	6 (0.2)	8 (0.1)
Grade 1	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 2	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	3746	3761	7507
Any	6 (0.2)	2 (<0.1)	8 (0.1)
Grade 1	4 (0.1)	1 (<0.1)	5 (<0.1)
Grade 2	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Lymphadenopathy - N1 [1]	3746	3761	7507
Any	8 (0.2)	11 (0.3)	19 (0.3)
Grade 1	4 (0.1)	9 (0.2)	13 (0.2)
Grade 2	4 (0.1)	1 (<0.1)	5 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	3748	3761	7509
Any Solicited Systemic Adverse Reactions	195 (5.2)	208 (5.5)	403 (5.4)
95% CI	4.5, 6.0	4.8, 6.3	4.9, 5.9
Grade 1	102 (2.7)	90 (2.4)	192 (2.6)
Grade 2	77 (2.1)	98 (2.6)	175 (2.3)
Grade 3	16 (0.4)	20 (0.5)	36 (0.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Fever - N1	3748	3760	7508
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	3745	3761	7506
Any	55 (1.5)	56 (1.5)	111 (1.5)
Grade 1	35 (0.9)	34 (0.9)	69 (0.9)
Grade 2	15 (0.4)	13 (0.3)	28 (0.4)
Grade 3	5 (0.1)	9 (0.2)	14 (0.2)
Grade 4	0	0	0
Fatigue - N1	3745	3761	7506
Any	107 (2.9)	132 (3.5)	239 (3.2)
Grade 1	47 (1.3)	46 (1.2)	93 (1.2)
Grade 2	48 (1.3)	73 (1.9)	121 (1.6)
Grade 3	12 (0.3)	13 (0.3)	25 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Myalgia - N1	3745	3761	7506
Any	71 (1.9)	64 (1.7)	135 (1.8)
Grade 1	37 (1.0)	30 (0.8)	67 (0.9)
Grade 2	31 (0.8)	28 (0.7)	59 (0.8)
Grade 3	3 (<0.1)	6 (0.2)	9 (0.1)
Grade 4	0	0	0
Arthralgia - N1	3745	3761	7506
Any	90 (2.4)	82 (2.2)	172 (2.3)
Grade 1	56 (1.5)	36 (1.0)	92 (1.2)
Grade 2	29 (0.8)	39 (1.0)	68 (0.9)
Grade 3	5 (0.1)	7 (0.2)	12 (0.2)
Grade 4	0	0	0
Nausea/Vomiting - N1	3745	3761	7506
Any	10 (0.3)	11 (0.3)	21 (0.3)
Grade 1	8 (0.2)	6 (0.2)	14 (0.2)
Grade 2	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.4

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3748) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7510) n (%)
Chills - N1	3745	3761	7506
Any	7 (0.2)	6 (0.2)	13 (0.2)
Grade 1	5 (0.1)	4 (0.1)	9 (0.1)
Grade 2	2 (<0.1)	0	2 (<0.1)
Grade 3	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Solicited Adverse Reactions - N1	10321	10358	20679
Any Solicited Adverse Reactions	552 (5.3)	726 (7.0)	1278 (6.2)
95% CI	4.9, 5.8	6.5, 7.5	5.9, 6.5
Grade 1	227 (2.2)	155 (1.5)	382 (1.8)
Grade 2	254 (2.5)	371 (3.6)	625 (3.0)
Grade 3	71 (0.7)	200 (1.9)	271 (1.3)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	10317	10357	20674
Any Solicited Local Adverse Reactions	84 (0.8)	213 (2.1)	297 (1.4)
95% CI	0.6, 1.0	1.8, 2.3	1.3, 1.6
Grade 1	67 (0.6)	78 (0.8)	145 (0.7)
Grade 2	9 (<0.1)	89 (0.9)	98 (0.5)
Grade 3	8 (<0.1)	46 (0.4)	54 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1). 95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Pain - N1	10317	10357	20674
Any	40 (0.4)	110 (1.1)	150 (0.7)
Grade 1	29 (0.3)	33 (0.3)	62 (0.3)
Grade 2	5 (<0.1)	56 (0.5)	61 (0.3)
Grade 3	6 (<0.1)	21 (0.2)	27 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	10317	10357	20674
Any	2 (<0.1)	29 (0.3)	31 (0.1)
Grade 1	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 2	0	10 (<0.1)	10 (<0.1)
Grade 3	0	17 (0.2)	17 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	10317	10357	20674
Any	6 (<0.1)	34 (0.3)	40 (0.2)
Grade 1	5 (<0.1)	11 (0.1)	16 (<0.1)
Grade 2	0	13 (0.1)	13 (<0.1)
Grade 3	1 (<0.1)	10 (<0.1)	11 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Lymphadenopathy - N1 [1]	10317	10357	20674
Any	42 (0.4)	79 (0.8)	121 (0.6)
Grade 1	37 (0.4)	53 (0.5)	90 (0.4)
Grade 2	4 (<0.1)	21 (0.2)	25 (0.1)
Grade 3	1 (<0.1)	5 (<0.1)	6 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	10320	10358	20678
Any Solicited Systemic Adverse Reactions	505 (4.9)	602 (5.8)	1107 (5.4)
95% CI	4.5, 5.3	5.4, 6.3	5.1, 5.7
Grade 1	189 (1.8)	106 (1.0)	295 (1.4)
Grade 2	252 (2.4)	331 (3.2)	583 (2.8)
Grade 3	64 (0.6)	165 (1.6)	229 (1.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Fever - N1	10315	10352	20667
Any	1 (<0.1)	4 (<0.1)	5 (<0.1)
Grade 1	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Headache - N1	10317	10357	20674
Any	231 (2.2)	314 (3.0)	545 (2.6)
Grade 1	111 (1.1)	76 (0.7)	187 (0.9)
Grade 2	94 (0.9)	186 (1.8)	280 (1.4)
Grade 3	26 (0.3)	52 (0.5)	78 (0.4)
Grade 4	0	0	0
Fatigue - N1	10315	10357	20672
Any	277 (2.7)	353 (3.4)	630 (3.0)
Grade 1	80 (0.8)	47 (0.5)	127 (0.6)
Grade 2	160 (1.6)	198 (1.9)	358 (1.7)
Grade 3	37 (0.4)	108 (1.0)	145 (0.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Myalgia - N1	10316	10357	20673
Any	162 (1.6)	166 (1.6)	328 (1.6)
Grade 1	58 (0.6)	29 (0.3)	87 (0.4)
Grade 2	83 (0.8)	93 (0.9)	176 (0.9)
Grade 3	21 (0.2)	44 (0.4)	65 (0.3)
Grade 4	0	0	0
Arthralgia - N1	10315	10357	20672
Any	173 (1.7)	177 (1.7)	350 (1.7)
Grade 1	64 (0.6)	37 (0.4)	101 (0.5)
Grade 2	93 (0.9)	108 (1.0)	201 (1.0)
Grade 3	16 (0.2)	32 (0.3)	48 (0.2)
Grade 4	0	0	0
Nausea/Vomiting - N1	10315	10357	20672
Any	43 (0.4)	50 (0.5)	93 (0.4)
Grade 1	18 (0.2)	10 (<0.1)	28 (0.1)
Grade 2	24 (0.2)	38 (0.4)	62 (0.3)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10321) n (%)	mRNA-1273 (N=10358) n (%)	Total (N=20679) n (%)
Chills - N1	10315	10357	20672
Any	36 (0.3)	42 (0.4)	78 (0.4)
Grade 1	15 (0.1)	9 (<0.1)	24 (0.1)
Grade 2	16 (0.2)	25 (0.2)	41 (0.2)
Grade 3	5 (<0.1)	8 (<0.1)	13 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Solicited Adverse Reactions - N1	3549	3589	7138
Any Solicited Adverse Reactions	181 (5.1)	241 (6.7)	422 (5.9)
95% CI	4.4, 5.9	5.9, 7.6	5.4, 6.5
Grade 1	90 (2.5)	68 (1.9)	158 (2.2)
Grade 2	74 (2.1)	112 (3.1)	186 (2.6)
Grade 3	17 (0.5)	60 (1.7)	77 (1.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	3549	3587	7136
Any Solicited Local Adverse Reactions	21 (0.6)	66 (1.8)	87 (1.2)
95% CI	0.4, 0.9	1.4, 2.3	1.0, 1.5
Grade 1	16 (0.5)	27 (0.8)	43 (0.6)
Grade 2	4 (0.1)	25 (0.7)	29 (0.4)
Grade 3	1 (<0.1)	14 (0.4)	15 (0.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Pain - N1	3549	3587	7136
Any	14 (0.4)	39 (1.1)	53 (0.7)
Grade 1	9 (0.3)	19 (0.5)	28 (0.4)
Grade 2	5 (0.1)	17 (0.5)	22 (0.3)
Grade 3	0	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	3549	3587	7136
Any	1 (<0.1)	22 (0.6)	23 (0.3)
Grade 1	1 (<0.1)	6 (0.2)	7 (<0.1)
Grade 2	0	6 (0.2)	6 (<0.1)
Grade 3	0	10 (0.3)	10 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	3549	3587	7136
Any	2 (<0.1)	10 (0.3)	12 (0.2)
Grade 1	2 (<0.1)	5 (0.1)	7 (<0.1)
Grade 2	0	2 (<0.1)	2 (<0.1)
Grade 3	0	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Lymphadenopathy - N1 [1]	3549	3587	7136
Any	5 (0.1)	6 (0.2)	11 (0.2)
Grade 1	4 (0.1)	5 (0.1)	9 (0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	3549	3589	7138
Any Solicited Systemic Adverse Reactions	170 (4.8)	194 (5.4)	364 (5.1)
95% CI	4.1, 5.5	4.7, 6.2	4.6, 5.6
Grade 1	83 (2.3)	49 (1.4)	132 (1.8)
Grade 2	71 (2.0)	98 (2.7)	169 (2.4)
Grade 3	16 (0.5)	46 (1.3)	62 (0.9)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Fever - N1	3549	3587	7136
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	3549	3587	7136
Any	58 (1.6)	57 (1.6)	115 (1.6)
Grade 1	34 (1.0)	22 (0.6)	56 (0.8)
Grade 2	22 (0.6)	31 (0.9)	53 (0.7)
Grade 3	2 (<0.1)	4 (0.1)	6 (<0.1)
Grade 4	0	0	0
Fatigue - N1	3549	3587	7136
Any	93 (2.6)	110 (3.1)	203 (2.8)
Grade 1	36 (1.0)	21 (0.6)	57 (0.8)
Grade 2	47 (1.3)	53 (1.5)	100 (1.4)
Grade 3	10 (0.3)	36 (1.0)	46 (0.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Myalgia - N1	3549	3587	7136
Any	50 (1.4)	58 (1.6)	108 (1.5)
Grade 1	25 (0.7)	13 (0.4)	38 (0.5)
Grade 2	21 (0.6)	32 (0.9)	53 (0.7)
Grade 3	4 (0.1)	13 (0.4)	17 (0.2)
Grade 4	0	0	0
Arthralgia - N1	3549	3587	7136
Any	76 (2.1)	72 (2.0)	148 (2.1)
Grade 1	40 (1.1)	19 (0.5)	59 (0.8)
Grade 2	32 (0.9)	38 (1.1)	70 (1.0)
Grade 3	4 (0.1)	15 (0.4)	19 (0.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	3549	3587	7136
Any	6 (0.2)	8 (0.2)	14 (0.2)
Grade 1	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 2	4 (0.1)	2 (<0.1)	6 (<0.1)
Grade 3	0	3 (<0.1)	3 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.5
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3549) n (%)	mRNA-1273 (N=3589) n (%)	Total (N=7138) n (%)
Chills - N1	3549	3587	7136
Any	12 (0.3)	10 (0.3)	22 (0.3)
Grade 1	7 (0.2)	2 (<0.1)	9 (0.1)
Grade 2	5 (0.1)	7 (0.2)	12 (0.2)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Solicited Adverse Reactions - N1	11412	11410	22823
Any Solicited Adverse Reactions	1103 (9.7)	1400 (12.3)	2503 (11.0)
95% CI	9.1, 10.2	11.7, 12.9	10.6, 11.4
Grade 1	443 (3.9)	460 (4.0)	903 (4.0)
Grade 2	515 (4.5)	664 (5.8)	1179 (5.2)
Grade 3	145 (1.3)	276 (2.4)	421 (1.8)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	11411	11410	22822
Any Solicited Local Adverse Reactions	155 (1.4)	475 (4.2)	630 (2.8)
95% CI	1.2, 1.6	3.8, 4.5	2.6, 3.0
Grade 1	121 (1.1)	264 (2.3)	385 (1.7)
Grade 2	23 (0.2)	148 (1.3)	171 (0.7)
Grade 3	11 (<0.1)	63 (0.6)	74 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Pain - N1	11411	11410	22822
Any	73 (0.6)	176 (1.5)	249 (1.1)
Grade 1	55 (0.5)	69 (0.6)	124 (0.5)
Grade 2	10 (<0.1)	78 (0.7)	88 (0.4)
Grade 3	8 (<0.1)	29 (0.3)	37 (0.2)
Grade 4	0	0	0
Erythema (Redness) - N1	11411	11410	22822
Any	4 (<0.1)	40 (0.4)	44 (0.2)
Grade 1	3 (<0.1)	7 (<0.1)	10 (<0.1)
Grade 2	0	14 (0.1)	14 (<0.1)
Grade 3	1 (<0.1)	19 (0.2)	20 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	11411	11410	22822
Any	10 (<0.1)	53 (0.5)	63 (0.3)
Grade 1	7 (<0.1)	23 (0.2)	30 (0.1)
Grade 2	1 (<0.1)	20 (0.2)	21 (<0.1)
Grade 3	2 (<0.1)	10 (<0.1)	12 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Lymphadenopathy - N1 [1]	11411	11410	22822
Any	83 (0.7)	280 (2.5)	363 (1.6)
Grade 1	69 (0.6)	208 (1.8)	277 (1.2)
Grade 2	13 (0.1)	59 (0.5)	72 (0.3)
Grade 3	1 (<0.1)	13 (0.1)	14 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	11412	11410	22823
Any Solicited Systemic Adverse Reactions	1020 (8.9)	1114 (9.8)	2134 (9.4)
95% CI	8.4, 9.5	9.2, 10.3	9.0, 9.7
Grade 1	375 (3.3)	292 (2.6)	667 (2.9)
Grade 2	509 (4.5)	591 (5.2)	1100 (4.8)
Grade 3	136 (1.2)	231 (2.0)	367 (1.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Fever - N1	11411	11409	22821
Any	4 (<0.1)	7 (<0.1)	11 (<0.1)
Grade 1	4 (<0.1)	3 (<0.1)	7 (<0.1)
Grade 2	0	2 (<0.1)	2 (<0.1)
Grade 3	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Headache - N1	11411	11410	22822
Any	453 (4.0)	548 (4.8)	1001 (4.4)
Grade 1	213 (1.9)	192 (1.7)	405 (1.8)
Grade 2	177 (1.6)	277 (2.4)	454 (2.0)
Grade 3	63 (0.6)	79 (0.7)	142 (0.6)
Grade 4	0	0	0
Fatigue - N1	11411	11410	22822
Any	574 (5.0)	656 (5.7)	1230 (5.4)
Grade 1	168 (1.5)	130 (1.1)	298 (1.3)
Grade 2	337 (3.0)	385 (3.4)	722 (3.2)
Grade 3	69 (0.6)	141 (1.2)	210 (0.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1). 95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Myalgia - N1	11411	11410	22822
Any	307 (2.7)	304 (2.7)	611 (2.7)
Grade 1	108 (0.9)	72 (0.6)	180 (0.8)
Grade 2	159 (1.4)	165 (1.4)	324 (1.4)
Grade 3	40 (0.4)	67 (0.6)	107 (0.5)
Grade 4	0	0	0
Arthralgia - N1	11411	11410	22822
Any	322 (2.8)	301 (2.6)	623 (2.7)
Grade 1	121 (1.1)	81 (0.7)	202 (0.9)
Grade 2	171 (1.5)	174 (1.5)	345 (1.5)
Grade 3	30 (0.3)	46 (0.4)	76 (0.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	11411	11410	22822
Any	89 (0.8)	99 (0.9)	188 (0.8)
Grade 1	45 (0.4)	36 (0.3)	81 (0.4)
Grade 2	42 (0.4)	61 (0.5)	103 (0.5)
Grade 3	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11412) n (%)	mRNA-1273 (N=11410) n (%)	Total (N=22823) n (%)
Chills - N1	11411	11410	22822
Any	72 (0.6)	68 (0.6)	140 (0.6)
Grade 1	35 (0.3)	16 (0.1)	51 (0.2)
Grade 2	31 (0.3)	42 (0.4)	73 (0.3)
Grade 3	6 (<0.1)	10 (<0.1)	16 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Solicited Adverse Reactions - N1	3750	3766	7516
Any Solicited Adverse Reactions	333 (8.9)	411 (10.9)	744 (9.9)
95% CI	8.0, 9.8	9.9, 12.0	9.2, 10.6
Grade 1	168 (4.5)	143 (3.8)	311 (4.1)
Grade 2	132 (3.5)	189 (5.0)	321 (4.3)
Grade 3	33 (0.9)	78 (2.1)	111 (1.5)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	3750	3766	7516
Any Solicited Local Adverse Reactions	41 (1.1)	86 (2.3)	127 (1.7)
95% CI	0.8, 1.5	1.8, 2.8	1.4, 2.0
Grade 1	26 (0.7)	39 (1.0)	65 (0.9)
Grade 2	13 (0.3)	30 (0.8)	43 (0.6)
Grade 3	2 (<0.1)	17 (0.5)	19 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1). 95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Pain - N1	3750	3766	7516
Any	24 (0.6)	44 (1.2)	68 (0.9)
Grade 1	16 (0.4)	21 (0.6)	37 (0.5)
Grade 2	8 (0.2)	19 (0.5)	27 (0.4)
Grade 3	0	4 (0.1)	4 (<0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	3750	3766	7516
Any	3 (<0.1)	28 (0.7)	31 (0.4)
Grade 1	2 (<0.1)	9 (0.2)	11 (0.1)
Grade 2	1 (<0.1)	8 (0.2)	9 (0.1)
Grade 3	0	11 (0.3)	11 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	3750	3766	7516
Any	7 (0.2)	12 (0.3)	19 (0.3)
Grade 1	5 (0.1)	6 (0.2)	11 (0.1)
Grade 2	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1). 95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Lymphadenopathy - N1 [1]	3750	3766	7516
Any	11 (0.3)	16 (0.4)	27 (0.4)
Grade 1	6 (0.2)	13 (0.3)	19 (0.3)
Grade 2	4 (0.1)	2 (<0.1)	6 (<0.1)
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	3750	3766	7516
Any Solicited Systemic Adverse Reactions	305 (8.1)	354 (9.4)	659 (8.8)
95% CI	7.3, 9.1	8.5, 10.4	8.1, 9.4
Grade 1	153 (4.1)	118 (3.1)	271 (3.6)
Grade 2	121 (3.2)	172 (4.6)	293 (3.9)
Grade 3	31 (0.8)	63 (1.7)	94 (1.3)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Fever - N1	3750	3766	7516
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	3750	3766	7516
Any	102 (2.7)	107 (2.8)	209 (2.8)
Grade 1	61 (1.6)	51 (1.4)	112 (1.5)
Grade 2	34 (0.9)	43 (1.1)	77 (1.0)
Grade 3	7 (0.2)	13 (0.3)	20 (0.3)
Grade 4	0	0	0
Fatigue - N1	3750	3766	7516
Any	169 (4.5)	218 (5.8)	387 (5.1)
Grade 1	69 (1.8)	57 (1.5)	126 (1.7)
Grade 2	78 (2.1)	112 (3.0)	190 (2.5)
Grade 3	22 (0.6)	49 (1.3)	71 (0.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Myalgia - N1	3750	3766	7516
Any	103 (2.7)	111 (2.9)	214 (2.8)
Grade 1	50 (1.3)	37 (1.0)	87 (1.2)
Grade 2	46 (1.2)	55 (1.5)	101 (1.3)
Grade 3	7 (0.2)	19 (0.5)	26 (0.3)
Grade 4	0	0	0
Arthralgia - N1	3750	3766	7516
Any	143 (3.8)	138 (3.7)	281 (3.7)
Grade 1	80 (2.1)	48 (1.3)	128 (1.7)
Grade 2	55 (1.5)	69 (1.8)	124 (1.6)
Grade 3	8 (0.2)	21 (0.6)	29 (0.4)
Grade 4	0	0	0
Nausea/Vomiting - N1	3750	3766	7516
Any	15 (0.4)	19 (0.5)	34 (0.5)
Grade 1	9 (0.2)	8 (0.2)	17 (0.2)
Grade 2	6 (0.2)	5 (0.1)	11 (0.1)
Grade 3	0	5 (0.1)	5 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.6

Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3750) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7516) n (%)
Chills - N1	3750	3766	7516
Any	17 (0.5)	16 (0.4)	33 (0.4)
Grade 1	11 (0.3)	6 (0.2)	17 (0.2)
Grade 2	6 (0.2)	7 (0.2)	13 (0.2)
Grade 3	0	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Solicited Adverse Reactions - N1	14356	14301	28657
Any Solicited Adverse Reactions	857 (6.0)	1053 (7.4)	1910 (6.7)
95% CI	5.6, 6.4	6.9, 7.8	6.4, 7.0
Grade 1	384 (2.7)	485 (3.4)	869 (3.0)
Grade 2	385 (2.7)	464 (3.2)	849 (3.0)
Grade 3	88 (0.6)	104 (0.7)	192 (0.7)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	14353	14297	28650
Any Solicited Local Adverse Reactions	102 (0.7)	315 (2.2)	417 (1.5)
95% CI	0.6, 0.9	2.0, 2.5	1.3, 1.6
Grade 1	75 (0.5)	216 (1.5)	291 (1.0)
Grade 2	23 (0.2)	80 (0.6)	103 (0.4)
Grade 3	4 (<0.1)	19 (0.1)	23 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Pain - N1	14353	14297	28650
Any	46 (0.3)	84 (0.6)	130 (0.5)
Grade 1	36 (0.3)	44 (0.3)	80 (0.3)
Grade 2	8 (<0.1)	32 (0.2)	40 (0.1)
Grade 3	2 (<0.1)	8 (<0.1)	10 (<0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	14353	14296	28649
Any	5 (<0.1)	18 (0.1)	23 (<0.1)
Grade 1	3 (<0.1)	8 (<0.1)	11 (<0.1)
Grade 2	1 (<0.1)	7 (<0.1)	8 (<0.1)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	14353	14296	28649
Any	10 (<0.1)	20 (0.1)	30 (0.1)
Grade 1	6 (<0.1)	12 (<0.1)	18 (<0.1)
Grade 2	2 (<0.1)	8 (<0.1)	10 (<0.1)
Grade 3	2 (<0.1)	0	2 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Lymphadenopathy - N1 [1]	14353	14296	28649
Any	52 (0.4)	226 (1.6)	278 (1.0)
Grade 1	39 (0.3)	174 (1.2)	213 (0.7)
Grade 2	13 (<0.1)	43 (0.3)	56 (0.2)
Grade 3	0	9 (<0.1)	9 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14356	14300	28656
Any Solicited Systemic Adverse Reactions	792 (5.5)	830 (5.8)	1622 (5.7)
95% CI	5.1, 5.9	5.4, 6.2	5.4, 5.9
Grade 1	335 (2.3)	324 (2.3)	659 (2.3)
Grade 2	372 (2.6)	415 (2.9)	787 (2.7)
Grade 3	85 (0.6)	91 (0.6)	176 (0.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Fever - N1	14355	14298	28653
Any	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 1	3 (<0.1)	0	3 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Headache - N1	14352	14296	28648
Any	287 (2.0)	318 (2.2)	605 (2.1)
Grade 1	150 (1.0)	170 (1.2)	320 (1.1)
Grade 2	99 (0.7)	114 (0.8)	213 (0.7)
Grade 3	38 (0.3)	34 (0.2)	72 (0.3)
Grade 4	0	0	0
Fatigue - N1	14352	14296	28648
Any	438 (3.1)	491 (3.4)	929 (3.2)
Grade 1	145 (1.0)	148 (1.0)	293 (1.0)
Grade 2	250 (1.7)	292 (2.0)	542 (1.9)
Grade 3	43 (0.3)	51 (0.4)	94 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Myalgia - N1	14352	14296	28648
Any	221 (1.5)	210 (1.5)	431 (1.5)
Grade 1	93 (0.6)	77 (0.5)	170 (0.6)
Grade 2	108 (0.8)	104 (0.7)	212 (0.7)
Grade 3	20 (0.1)	29 (0.2)	49 (0.2)
Grade 4	0	0	0
Arthralgia - N1	14352	14296	28648
Any	260 (1.8)	237 (1.7)	497 (1.7)
Grade 1	130 (0.9)	101 (0.7)	231 (0.8)
Grade 2	113 (0.8)	112 (0.8)	225 (0.8)
Grade 3	17 (0.1)	24 (0.2)	41 (0.1)
Grade 4	0	0	0
Nausea/Vomiting - N1	14352	14296	28648
Any	61 (0.4)	63 (0.4)	124 (0.4)
Grade 1	38 (0.3)	34 (0.2)	72 (0.3)
Grade 2	22 (0.2)	27 (0.2)	49 (0.2)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14356) n (%)	mRNA-1273 (N=14301) n (%)	Total (N=28657) n (%)
Chills - N1	14352	14296	28648
Any	43 (0.3)	34 (0.2)	77 (0.3)
Grade 1	24 (0.2)	12 (<0.1)	36 (0.1)
Grade 2	19 (0.1)	17 (0.1)	36 (0.1)
Grade 3	0	5 (<0.1)	5 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Solicited Adverse Reactions - N1	334	340	674
Any Solicited Adverse Reactions	24 (7.2)	22 (6.5)	46 (6.8)
95% CI	4.7, 10.5	4.1, 9.6	5.0, 9.0
Grade 1	6 (1.8)	7 (2.1)	13 (1.9)
Grade 2	12 (3.6)	11 (3.2)	23 (3.4)
Grade 3	6 (1.8)	4 (1.2)	10 (1.5)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	334	340	674
Any Solicited Local Adverse Reactions	3 (0.9)	5 (1.5)	8 (1.2)
95% CI	0.2, 2.6	0.5, 3.4	0.5, 2.3
Grade 1	3 (0.9)	4 (1.2)	7 (1.0)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Pain - N1	334	340	674
Any	1 (0.3)	3 (0.9)	4 (0.6)
Grade 1	1 (0.3)	2 (0.6)	3 (0.4)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	334	340	674
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Swelling (Hardness) - N1	334	340	674
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Lymphadenopathy - N1 [1]	334	340	674
Any	3 (0.9)	2 (0.6)	5 (0.7)
Grade 1	3 (0.9)	1 (0.3)	4 (0.6)
Grade 2	0	1 (0.3)	1 (0.1)
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	334	340	674
Any Solicited Systemic Adverse Reactions	22 (6.6)	18 (5.3)	40 (5.9)
95% CI	4.2, 9.8	3.2, 8.2	4.3, 8.0
Grade 1	4 (1.2)	3 (0.9)	7 (1.0)
Grade 2	12 (3.6)	11 (3.2)	23 (3.4)
Grade 3	6 (1.8)	4 (1.2)	10 (1.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Fever - N1	333	340	673
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	334	340	674
Any	10 (3.0)	13 (3.8)	23 (3.4)
Grade 1	2 (0.6)	4 (1.2)	6 (0.9)
Grade 2	5 (1.5)	6 (1.8)	11 (1.6)
Grade 3	3 (0.9)	3 (0.9)	6 (0.9)
Grade 4	0	0	0
Fatigue - N1	334	340	674
Any	14 (4.2)	9 (2.6)	23 (3.4)
Grade 1	3 (0.9)	2 (0.6)	5 (0.7)
Grade 2	9 (2.7)	6 (1.8)	15 (2.2)
Grade 3	2 (0.6)	1 (0.3)	3 (0.4)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Myalgia - N1	334	340	674
Any	11 (3.3)	7 (2.1)	18 (2.7)
Grade 1	2 (0.6)	3 (0.9)	5 (0.7)
Grade 2	8 (2.4)	4 (1.2)	12 (1.8)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Arthralgia - N1	334	340	674
Any	8 (2.4)	3 (0.9)	11 (1.6)
Grade 1	1 (0.3)	0	1 (0.1)
Grade 2	6 (1.8)	3 (0.9)	9 (1.3)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Nausea/Vomiting - N1	334	340	674
Any	1 (0.3)	1 (0.3)	2 (0.3)
Grade 1	0	0	0
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Chills - N1	334	340	674
Any	3 (0.9)	1 (0.3)	4 (0.6)
Grade 1	2 (0.6)	0	2 (0.3)
Grade 2	0	1 (0.3)	1 (0.1)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Solicited Adverse Reactions - N1	464	526	991
Any Solicited Adverse Reactions	45 (9.7)	38 (7.2)	83 (8.4)
95% CI	7.2, 12.8	5.2, 9.8	6.7, 10.3
Grade 1	23 (5.0)	14 (2.7)	37 (3.7)
Grade 2	18 (3.9)	21 (4.0)	39 (3.9)
Grade 3	4 (0.9)	3 (0.6)	7 (0.7)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	463	526	990
Any Solicited Local Adverse Reactions	4 (0.9)	8 (1.5)	12 (1.2)
95% CI	0.2, 2.2	0.7, 3.0	0.6, 2.1
Grade 1	4 (0.9)	8 (1.5)	12 (1.2)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Pain - N1	463	526	990
Any	2 (0.4)	2 (0.4)	4 (0.4)
Grade 1	2 (0.4)	2 (0.4)	4 (0.4)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Erythema (Redness) - N1	463	526	990
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Swelling (Hardness) - N1	463	526	990
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Lymphadenopathy - N1 [1]	463	526	990
Any	2 (0.4)	6 (1.1)	8 (0.8)
Grade 1	2 (0.4)	6 (1.1)	8 (0.8)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	464	526	991
Any Solicited Systemic Adverse Reactions	42 (9.1)	31 (5.9)	73 (7.4)
95% CI	6.6, 12.0	4.0, 8.3	5.8, 9.2
Grade 1	20 (4.3)	7 (1.3)	27 (2.7)
Grade 2	18 (3.9)	21 (4.0)	39 (3.9)
Grade 3	4 (0.9)	3 (0.6)	7 (0.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Fever - N1	464	525	990
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	463	526	990
Any	14 (3.0)	9 (1.7)	23 (2.3)
Grade 1	5 (1.1)	4 (0.8)	9 (0.9)
Grade 2	6 (1.3)	5 (1.0)	11 (1.1)
Grade 3	3 (0.6)	0	3 (0.3)
Grade 4	0	0	0
Fatigue - N1	463	526	990
Any	22 (4.8)	23 (4.4)	45 (4.5)
Grade 1	12 (2.6)	4 (0.8)	16 (1.6)
Grade 2	7 (1.5)	17 (3.2)	24 (2.4)
Grade 3	3 (0.6)	2 (0.4)	5 (0.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Myalgia - N1	463	526	990
Any	13 (2.8)	10 (1.9)	23 (2.3)
Grade 1	6 (1.3)	3 (0.6)	9 (0.9)
Grade 2	6 (1.3)	4 (0.8)	10 (1.0)
Grade 3	1 (0.2)	3 (0.6)	4 (0.4)
Grade 4	0	0	0
Arthralgia - N1	463	526	990
Any	13 (2.8)	9 (1.7)	22 (2.2)
Grade 1	7 (1.5)	3 (0.6)	10 (1.0)
Grade 2	5 (1.1)	4 (0.8)	9 (0.9)
Grade 3	1 (0.2)	2 (0.4)	3 (0.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	463	526	990
Any	4 (0.9)	2 (0.4)	6 (0.6)
Grade 1	2 (0.4)	2 (0.4)	4 (0.4)
Grade 2	2 (0.4)	0	2 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.7
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=464) n (%)	mRNA-1273 (N=526) n (%)	Total (N=991) n (%)
Chills - N1	463	526	990
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Solicited Adverse Reactions - N1	13252	13286	26538
Any Solicited Adverse Reactions	683 (5.2)	924 (7.0)	1607 (6.1)
95% CI	4.8, 5.5	6.5, 7.4	5.8, 6.3
Grade 1	293 (2.2)	218 (1.6)	511 (1.9)
Grade 2	308 (2.3)	455 (3.4)	763 (2.9)
Grade 3	82 (0.6)	250 (1.9)	332 (1.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	13249	13283	26532
Any Solicited Local Adverse Reactions	95 (0.7)	267 (2.0)	362 (1.4)
95% CI	0.6, 0.9	1.8, 2.3	1.2, 1.5
Grade 1	75 (0.6)	102 (0.8)	177 (0.7)
Grade 2	12 (<0.1)	107 (0.8)	119 (0.4)
Grade 3	8 (<0.1)	58 (0.4)	66 (0.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Pain - N1	13249	13283	26532
Any	50 (0.4)	140 (1.1)	190 (0.7)
Grade 1	35 (0.3)	51 (0.4)	86 (0.3)
Grade 2	10 (<0.1)	66 (0.5)	76 (0.3)
Grade 3	5 (<0.1)	23 (0.2)	28 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	13249	13283	26532
Any	2 (<0.1)	50 (0.4)	52 (0.2)
Grade 1	2 (<0.1)	8 (<0.1)	10 (<0.1)
Grade 2	0	16 (0.1)	16 (<0.1)
Grade 3	0	26 (0.2)	26 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	13249	13283	26532
Any	8 (<0.1)	43 (0.3)	51 (0.2)
Grade 1	7 (<0.1)	15 (0.1)	22 (<0.1)
Grade 2	0	15 (0.1)	15 (<0.1)
Grade 3	1 (<0.1)	13 (<0.1)	14 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Lymphadenopathy - N1 [1]	13249	13283	26532
Any	42 (0.3)	82 (0.6)	124 (0.5)
Grade 1	37 (0.3)	55 (0.4)	92 (0.3)
Grade 2	3 (<0.1)	22 (0.2)	25 (<0.1)
Grade 3	2 (<0.1)	5 (<0.1)	7 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	13251	13286	26537
Any Solicited Systemic Adverse Reactions	629 (4.7)	758 (5.7)	1387 (5.2)
95% CI	4.4, 5.1	5.3, 6.1	5.0, 5.5
Grade 1	252 (1.9)	151 (1.1)	403 (1.5)
Grade 2	303 (2.3)	403 (3.0)	706 (2.7)
Grade 3	74 (0.6)	203 (1.5)	277 (1.0)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Fever - N1	13247	13279	26526
Any	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 1	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	13249	13283	26532
Any	270 (2.0)	353 (2.7)	623 (2.3)
Grade 1	136 (1.0)	93 (0.7)	229 (0.9)
Grade 2	109 (0.8)	209 (1.6)	318 (1.2)
Grade 3	25 (0.2)	51 (0.4)	76 (0.3)
Grade 4	0	0	0
Fatigue - N1	13247	13283	26530
Any	344 (2.6)	442 (3.3)	786 (3.0)
Grade 1	107 (0.8)	65 (0.5)	172 (0.6)
Grade 2	194 (1.5)	237 (1.8)	431 (1.6)
Grade 3	43 (0.3)	140 (1.1)	183 (0.7)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Myalgia - N1	13248	13283	26531
Any	195 (1.5)	208 (1.6)	403 (1.5)
Grade 1	79 (0.6)	41 (0.3)	120 (0.5)
Grade 2	93 (0.7)	113 (0.9)	206 (0.8)
Grade 3	23 (0.2)	54 (0.4)	77 (0.3)
Grade 4	0	0	0
Arthralgia - N1	13247	13283	26530
Any	230 (1.7)	237 (1.8)	467 (1.8)
Grade 1	97 (0.7)	55 (0.4)	152 (0.6)
Grade 2	115 (0.9)	138 (1.0)	253 (1.0)
Grade 3	18 (0.1)	44 (0.3)	62 (0.2)
Grade 4	0	0	0
Nausea/Vomiting - N1	13247	13283	26530
Any	48 (0.4)	55 (0.4)	103 (0.4)
Grade 1	19 (0.1)	11 (<0.1)	30 (0.1)
Grade 2	28 (0.2)	38 (0.3)	66 (0.2)
Grade 3	1 (<0.1)	5 (<0.1)	6 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=13252) n (%)	mRNA-1273 (N=13286) n (%)	Total (N=26538) n (%)
Chills - N1	13247	13283	26530
Any	42 (0.3)	48 (0.4)	90 (0.3)
Grade 1	18 (0.1)	11 (<0.1)	29 (0.1)
Grade 2	20 (0.2)	28 (0.2)	48 (0.2)
Grade 3	4 (<0.1)	9 (<0.1)	13 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Solicited Adverse Reactions - N1	213	203	416
Any Solicited Adverse Reactions	14 (6.6)	8 (3.9)	22 (5.3)
95% CI	3.6, 10.8	1.7, 7.6	3.3, 7.9
Grade 1	7 (3.3)	1 (0.5)	8 (1.9)
Grade 2	6 (2.8)	7 (3.4)	13 (3.1)
Grade 3	1 (0.5)	0	1 (0.2)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	212	203	415
Any Solicited Local Adverse Reactions	3 (1.4)	2 (1.0)	5 (1.2)
95% CI	0.3, 4.1	0.1, 3.5	0.4, 2.8
Grade 1	2 (0.9)	1 (0.5)	3 (0.7)
Grade 2	1 (0.5)	1 (0.5)	2 (0.5)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Pain - N1	212	203	415
Any	0	2 (1.0)	2 (0.5)
Grade 1	0	1 (0.5)	1 (0.2)
Grade 2	0	1 (0.5)	1 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Erythema (Redness) - N1	212	203	415
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Swelling (Hardness) - N1	212	203	415
Any	0	1 (0.5)	1 (0.2)
Grade 1	0	1 (0.5)	1 (0.2)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Lymphadenopathy - N1 [1]	212	203	415
Any	3 (1.4)	1 (0.5)	4 (1.0)
Grade 1	2 (0.9)	1 (0.5)	3 (0.7)
Grade 2	1 (0.5)	0	1 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	213	203	416
Any Solicited Systemic Adverse Reactions	12 (5.6)	7 (3.4)	19 (4.6)
95% CI	2.9, 9.6	1.4, 7.0	2.8, 7.0
Grade 1	5 (2.3)	1 (0.5)	6 (1.4)
Grade 2	6 (2.8)	6 (3.0)	12 (2.9)
Grade 3	1 (0.5)	0	1 (0.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Fever - N1	212	203	415
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	212	203	415
Any	4 (1.9)	5 (2.5)	9 (2.2)
Grade 1	2 (0.9)	3 (1.5)	5 (1.2)
Grade 2	2 (0.9)	2 (1.0)	4 (1.0)
Grade 3	0	0	0
Grade 4	0	0	0
Fatigue - N1	212	203	415
Any	8 (3.8)	4 (2.0)	12 (2.9)
Grade 1	2 (0.9)	0	2 (0.5)
Grade 2	5 (2.4)	4 (2.0)	9 (2.2)
Grade 3	1 (0.5)	0	1 (0.2)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Myalgia - N1	212	203	415
Any	5 (2.4)	2 (1.0)	7 (1.7)
Grade 1	2 (0.9)	0	2 (0.5)
Grade 2	3 (1.4)	2 (1.0)	5 (1.2)
Grade 3	0	0	0
Grade 4	0	0	0
Arthralgia - N1	212	203	415
Any	7 (3.3)	2 (1.0)	9 (2.2)
Grade 1	4 (1.9)	0	4 (1.0)
Grade 2	3 (1.4)	2 (1.0)	5 (1.2)
Grade 3	0	0	0
Grade 4	0	0	0
Nausea/Vomiting - N1	212	203	415
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=213) n (%)	mRNA-1273 (N=203) n (%)	Total (N=416) n (%)
Chills - N1	212	203	415
Any	3 (1.4)	0	3 (0.7)
Grade 1	2 (0.9)	0	2 (0.5)
Grade 2	1 (0.5)	0	1 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Solicited Adverse Reactions - N1	405	458	863
Any Solicited Adverse Reactions	36 (8.9)	35 (7.6)	71 (8.2)
95% CI	6.3, 12.1	5.4, 10.5	6.5, 10.3
Grade 1	17 (4.2)	4 (0.9)	21 (2.4)
Grade 2	14 (3.5)	21 (4.6)	35 (4.1)
Grade 3	5 (1.2)	10 (2.2)	15 (1.7)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	405	458	863
Any Solicited Local Adverse Reactions	7 (1.7)	10 (2.2)	17 (2.0)
95% CI	0.7, 3.5	1.1, 4.0	1.2, 3.1
Grade 1	6 (1.5)	2 (0.4)	8 (0.9)
Grade 2	0	6 (1.3)	6 (0.7)
Grade 3	1 (0.2)	2 (0.4)	3 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Pain - N1	405	458	863
Any	4 (1.0)	7 (1.5)	11 (1.3)
Grade 1	3 (0.7)	0	3 (0.3)
Grade 2	0	6 (1.3)	6 (0.7)
Grade 3	1 (0.2)	1 (0.2)	2 (0.2)
Grade 4	0	0	0
Erythema (Redness) - N1	405	458	863
Any	1 (0.2)	1 (0.2)	2 (0.2)
Grade 1	1 (0.2)	0	1 (0.1)
Grade 2	0	0	0
Grade 3	0	1 (0.2)	1 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	405	458	863
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Lymphadenopathy - N1 [1]	405	458	863
Any	2 (0.5)	2 (0.4)	4 (0.5)
Grade 1	2 (0.5)	2 (0.4)	4 (0.5)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	405	458	863
Any Solicited Systemic Adverse Reactions	34 (8.4)	31 (6.8)	65 (7.5)
95% CI	5.9, 11.5	4.6, 9.5	5.9, 9.5
Grade 1	15 (3.7)	3 (0.7)	18 (2.1)
Grade 2	14 (3.5)	20 (4.4)	34 (3.9)
Grade 3	5 (1.2)	8 (1.7)	13 (1.5)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Fever - N1	405	457	862
Any	0	1 (0.2)	1 (0.1)
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.2)	1 (0.1)
Grade 4	0	0	0
Headache - N1	405	458	863
Any	15 (3.7)	13 (2.8)	28 (3.2)
Grade 1	7 (1.7)	2 (0.4)	9 (1.0)
Grade 2	5 (1.2)	6 (1.3)	11 (1.3)
Grade 3	3 (0.7)	5 (1.1)	8 (0.9)
Grade 4	0	0	0
Fatigue - N1	405	458	863
Any	18 (4.4)	17 (3.7)	35 (4.1)
Grade 1	7 (1.7)	3 (0.7)	10 (1.2)
Grade 2	8 (2.0)	10 (2.2)	18 (2.1)
Grade 3	3 (0.7)	4 (0.9)	7 (0.8)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Myalgia - N1	405	458	863
Any	12 (3.0)	14 (3.1)	26 (3.0)
Grade 1	2 (0.5)	1 (0.2)	3 (0.3)
Grade 2	8 (2.0)	10 (2.2)	18 (2.1)
Grade 3	2 (0.5)	3 (0.7)	5 (0.6)
Grade 4	0	0	0
Arthralgia - N1	405	458	863
Any	12 (3.0)	10 (2.2)	22 (2.5)
Grade 1	3 (0.7)	1 (0.2)	4 (0.5)
Grade 2	7 (1.7)	6 (1.3)	13 (1.5)
Grade 3	2 (0.5)	3 (0.7)	5 (0.6)
Grade 4	0	0	0
Nausea/Vomiting - N1	405	458	863
Any	1 (0.2)	3 (0.7)	4 (0.5)
Grade 1	1 (0.2)	1 (0.2)	2 (0.2)
Grade 2	0	2 (0.4)	2 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.8
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=405) n (%)	mRNA-1273 (N=458) n (%)	Total (N=863) n (%)
Chills - N1	405	458	863
Any	3 (0.7)	4 (0.9)	7 (0.8)
Grade 1	2 (0.5)	0	2 (0.2)
Grade 2	0	4 (0.9)	4 (0.5)
Grade 3	1 (0.2)	0	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Solicited Adverse Reactions - N1	14363	14309	28672
Any Solicited Adverse Reactions	1339 (9.3)	1720 (12.0)	3059 (10.7)
95% CI	8.9, 9.8	11.5, 12.6	10.3, 11.0
Grade 1	570 (4.0)	580 (4.1)	1150 (4.0)
Grade 2	606 (4.2)	801 (5.6)	1407 (4.9)
Grade 3	163 (1.1)	338 (2.4)	501 (1.7)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	14362	14309	28671
Any Solicited Local Adverse Reactions	182 (1.3)	536 (3.7)	718 (2.5)
95% CI	1.1, 1.5	3.4, 4.1	2.3, 2.7
Grade 1	135 (0.9)	288 (2.0)	423 (1.5)
Grade 2	35 (0.2)	171 (1.2)	206 (0.7)
Grade 3	12 (<0.1)	77 (0.5)	89 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Pain - N1	14362	14309	28671
Any	91 (0.6)	206 (1.4)	297 (1.0)
Grade 1	66 (0.5)	85 (0.6)	151 (0.5)
Grade 2	18 (0.1)	90 (0.6)	108 (0.4)
Grade 3	7 (<0.1)	31 (0.2)	38 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	14362	14309	28671
Any	6 (<0.1)	66 (0.5)	72 (0.3)
Grade 1	4 (<0.1)	15 (0.1)	19 (<0.1)
Grade 2	1 (<0.1)	22 (0.2)	23 (<0.1)
Grade 3	1 (<0.1)	29 (0.2)	30 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	14362	14309	28671
Any	17 (0.1)	63 (0.4)	80 (0.3)
Grade 1	12 (<0.1)	27 (0.2)	39 (0.1)
Grade 2	2 (<0.1)	23 (0.2)	25 (<0.1)
Grade 3	3 (<0.1)	13 (<0.1)	16 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Lymphadenopathy - N1 [1]	14362	14309	28671
Any	86 (0.6)	285 (2.0)	371 (1.3)
Grade 1	68 (0.5)	211 (1.5)	279 (1.0)
Grade 2	16 (0.1)	60 (0.4)	76 (0.3)
Grade 3	2 (<0.1)	14 (<0.1)	16 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14363	14309	28672
Any Solicited Systemic Adverse Reactions	1235 (8.6)	1392 (9.7)	2627 (9.2)
95% CI	8.1, 9.1	9.2, 10.2	8.8, 9.5
Grade 1	494 (3.4)	398 (2.8)	892 (3.1)
Grade 2	589 (4.1)	713 (5.0)	1302 (4.5)
Grade 3	152 (1.1)	280 (2.0)	432 (1.5)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Fever - N1	14363	14309	28672
Any	4 (<0.1)	5 (<0.1)	9 (<0.1)
Grade 1	4 (<0.1)	2 (<0.1)	6 (<0.1)
Grade 2	0	2 (<0.1)	2 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Headache - N1	14362	14309	28671
Any	517 (3.6)	619 (4.3)	1136 (4.0)
Grade 1	261 (1.8)	232 (1.6)	493 (1.7)
Grade 2	194 (1.4)	303 (2.1)	497 (1.7)
Grade 3	62 (0.4)	84 (0.6)	146 (0.5)
Grade 4	0	0	0
Fatigue - N1	14362	14309	28671
Any	689 (4.8)	828 (5.8)	1517 (5.3)
Grade 1	218 (1.5)	181 (1.3)	399 (1.4)
Grade 2	388 (2.7)	464 (3.2)	852 (3.0)
Grade 3	83 (0.6)	183 (1.3)	266 (0.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Myalgia - N1	14362	14309	28671
Any	374 (2.6)	384 (2.7)	758 (2.6)
Grade 1	146 (1.0)	103 (0.7)	249 (0.9)
Grade 2	185 (1.3)	200 (1.4)	385 (1.3)
Grade 3	43 (0.3)	81 (0.6)	124 (0.4)
Grade 4	0	0	0
Arthralgia - N1	14362	14309	28671
Any	429 (3.0)	418 (2.9)	847 (3.0)
Grade 1	188 (1.3)	127 (0.9)	315 (1.1)
Grade 2	207 (1.4)	228 (1.6)	435 (1.5)
Grade 3	34 (0.2)	63 (0.4)	97 (0.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	14362	14309	28671
Any	99 (0.7)	112 (0.8)	211 (0.7)
Grade 1	52 (0.4)	41 (0.3)	93 (0.3)
Grade 2	45 (0.3)	63 (0.4)	108 (0.4)
Grade 3	2 (<0.1)	7 (<0.1)	9 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14363) n (%)	mRNA-1273 (N=14309) n (%)	Total (N=28672) n (%)
Chills - N1	14362	14309	28671
Any	80 (0.6)	79 (0.6)	159 (0.6)
Grade 1	40 (0.3)	22 (0.2)	62 (0.2)
Grade 2	36 (0.3)	44 (0.3)	80 (0.3)
Grade 3	4 (<0.1)	13 (<0.1)	17 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Solicited Adverse Reactions - N1	334	340	674
Any Solicited Adverse Reactions	34 (10.2)	28 (8.2)	62 (9.2)
95% CI	7.2, 13.9	5.5, 11.7	7.1, 11.6
Grade 1	11 (3.3)	8 (2.4)	19 (2.8)
Grade 2	16 (4.8)	16 (4.7)	32 (4.7)
Grade 3	7 (2.1)	4 (1.2)	11 (1.6)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	334	340	674
Any Solicited Local Adverse Reactions	5 (1.5)	7 (2.1)	12 (1.8)
95% CI	0.5, 3.5	0.8, 4.2	0.9, 3.1
Grade 1	4 (1.2)	5 (1.5)	9 (1.3)
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Pain - N1	334	340	674
Any	1 (0.3)	5 (1.5)	6 (0.9)
Grade 1	1 (0.3)	3 (0.9)	4 (0.6)
Grade 2	0	1 (0.3)	1 (0.1)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	334	340	674
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Swelling (Hardness) - N1	334	340	674
Any	0	2 (0.6)	2 (0.3)
Grade 1	0	2 (0.6)	2 (0.3)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Lymphadenopathy - N1 [1]	334	340	674
Any	5 (1.5)	3 (0.9)	8 (1.2)
Grade 1	4 (1.2)	2 (0.6)	6 (0.9)
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	334	340	674
Any Solicited Systemic Adverse Reactions	31 (9.3)	23 (6.8)	54 (8.0)
95% CI	6.4, 12.9	4.3, 10.0	6.1, 10.3
Grade 1	8 (2.4)	4 (1.2)	12 (1.8)
Grade 2	16 (4.8)	15 (4.4)	31 (4.6)
Grade 3	7 (2.1)	4 (1.2)	11 (1.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Fever - N1	333	340	673
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	334	340	674
Any	13 (3.9)	16 (4.7)	29 (4.3)
Grade 1	3 (0.9)	6 (1.8)	9 (1.3)
Grade 2	7 (2.1)	7 (2.1)	14 (2.1)
Grade 3	3 (0.9)	3 (0.9)	6 (0.9)
Grade 4	0	0	0
Fatigue - N1	334	340	674
Any	20 (6.0)	12 (3.5)	32 (4.7)
Grade 1	4 (1.2)	2 (0.6)	6 (0.9)
Grade 2	13 (3.9)	9 (2.6)	22 (3.3)
Grade 3	3 (0.9)	1 (0.3)	4 (0.6)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Myalgia - N1	334	340	674
Any	15 (4.5)	9 (2.6)	24 (3.6)
Grade 1	4 (1.2)	3 (0.9)	7 (1.0)
Grade 2	10 (3.0)	6 (1.8)	16 (2.4)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Arthralgia - N1	334	340	674
Any	14 (4.2)	5 (1.5)	19 (2.8)
Grade 1	5 (1.5)	0	5 (0.7)
Grade 2	8 (2.4)	5 (1.5)	13 (1.9)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Nausea/Vomiting - N1	334	340	674
Any	1 (0.3)	1 (0.3)	2 (0.3)
Grade 1	0	0	0
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=334) n (%)	mRNA-1273 (N=340) n (%)	Total (N=674) n (%)
Chills - N1	334	340	674
Any	6 (1.8)	1 (0.3)	7 (1.0)
Grade 1	4 (1.2)	0	4 (0.6)
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Solicited Adverse Reactions - N1	465	527	993
Any Solicited Adverse Reactions	63 (13.5)	63 (12.0)	126 (12.7)
95% CI	10.6, 17.0	9.3, 15.0	10.7, 14.9
Grade 1	30 (6.5)	15 (2.8)	45 (4.5)
Grade 2	25 (5.4)	36 (6.8)	61 (6.1)
Grade 3	8 (1.7)	12 (2.3)	20 (2.0)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	465	527	993
Any Solicited Local Adverse Reactions	9 (1.9)	18 (3.4)	27 (2.7)
95% CI	0.9, 3.6	2.0, 5.3	1.8, 3.9
Grade 1	8 (1.7)	10 (1.9)	18 (1.8)
Grade 2	0	6 (1.1)	6 (0.6)
Grade 3	1 (0.2)	2 (0.4)	3 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Pain - N1	465	527	993
Any	5 (1.1)	9 (1.7)	14 (1.4)
Grade 1	4 (0.9)	2 (0.4)	6 (0.6)
Grade 2	0	6 (1.1)	6 (0.6)
Grade 3	1 (0.2)	1 (0.2)	2 (0.2)
Grade 4	0	0	0
Erythema (Redness) - N1	465	527	993
Any	1 (0.2)	1 (0.2)	2 (0.2)
Grade 1	1 (0.2)	0	1 (0.1)
Grade 2	0	0	0
Grade 3	0	1 (0.2)	1 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	465	527	993
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Lymphadenopathy - N1 [1]	465	527	993
Any	3 (0.6)	8 (1.5)	11 (1.1)
Grade 1	3 (0.6)	8 (1.5)	11 (1.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	465	527	993
Any Solicited Systemic Adverse Reactions	59 (12.7)	53 (10.1)	112 (11.3)
95% CI	9.8, 16.1	7.6, 12.9	9.4, 13.4
Grade 1	26 (5.6)	8 (1.5)	34 (3.4)
Grade 2	25 (5.4)	35 (6.6)	60 (6.0)
Grade 3	8 (1.7)	10 (1.9)	18 (1.8)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Fever - N1	465	526	992
Any	0	1 (0.2)	1 (0.1)
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.2)	1 (0.1)
Grade 4	0	0	0
Headache - N1	465	527	993
Any	25 (5.4)	20 (3.8)	45 (4.5)
Grade 1	10 (2.2)	5 (0.9)	15 (1.5)
Grade 2	10 (2.2)	10 (1.9)	20 (2.0)
Grade 3	5 (1.1)	5 (0.9)	10 (1.0)
Grade 4	0	0	0
Fatigue - N1	465	527	993
Any	34 (7.3)	34 (6.5)	68 (6.8)
Grade 1	15 (3.2)	4 (0.8)	19 (1.9)
Grade 2	14 (3.0)	24 (4.6)	38 (3.8)
Grade 3	5 (1.1)	6 (1.1)	11 (1.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Myalgia - N1	465	527	993
Any	21 (4.5)	22 (4.2)	43 (4.3)
Grade 1	8 (1.7)	3 (0.6)	11 (1.1)
Grade 2	10 (2.2)	14 (2.7)	24 (2.4)
Grade 3	3 (0.6)	5 (0.9)	8 (0.8)
Grade 4	0	0	0
Arthralgia - N1	465	527	993
Any	22 (4.7)	16 (3.0)	38 (3.8)
Grade 1	8 (1.7)	2 (0.4)	10 (1.0)
Grade 2	11 (2.4)	10 (1.9)	21 (2.1)
Grade 3	3 (0.6)	4 (0.8)	7 (0.7)
Grade 4	0	0	0
Nausea/Vomiting - N1	465	527	993
Any	4 (0.9)	5 (0.9)	9 (0.9)
Grade 1	2 (0.4)	3 (0.6)	5 (0.5)
Grade 2	2 (0.4)	2 (0.4)	4 (0.4)
Grade 3	0	0	0
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.9
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Chills - N1	465	527	993
Any	3 (0.6)	4 (0.8)	7 (0.7)
Grade 1	2 (0.4)	0	2 (0.2)
Grade 2	0	4 (0.8)	4 (0.4)
Grade 3	1 (0.2)	0	1 (0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.7.6
Summary of Unsolicited TEAE by Age Group in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	2475 (21.7)	2615 (22.9)	5090 (22.3)
Serious	66 (0.6)	60 (0.5)	126 (0.6)
Fatal	1 (<0.1)	2 (<0.1)	3 (<0.1)
Medically-Attended	1102 (9.7)	997 (8.7)	2099 (9.2)
Leading to Discontinuation from Study Vaccine	65 (0.6)	33 (0.3)	98 (0.4)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	149 (1.3)	161 (1.4)	310 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	483 (4.2)	872 (7.6)	1355 (5.9)
Serious	3 (<0.1)	3 (<0.1)	6 (<0.1)
Fatal	0	0	0
Medically-Attended	63 (0.6)	101 (0.9)	164 (0.7)
Leading to Discontinuation from Study Vaccine	9 (<0.1)	12 (0.1)	21 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	21 (0.2)	49 (0.4)	70 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.7.6
Summary of Unsolicited TEAE by Age Group in Overall Stage
Safety Set

Age Group: >=65 Years

	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	816 (21.8)	952 (25.3)	1768 (23.5)
Serious	54 (1.4)	53 (1.4)	107 (1.4)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Medically-Attended	427 (11.4)	417 (11.1)	844 (11.2)
Leading to Discontinuation from Study Vaccine	20 (0.5)	12 (0.3)	32 (0.4)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	87 (2.3)	95 (2.5)	182 (2.4)
Unsolicited TEAEs Related to Study Vaccination			
All	141 (3.8)	265 (7.0)	406 (5.4)
Serious	2 (<0.1)	3 (<0.1)	5 (<0.1)
Fatal	0	0	0
Medically-Attended	14 (0.4)	23 (0.6)	37 (0.5)
Leading to Discontinuation from Study Vaccine	5 (0.1)	3 (<0.1)	8 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	10 (0.3)	22 (0.6)	32 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010706.sas 20NOV2020 06:54

Table 14.3.1.7.7
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	2846 (19.8)	3204 (22.4)	6050 (21.1)
Serious	82 (0.6)	79 (0.6)	161 (0.6)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Medically-Attended	1243 (8.7)	1167 (8.2)	2410 (8.4)
Leading to Discontinuation from Study Vaccine	68 (0.5)	34 (0.2)	102 (0.4)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	181 (1.3)	210 (1.5)	391 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	585 (4.1)	1095 (7.6)	1680 (5.9)
Serious	4 (<0.1)	5 (<0.1)	9 (<0.1)
Fatal	0	0	0
Medically-Attended	68 (0.5)	118 (0.8)	186 (0.6)
Leading to Discontinuation from Study Vaccine	13 (<0.1)	15 (0.1)	28 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	27 (0.2)	69 (0.5)	96 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010707.sas 20NOV2020 06:54

Table 14.3.1.7.7
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	56 (16.8)	49 (14.4)	105 (15.6)
Serious	3 (0.9)	0	3 (0.4)
Fatal	0	0	0
Medically-Attended	18 (5.4)	19 (5.6)	37 (5.5)
Leading to Discontinuation from Study Vaccine	3 (0.9)	4 (1.2)	7 (1.0)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	6 (1.8)	1 (0.3)	7 (1.0)
Unsolicited TEAEs Related to Study Vaccination			
All	14 (4.2)	16 (4.7)	30 (4.4)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (1.5)	0	5 (0.7)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.3)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010707.sas 20NOV2020 06:54

Table 14.3.1.7.7
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	47 (10.1)	72 (13.7)	119 (12.0)
Serious	1 (0.2)	3 (0.6)	4 (0.4)
Fatal	0	0	0
Medically-Attended	15 (3.2)	29 (5.5)	44 (4.4)
Leading to Discontinuation from Study Vaccine	0	3 (0.6)	3 (0.3)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	3 (0.6)	5 (0.9)	8 (0.8)
Unsolicited TEAEs Related to Study Vaccination			
All	10 (2.2)	16 (3.0)	26 (2.6)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	4 (0.8)	4 (0.4)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.2)	1 (0.2)	2 (0.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010707.sas 20NOV2020 06:54

Table 14.3.1.7.9
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3167 (22.0)	3436 (24.0)	6603 (23.0)
Serious	116 (0.8)	110 (0.8)	226 (0.8)
Fatal	4 (<0.1)	4 (<0.1)	8 (<0.1)
Medically-Attended	1483 (10.3)	1362 (9.5)	2845 (9.9)
Leading to Discontinuation from Study Vaccine	81 (0.6)	38 (0.3)	119 (0.4)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	227 (1.6)	249 (1.7)	476 (1.7)
Unsolicited TEAEs Related to Study Vaccination			
All	600 (4.2)	1104 (7.7)	1704 (5.9)
Serious	5 (<0.1)	6 (<0.1)	11 (<0.1)
Fatal	0	0	0
Medically-Attended	72 (0.5)	120 (0.8)	192 (0.7)
Leading to Discontinuation from Study Vaccine	14 (<0.1)	15 (0.1)	29 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	29 (0.2)	70 (0.5)	99 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010709.sas 20NOV2020 06:54

Table 14.3.1.7.9
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	68 (20.4)	55 (16.1)	123 (18.2)
Serious	3 (0.9)	0	3 (0.4)
Fatal	0	0	0
Medically-Attended	23 (6.9)	20 (5.9)	43 (6.4)
Leading to Discontinuation from Study Vaccine	3 (0.9)	4 (1.2)	7 (1.0)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	6 (1.8)	2 (0.6)	8 (1.2)
Unsolicited TEAEs Related to Study Vaccination			
All	14 (4.2)	17 (5.0)	31 (4.6)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (1.5)	0	5 (0.7)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.3)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.7.9
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Missing

	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	56 (12.0)	76 (14.4)	132 (13.3)
Serious	1 (0.2)	3 (0.6)	4 (0.4)
Fatal	0	0	0
Medically-Attended	23 (4.9)	32 (6.1)	55 (5.5)
Leading to Discontinuation from Study Vaccine	1 (0.2)	3 (0.6)	4 (0.4)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	3 (0.6)	5 (0.9)	8 (0.8)
Unsolicited TEAEs Related to Study Vaccination			
All	10 (2.2)	16 (3.0)	26 (2.6)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	4 (0.8)	4 (0.4)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.2)	1 (0.2)	2 (0.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3291 (21.7)	3567 (23.5)	6858 (22.6)
Number of Unsolicited Adverse Events	6252	6922	13174
Infections and infestations	818 (5.4)	637 (4.2)	1455 (4.8)
Urinary tract infection	103 (0.7)	89 (0.6)	192 (0.6)
Upper respiratory tract infection	82 (0.5)	65 (0.4)	147 (0.5)
Sinusitis	40 (0.3)	59 (0.4)	99 (0.3)
COVID-19	196 (1.3)	33 (0.2)	229 (0.8)
Viral infection	41 (0.3)	29 (0.2)	70 (0.2)
Herpes zoster	14 (<0.1)	20 (0.1)	34 (0.1)
Gastroenteritis	17 (0.1)	17 (0.1)	34 (0.1)
Pharyngitis	24 (0.2)	16 (0.1)	40 (0.1)
Rhinovirus infection	5 (<0.1)	16 (0.1)	21 (<0.1)
Tooth infection	15 (<0.1)	16 (0.1)	31 (0.1)
Ear infection	10 (<0.1)	15 (<0.1)	25 (<0.1)
Tooth abscess	22 (0.1)	15 (<0.1)	37 (0.1)
Pharyngitis streptococcal	19 (0.1)	14 (<0.1)	33 (0.1)
Cellulitis	15 (<0.1)	13 (<0.1)	28 (<0.1)
Conjunctivitis	6 (<0.1)	12 (<0.1)	18 (<0.1)
Hordeolum	13 (<0.1)	10 (<0.1)	23 (<0.1)
Gingivitis	6 (<0.1)	9 (<0.1)	15 (<0.1)
Oral herpes	6 (<0.1)	9 (<0.1)	15 (<0.1)
Diverticulitis	9 (<0.1)	8 (<0.1)	17 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Acute sinusitis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Folliculitis	5 (<0.1)	7 (<0.1)	12 (<0.1)
Fungal infection	10 (<0.1)	7 (<0.1)	17 (<0.1)
Herpes simplex	1 (<0.1)	7 (<0.1)	8 (<0.1)
Viral upper respiratory tract infection	11 (<0.1)	7 (<0.1)	18 (<0.1)
Bronchitis	9 (<0.1)	6 (<0.1)	15 (<0.1)
Localised infection	8 (<0.1)	6 (<0.1)	14 (<0.1)
Otitis media	9 (<0.1)	6 (<0.1)	15 (<0.1)
Paronychia	2 (<0.1)	6 (<0.1)	8 (<0.1)
Pneumonia	10 (<0.1)	6 (<0.1)	16 (<0.1)
Rhinitis	10 (<0.1)	6 (<0.1)	16 (<0.1)
Bacterial vaginosis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Respiratory tract infection	6 (<0.1)	5 (<0.1)	11 (<0.1)
Vulvovaginal candidiasis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Enterovirus infection	0	4 (<0.1)	4 (<0.1)
Laryngitis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Nasopharyngitis	11 (<0.1)	4 (<0.1)	15 (<0.1)
Onychomycosis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Staphylococcal infection	1 (<0.1)	4 (<0.1)	5 (<0.1)
Subcutaneous abscess	1 (<0.1)	4 (<0.1)	5 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gonorrhoea	1 (<0.1)	3 (<0.1)	4 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	4 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010803.sas 20NOV2020 06:54

Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Impetigo	0	3 (<0.1)	3 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Lyme disease	0	3 (<0.1)	3 (<0.1)
Skin infection	3 (<0.1)	3 (<0.1)	6 (<0.1)
Vulvovaginal mycotic infection	11 (<0.1)	3 (<0.1)	14 (<0.1)
Appendicitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Clostridium difficile colitis	0	2 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Cystitis	6 (<0.1)	2 (<0.1)	8 (<0.1)
Gastroenteritis viral	7 (<0.1)	2 (<0.1)	9 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Otitis externa	10 (<0.1)	2 (<0.1)	12 (<0.1)
Otitis media acute	3 (<0.1)	2 (<0.1)	5 (<0.1)
Postoperative wound infection	0	2 (<0.1)	2 (<0.1)
Sinusitis bacterial	2 (<0.1)	2 (<0.1)	4 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Staphylococcal skin infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tinea pedis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Tonsillitis	7 (<0.1)	2 (<0.1)	9 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)	2 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)	3 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Abscess jaw	0	1 (<0.1)	1 (<0.1)
Bacterial infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Candida infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cat scratch disease	0	1 (<0.1)	1 (<0.1)
Catheter site infection	0	1 (<0.1)	1 (<0.1)
Colonic abscess	0	1 (<0.1)	1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Coronavirus infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Furuncle	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal infection	0	1 (<0.1)	1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected bite	0	1 (<0.1)	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Joint abscess	0	1 (<0.1)	1 (<0.1)
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010803.sas 20NOV2020 06:54

Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Osteomyelitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Papilloma viral infection	0	1 (<0.1)	1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)
Parotitis	0	1 (<0.1)	1 (<0.1)
Periodontitis	0	1 (<0.1)	1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)	1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Postoperative abscess	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Pyelonephritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory tract infection viral	5 (<0.1)	1 (<0.1)	6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Streptococcal infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Suspected COVID-19	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tinea infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Abscess	1 (<0.1)	0	1 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010803.sas 20NOV2020 06:54

Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Breast abscess	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Denture stomatitis	1 (<0.1)	0	1 (<0.1)
Eye infection	4 (<0.1)	0	4 (<0.1)
Eye infection bacterial	1 (<0.1)	0	1 (<0.1)
Fungal skin infection	1 (<0.1)	0	1 (<0.1)
Gardnerella infection	2 (<0.1)	0	2 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	1 (<0.1)	0	1 (<0.1)
Herpes virus infection	1 (<0.1)	0	1 (<0.1)
Influenza	2 (<0.1)	0	2 (<0.1)
Labyrinthitis	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Nasal abscess	1 (<0.1)	0	1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0	1 (<0.1)
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Perirectal abscess	1 (<0.1)	0	1 (<0.1)
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Pustule	1 (<0.1)	0	1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0	1 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Septic shock	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Skin candida	1 (<0.1)	0	1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Syphilis	1 (<0.1)	0	1 (<0.1)
Tinea cruris	1 (<0.1)	0	1 (<0.1)
Tinea versicolour	1 (<0.1)	0	1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Viral sinusitis	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	37 (0.2)	45 (0.3)	82 (0.3)
Basal cell carcinoma	11 (<0.1)	7 (<0.1)	18 (<0.1)
Malignant melanoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Squamous cell carcinoma	7 (<0.1)	3 (<0.1)	10 (<0.1)
Melanocytic naevus	0	2 (<0.1)	2 (<0.1)
Prostate cancer	4 (<0.1)	2 (<0.1)	6 (<0.1)
Uterine leiomyoma	0	2 (<0.1)	2 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)	1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)	1 (<0.1)
Breast neoplasm	0	1 (<0.1)	1 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Gastric cancer	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Haemangioma of liver	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	0	1 (<0.1)	1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lipoma of breast	0	1 (<0.1)	1 (<0.1)
Lung cancer metastatic	0	1 (<0.1)	1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)	1 (<0.1)
Meningioma	0	1 (<0.1)	1 (<0.1)
Meningioma benign	0	1 (<0.1)	1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Neoplasm malignant	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	1 (<0.1)	3 (<0.1)
Thyroid cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Chondromatosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Colon cancer stage III	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Skin cancer	2 (<0.1)	0	2 (<0.1)
Blood and lymphatic system disorders	67 (0.4)	120 (0.8)	187 (0.6)
Lymphadenopathy	56 (0.4)	100 (0.7)	156 (0.5)
Anaemia	1 (<0.1)	7 (<0.1)	8 (<0.1)
Lymph node pain	3 (<0.1)	5 (<0.1)	8 (<0.1)
Lymphadenitis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Increased tendency to bruise	1 (<0.1)	0	1 (<0.1)
Immune system disorders	34 (0.2)	29 (0.2)	63 (0.2)
Seasonal allergy	23 (0.2)	16 (0.1)	39 (0.1)
Hypersensitivity	2 (<0.1)	6 (<0.1)	8 (<0.1)
Drug hypersensitivity	3 (<0.1)	3 (<0.1)	6 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Autoimmune disorder	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Immune system disorders (Cont.)			
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to chemicals	1 (<0.1)	0	1 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	9 (<0.1)	8 (<0.1)	17 (<0.1)
Hypothyroidism	5 (<0.1)	5 (<0.1)	10 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Thyroid mass	0	1 (<0.1)	1 (<0.1)
Addison's disease	1 (<0.1)	0	1 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Hypogonadism	1 (<0.1)	0	1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	84 (0.6)	81 (0.5)	165 (0.5)
Hyperlipidaemia	12 (<0.1)	13 (<0.1)	25 (<0.1)
Type 2 diabetes mellitus	3 (<0.1)	12 (<0.1)	15 (<0.1)
Hypercholesterolaemia	15 (<0.1)	10 (<0.1)	25 (<0.1)
Decreased appetite	7 (<0.1)	9 (<0.1)	16 (<0.1)
Dehydration	9 (<0.1)	7 (<0.1)	16 (<0.1)
Vitamin D deficiency	8 (<0.1)	7 (<0.1)	15 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Metabolism and nutrition disorders (Cont.)			
Gout	9 (<0.1)	4 (<0.1)	13 (<0.1)
Diabetes mellitus	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hyperglycaemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Insulin resistance	0	2 (<0.1)	2 (<0.1)
Abnormal loss of weight	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)	1 (<0.1)
Food intolerance	0	1 (<0.1)	1 (<0.1)
Glucose tolerance impaired	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)
Hypoglycaemia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypophosphataemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abnormal weight gain	1 (<0.1)	0	1 (<0.1)
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	2 (<0.1)	0	2 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hypocalcaemia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Increased appetite	1 (<0.1)	0	1 (<0.1)
Polydipsia	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	78 (0.5)	99 (0.7)	177 (0.6)
Anxiety	24 (0.2)	27 (0.2)	51 (0.2)
Depression	17 (0.1)	25 (0.2)	42 (0.1)
Insomnia	13 (<0.1)	14 (<0.1)	27 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<0.1)
Attention deficit hyperactivity disorder	7 (<0.1)	5 (<0.1)	12 (<0.1)
Sleep disorder	0	5 (<0.1)	5 (<0.1)
Nightmare	0	3 (<0.1)	3 (<0.1)
Bipolar disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	1 (<0.1)	2 (<0.1)
Affect lability	0	1 (<0.1)	1 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bruxism	0	1 (<0.1)	1 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Intentional self-injury	0	1 (<0.1)	1 (<0.1)
Libido decreased	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Psychiatric disorders (Cont.)			
Major depression	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mental fatigue	1 (<0.1)	1 (<0.1)	2 (<0.1)
Panic attack	3 (<0.1)	1 (<0.1)	4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)	1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Stress	1 (<0.1)	1 (<0.1)	2 (<0.1)
Substance abuse	0	1 (<0.1)	1 (<0.1)
Confusional state	2 (<0.1)	0	2 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Generalised anxiety disorder	2 (<0.1)	0	2 (<0.1)
Mental status changes	2 (<0.1)	0	2 (<0.1)
Nicotine dependence	1 (<0.1)	0	1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Suicidal ideation	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	620 (4.1)	672 (4.4)	1292 (4.3)
Headache	453 (3.0)	462 (3.0)	915 (3.0)
Dizziness	49 (0.3)	62 (0.4)	111 (0.4)
Paraesthesia	19 (0.1)	25 (0.2)	44 (0.1)
Presyncope	11 (<0.1)	12 (<0.1)	23 (<0.1)
Sciatica	6 (<0.1)	12 (<0.1)	18 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Nervous system disorders (Cont.)			
Ageusia	14 (<0.1)	11 (<0.1)	25 (<0.1)
Dysgeusia	6 (<0.1)	11 (<0.1)	17 (<0.1)
Migraine	23 (0.2)	11 (<0.1)	34 (0.1)
Sinus headache	5 (<0.1)	11 (<0.1)	16 (<0.1)
Anosmia	10 (<0.1)	10 (<0.1)	20 (<0.1)
Syncope	20 (0.1)	9 (<0.1)	29 (<0.1)
Hypoaesthesia	5 (<0.1)	8 (<0.1)	13 (<0.1)
Tension headache	3 (<0.1)	8 (<0.1)	11 (<0.1)
Hyperaesthesia	0	6 (<0.1)	6 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	4 (<0.1)	6 (<0.1)
Cervical radiculopathy	0	4 (<0.1)	4 (<0.1)
Mental impairment	0	3 (<0.1)	3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Burning sensation	0	2 (<0.1)	2 (<0.1)
Cerebrovascular accident	1 (<0.1)	2 (<0.1)	3 (<0.1)
Disturbance in attention	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dizziness postural	0	2 (<0.1)	2 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Nerve compression	2 (<0.1)	2 (<0.1)	4 (<0.1)
Neuralgia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)	3 (<0.1)
Transient ischaemic attack	0	2 (<0.1)	2 (<0.1)
Amnesia	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Nervous system disorders (Cont.)			
Balance disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)	1 (<0.1)
Essential tremor	0	1 (<0.1)	1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Lethargy	0	1 (<0.1)	1 (<0.1)
Lumbar radiculopathy	4 (<0.1)	1 (<0.1)	5 (<0.1)
Memory impairment	0	1 (<0.1)	1 (<0.1)
Migraine with aura	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)	1 (<0.1)
Parosmia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Post-traumatic headache	1 (<0.1)	1 (<0.1)	2 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)	1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thoracic outlet syndrome	0	1 (<0.1)	1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Nervous system disorders (Cont.)			
Tremor	1 (<0.1)	1 (<0.1)	2 (<0.1)
Visual field defect	0	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Encephalitis autoimmune	1 (<0.1)	0	1 (<0.1)
Head discomfort	1 (<0.1)	0	1 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Muscle contractions involuntary	2 (<0.1)	0	2 (<0.1)
Restless legs syndrome	1 (<0.1)	0	1 (<0.1)
Shift work disorder	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Eye disorders	48 (0.3)	55 (0.4)	103 (0.3)
Eye pruritus	4 (<0.1)	7 (<0.1)	11 (<0.1)
Eye irritation	0	5 (<0.1)	5 (<0.1)
Eye pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vision blurred	3 (<0.1)	3 (<0.1)	6 (<0.1)
Blepharitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Dry eye	5 (<0.1)	2 (<0.1)	7 (<0.1)
Eye inflammation	0	2 (<0.1)	2 (<0.1)
Eye swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Eye disorders (Cont.)			
Glaucoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lacrimation increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ocular hyperaemia	6 (<0.1)	2 (<0.1)	8 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)	3 (<0.1)
Visual impairment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vitreous floaters	3 (<0.1)	2 (<0.1)	5 (<0.1)
Accommodation disorder	0	1 (<0.1)	1 (<0.1)
Blepharospasm	0	1 (<0.1)	1 (<0.1)
Blindness transient	0	1 (<0.1)	1 (<0.1)
Cataract	0	1 (<0.1)	1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Eye discharge	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eyelid cyst	0	1 (<0.1)	1 (<0.1)
Iris disorder	0	1 (<0.1)	1 (<0.1)
Keratitis	0	1 (<0.1)	1 (<0.1)
Macular oedema	0	1 (<0.1)	1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Presbyopia	0	1 (<0.1)	1 (<0.1)
Vitreous disorder	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Eye disorders (Cont.)			
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0	1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Eye ulcer	1 (<0.1)	0	1 (<0.1)
Eyelid ptosis	1 (<0.1)	0	1 (<0.1)
Macular degeneration	1 (<0.1)	0	1 (<0.1)
Macular hole	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	0	1 (<0.1)
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	2 (<0.1)	0	2 (<0.1)
Retinal tear	1 (<0.1)	0	1 (<0.1)
Strabismus	1 (<0.1)	0	1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	63 (0.4)	56 (0.4)	119 (0.4)
Vertigo	16 (0.1)	17 (0.1)	33 (0.1)
Ear pain	14 (<0.1)	11 (<0.1)	25 (<0.1)
Tinnitus	8 (<0.1)	8 (<0.1)	16 (<0.1)
Vertigo positional	0	6 (<0.1)	6 (<0.1)
Ear discomfort	6 (<0.1)	3 (<0.1)	9 (<0.1)
Cerumen impaction	3 (<0.1)	2 (<0.1)	5 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Ear and labyrinth disorders (Cont.)			
Ear canal erythema	1 (<0.1)	2 (<0.1)	3 (<0.1)
Middle ear effusion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Motion sickness	0	2 (<0.1)	2 (<0.1)
Deafness neurosensory	0	1 (<0.1)	1 (<0.1)
Deafness unilateral	0	1 (<0.1)	1 (<0.1)
Ear congestion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Otorrhoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Deafness	1 (<0.1)	0	1 (<0.1)
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Ear pruritus	1 (<0.1)	0	1 (<0.1)
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	5 (<0.1)	0	5 (<0.1)
Cardiac disorders	70 (0.5)	67 (0.4)	137 (0.5)
Tachycardia	11 (<0.1)	14 (<0.1)	25 (<0.1)
Bradycardia	21 (0.1)	10 (<0.1)	31 (0.1)
Atrial fibrillation	9 (<0.1)	9 (<0.1)	18 (<0.1)
Palpitations	5 (<0.1)	8 (<0.1)	13 (<0.1)
Coronary artery disease	4 (<0.1)	6 (<0.1)	10 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Angina pectoris	1 (<0.1)	4 (<0.1)	5 (<0.1)
Cardiac failure congestive	2 (<0.1)	3 (<0.1)	5 (<0.1)
Sinus tachycardia	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Cardiac disorders (Cont.)			
Arrhythmia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute myocardial infarction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cardiac failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic left ventricular failure	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	0	1 (<0.1)	1 (<0.1)
Tachyarrhythmia	0	1 (<0.1)	1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0	1 (<0.1)
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Atrial tachycardia	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)
Pericarditis	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	167 (1.1)	171 (1.1)	338 (1.1)
Hypertension	128 (0.8)	131 (0.9)	259 (0.9)
Hot flush	6 (<0.1)	11 (<0.1)	17 (<0.1)
Flushing	3 (<0.1)	7 (<0.1)	10 (<0.1)
Haematoma	4 (<0.1)	3 (<0.1)	7 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Vascular disorders (Cont.)			
Hypertensive urgency	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypotension	4 (<0.1)	3 (<0.1)	7 (<0.1)
Orthostatic hypotension	0	3 (<0.1)	3 (<0.1)
Systolic hypertension	4 (<0.1)	3 (<0.1)	7 (<0.1)
Deep vein thrombosis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Pallor	0	1 (<0.1)	1 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
Peripheral coldness	0	1 (<0.1)	1 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)	1 (<0.1)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Diastolic hypertension	1 (<0.1)	0	1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	2 (<0.1)	0	2 (<0.1)
Ischaemia	1 (<0.1)	0	1 (<0.1)
Lymphoedema	1 (<0.1)	0	1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0	1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0	1 (<0.1)
Vasodilatation	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Respiratory, thoracic and mediastinal disorders	597 (3.9)	546 (3.6)	1143 (3.8)
Cough	165 (1.1)	174 (1.1)	339 (1.1)
Oropharyngeal pain	211 (1.4)	169 (1.1)	380 (1.3)
Nasal congestion	138 (0.9)	152 (1.0)	290 (1.0)
Rhinorrhoea	145 (1.0)	147 (1.0)	292 (1.0)
Dyspnoea	41 (0.3)	51 (0.3)	92 (0.3)
Tachypnoea	35 (0.2)	38 (0.3)	73 (0.2)
Throat irritation	12 (<0.1)	16 (0.1)	28 (<0.1)
Epistaxis	10 (<0.1)	15 (<0.1)	25 (<0.1)
Sinus congestion	31 (0.2)	14 (<0.1)	45 (0.1)
Asthma	11 (<0.1)	12 (<0.1)	23 (<0.1)
Upper-airway cough syndrome	9 (<0.1)	11 (<0.1)	20 (<0.1)
Respiratory tract congestion	8 (<0.1)	9 (<0.1)	17 (<0.1)
Rhinitis allergic	10 (<0.1)	9 (<0.1)	19 (<0.1)
Sneezing	12 (<0.1)	8 (<0.1)	20 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	7 (<0.1)	15 (<0.1)
Productive cough	6 (<0.1)	5 (<0.1)	11 (<0.1)
Dry throat	3 (<0.1)	4 (<0.1)	7 (<0.1)
Dysphonia	8 (<0.1)	4 (<0.1)	12 (<0.1)
Dyspnoea exertional	1 (<0.1)	4 (<0.1)	5 (<0.1)
Paranasal sinus discomfort	2 (<0.1)	4 (<0.1)	6 (<0.1)
Sinus pain	3 (<0.1)	4 (<0.1)	7 (<0.1)
Wheezing	3 (<0.1)	4 (<0.1)	7 (<0.1)
Pulmonary embolism	4 (<0.1)	3 (<0.1)	7 (<0.1)
Pharyngeal erythema	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Acute respiratory failure	2 (<0.1)	1 (<0.1)	3 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchiectasis	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)	1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal discomfort	0	1 (<0.1)	1 (<0.1)
Nasal dryness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	1 (<0.1)	3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rhonchi	0	1 (<0.1)	1 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)	1 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)	4 (<0.1)
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Nasal disorder	1 (<0.1)	0	1 (<0.1)
Nasal septum deviation	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Pleural effusion	3 (<0.1)	0	3 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Respiratory failure	1 (<0.1)	0	1 (<0.1)
Respiratory symptom	2 (<0.1)	0	2 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Tonsillar exudate	1 (<0.1)	0	1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	425 (2.8)	471 (3.1)	896 (3.0)
Diarrhoea	160 (1.1)	191 (1.3)	351 (1.2)
Nausea	118 (0.8)	118 (0.8)	236 (0.8)
Vomiting	37 (0.2)	42 (0.3)	79 (0.3)
Gastrooesophageal reflux disease	14 (<0.1)	31 (0.2)	45 (0.1)
Toothache	20 (0.1)	27 (0.2)	47 (0.2)
Abdominal pain	19 (0.1)	17 (0.1)	36 (0.1)
Constipation	13 (<0.1)	12 (<0.1)	25 (<0.1)
Abdominal pain upper	14 (<0.1)	11 (<0.1)	25 (<0.1)
Food poisoning	8 (<0.1)	10 (<0.1)	18 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders (Cont.)			
Abdominal pain lower	6 (<0.1)	9 (<0.1)	15 (<0.1)
Dyspepsia	11 (<0.1)	8 (<0.1)	19 (<0.1)
Dental caries	6 (<0.1)	7 (<0.1)	13 (<0.1)
Abdominal discomfort	5 (<0.1)	6 (<0.1)	11 (<0.1)
Colitis	3 (<0.1)	6 (<0.1)	9 (<0.1)
Gastric ulcer	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haematochezia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aphthous ulcer	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	3 (<0.1)	5 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hiatus hernia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Proctalgia	0	2 (<0.1)	2 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Swollen tongue	0	2 (<0.1)	2 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders (Cont.)			
Diverticular perforation	0	1 (<0.1)	1 (<0.1)
Diverticulum	1 (<0.1)	1 (<0.1)	2 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Faeces soft	0	1 (<0.1)	1 (<0.1)
Flatulence	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastric disorder	0	1 (<0.1)	1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Hyperchlorhydria	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Oesophageal pain	0	1 (<0.1)	1 (<0.1)
Oesophageal ulcer	0	1 (<0.1)	1 (<0.1)
Oral mucosal blistering	0	1 (<0.1)	1 (<0.1)
Oral pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Paraesthesia oral	3 (<0.1)	1 (<0.1)	4 (<0.1)
Peptic ulcer	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders (Cont.)			
Saliva altered	1 (<0.1)	1 (<0.1)	2 (<0.1)
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Salivary hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)	1 (<0.1)
Tongue discolouration	0	1 (<0.1)	1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Tooth impacted	2 (<0.1)	1 (<0.1)	3 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysphagia	2 (<0.1)	0	2 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorder	1 (<0.1)	0	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0	1 (<0.1)
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Gingival pain	3 (<0.1)	0	3 (<0.1)
Glossitis	1 (<0.1)	0	1 (<0.1)
Glossodynia	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders (Cont.)			
Large intestine polyp	3 (<0.1)	0	3 (<0.1)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Oral discomfort	1 (<0.1)	0	1 (<0.1)
Oral disorder	1 (<0.1)	0	1 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Regurgitation	1 (<0.1)	0	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Tongue coated	1 (<0.1)	0	1 (<0.1)
Tooth disorder	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	11 (<0.1)	12 (<0.1)
Cholelithiasis	1 (<0.1)	6 (<0.1)	7 (<0.1)
Cholecystitis	0	2 (<0.1)	2 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	177 (1.2)	223 (1.5)	400 (1.3)
Rash	30 (0.2)	42 (0.3)	72 (0.2)
Pruritus	18 (0.1)	20 (0.1)	38 (0.1)
Urticaria	14 (<0.1)	18 (0.1)	32 (0.1)
Dermatitis contact	25 (0.2)	16 (0.1)	41 (0.1)
Hyperhidrosis	10 (<0.1)	14 (<0.1)	24 (<0.1)
Erythema	4 (<0.1)	11 (<0.1)	15 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Night sweats	7 (<0.1)	9 (<0.1)	16 (<0.1)
Acne	2 (<0.1)	7 (<0.1)	9 (<0.1)
Dermatitis	5 (<0.1)	7 (<0.1)	12 (<0.1)
Alopecia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Rash erythematous	2 (<0.1)	6 (<0.1)	8 (<0.1)
Ecchymosis	7 (<0.1)	5 (<0.1)	12 (<0.1)
Blister	2 (<0.1)	4 (<0.1)	6 (<0.1)
Dermatitis atopic	6 (<0.1)	4 (<0.1)	10 (<0.1)
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Rash pruritic	2 (<0.1)	4 (<0.1)	6 (<0.1)
Skin lesion	4 (<0.1)	4 (<0.1)	8 (<0.1)
Actinic keratosis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Eczema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Psoriasis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)	5 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Dermatitis allergic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Macule	0	2 (<0.1)	2 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Rash papular	0	2 (<0.1)	2 (<0.1)
Urticaria papular	4 (<0.1)	2 (<0.1)	6 (<0.1)
Angioedema	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermal cyst	4 (<0.1)	1 (<0.1)	5 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)	2 (<0.1)
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	1 (<0.1)	1 (<0.1)
Ingrowing nail	0	1 (<0.1)	1 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Nail disorder	0	1 (<0.1)	1 (<0.1)
Pain of skin	0	1 (<0.1)	1 (<0.1)
Papule	2 (<0.1)	1 (<0.1)	3 (<0.1)
Petechiae	0	1 (<0.1)	1 (<0.1)
Rash maculo-papular	3 (<0.1)	1 (<0.1)	4 (<0.1)
Rash vesicular	0	1 (<0.1)	1 (<0.1)
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Skin hypopigmentation	0	1 (<0.1)	1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin warm	0	1 (<0.1)	1 (<0.1)
Solar lentigo	0	1 (<0.1)	1 (<0.1)
Dermatitis bullous	2 (<0.1)	0	2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Ingrown hair	1 (<0.1)	0	1 (<0.1)
Intertrigo	1 (<0.1)	0	1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Livedo reticularis	1 (<0.1)	0	1 (<0.1)
Onychoclasia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash macular	1 (<0.1)	0	1 (<0.1)
Scab	1 (<0.1)	0	1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0	1 (<0.1)
Skin discolouration	2 (<0.1)	0	2 (<0.1)
Skin hyperpigmentation	1 (<0.1)	0	1 (<0.1)
Skin irritation	1 (<0.1)	0	1 (<0.1)
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Umbilical erythema	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	562 (3.7)	623 (4.1)	1185 (3.9)
Myalgia	150 (1.0)	183 (1.2)	333 (1.1)
Arthralgia	160 (1.1)	182 (1.2)	342 (1.1)
Back pain	92 (0.6)	80 (0.5)	172 (0.6)
Pain in extremity	62 (0.4)	55 (0.4)	117 (0.4)
Neck pain	25 (0.2)	36 (0.2)	61 (0.2)
Musculoskeletal pain	27 (0.2)	33 (0.2)	60 (0.2)
Muscle spasms	15 (<0.1)	27 (0.2)	42 (0.1)
Tendonitis	9 (<0.1)	15 (<0.1)	24 (<0.1)
Musculoskeletal chest pain	12 (<0.1)	10 (<0.1)	22 (<0.1)
Musculoskeletal stiffness	10 (<0.1)	10 (<0.1)	20 (<0.1)
Rotator cuff syndrome	6 (<0.1)	7 (<0.1)	13 (<0.1)
Arthritis	1 (<0.1)	6 (<0.1)	7 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	6 (<0.1)	10 (<0.1)
Osteoarthritis	13 (<0.1)	6 (<0.1)	19 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Bursitis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Joint swelling	6 (<0.1)	5 (<0.1)	11 (<0.1)
Flank pain	0	4 (<0.1)	4 (<0.1)
Groin pain	1 (<0.1)	4 (<0.1)	5 (<0.1)
Limb discomfort	3 (<0.1)	4 (<0.1)	7 (<0.1)
Osteoporosis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Pain in jaw	4 (<0.1)	4 (<0.1)	8 (<0.1)
Bone pain	0	3 (<0.1)	3 (<0.1)
Costochondritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Joint range of motion decreased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Muscular weakness	1 (<0.1)	3 (<0.1)	4 (<0.1)
Neck mass	0	3 (<0.1)	3 (<0.1)
Axillary mass	2 (<0.1)	2 (<0.1)	4 (<0.1)
Exostosis	0	2 (<0.1)	2 (<0.1)
Fibromyalgia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Joint stiffness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle tightness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Plantar fasciitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Spinal osteoarthritis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Spinal pain	0	2 (<0.1)	2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Trigger finger	0	2 (<0.1)	2 (<0.1)
Arthropathy	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Bone lesion	0	1 (<0.1)	1 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	0	1 (<0.1)	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	1 (<0.1)
Floating patella	0	1 (<0.1)	1 (<0.1)
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Muscle twitching	3 (<0.1)	1 (<0.1)	4 (<0.1)
Osteopenia	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthritis	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spondylitis	0	1 (<0.1)	1 (<0.1)
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Synovial cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Torticollis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Foot deformity	1 (<0.1)	0	1 (<0.1)
Intervertebral disc disorder	1 (<0.1)	0	1 (<0.1)
Limb mass	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Lumbar spinal stenosis	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteitis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	45 (0.3)	45 (0.3)	90 (0.3)
Nephrolithiasis	23 (0.2)	18 (0.1)	41 (0.1)
Dysuria	1 (<0.1)	5 (<0.1)	6 (<0.1)
Chronic kidney disease	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematuria	8 (<0.1)	2 (<0.1)	10 (<0.1)
Polyuria	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute kidney injury	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bladder pain	0	1 (<0.1)	1 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
End stage renal disease	0	1 (<0.1)	1 (<0.1)
Hydronephrosis	0	1 (<0.1)	1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Renal and urinary disorders (Cont.)			
Nocturia	0	1 (<0.1)	1 (<0.1)
Pollakiuria	2 (<0.1)	1 (<0.1)	3 (<0.1)
Renal mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal pain	0	1 (<0.1)	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chromaturia	1 (<0.1)	0	1 (<0.1)
Micturition urgency	1 (<0.1)	0	1 (<0.1)
Renal colic	2 (<0.1)	0	2 (<0.1)
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pregnancy	0	2 (<0.1)	2 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)	1 (<0.1)
Morning sickness	0	1 (<0.1)	1 (<0.1)
Abortion spontaneous	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	36 (0.2)	43 (0.3)	79 (0.3)
Benign prostatic hyperplasia	5 (<0.1)	6 (<0.1)	11 (<0.1)
Dysmenorrhoea	4 (<0.1)	4 (<0.1)	8 (<0.1)
Erectile dysfunction	2 (<0.1)	4 (<0.1)	6 (<0.1)
Pelvic pain	0	4 (<0.1)	4 (<0.1)
Menorrhagia	0	2 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Reproductive system and breast disorders (Cont.)			
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast discharge	0	1 (<0.1)	1 (<0.1)
Breast disorder	0	1 (<0.1)	1 (<0.1)
Breast mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopausal symptoms	0	1 (<0.1)	1 (<0.1)
Menstrual disorder	0	1 (<0.1)	1 (<0.1)
Metrorrhagia	0	1 (<0.1)	1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)	1 (<0.1)
Ovarian cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ovarian mass	0	1 (<0.1)	1 (<0.1)
Prostatitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Testicular pain	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
Uterine polyp	0	1 (<0.1)	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Vaginal haemorrhage	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)	1 (<0.1)
Amenorrhoea	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Reproductive system and breast disorders (Cont.)			
Bartholin's cyst	1 (<0.1)	0	1 (<0.1)
Cystocele	1 (<0.1)	0	1 (<0.1)
Endometriosis	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	1 (<0.1)	0	1 (<0.1)
Nipple pain	1 (<0.1)	0	1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0	1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	1 (<0.1)	0	1 (<0.1)
Testicular swelling	1 (<0.1)	0	1 (<0.1)
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Uterine spasm	2 (<0.1)	0	2 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	1 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	618 (4.1)	940 (6.2)	1558 (5.1)
Fatigue	336 (2.2)	369 (2.4)	705 (2.3)
Injection site pain	52 (0.3)	152 (1.0)	204 (0.7)
Injection site erythema	13 (<0.1)	102 (0.7)	115 (0.4)
Chills	69 (0.5)	90 (0.6)	159 (0.5)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
General disorders and administration site conditions (Cont.)			
Pyrexia	56 (0.4)	77 (0.5)	133 (0.4)
Pain	55 (0.4)	72 (0.5)	127 (0.4)
Injection site pruritus	12 (<0.1)	68 (0.4)	80 (0.3)
Injection site swelling	12 (<0.1)	67 (0.4)	79 (0.3)
Injection site induration	7 (<0.1)	30 (0.2)	37 (0.1)
Injection site rash	1 (<0.1)	30 (0.2)	31 (0.1)
Axillary pain	10 (<0.1)	23 (0.2)	33 (0.1)
Chest discomfort	12 (<0.1)	12 (<0.1)	24 (<0.1)
Injection site bruising	17 (0.1)	12 (<0.1)	29 (<0.1)
Malaise	10 (<0.1)	12 (<0.1)	22 (<0.1)
Chest pain	10 (<0.1)	11 (<0.1)	21 (<0.1)
Swelling	4 (<0.1)	11 (<0.1)	15 (<0.1)
Injection site warmth	1 (<0.1)	8 (<0.1)	9 (<0.1)
Injection site urticaria	0	7 (<0.1)	7 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	6 (<0.1)	7 (<0.1)
Oedema peripheral	6 (<0.1)	6 (<0.1)	12 (<0.1)
Peripheral swelling	10 (<0.1)	6 (<0.1)	16 (<0.1)
Feeling hot	3 (<0.1)	5 (<0.1)	8 (<0.1)
Injection site haemorrhage	2 (<0.1)	5 (<0.1)	7 (<0.1)
Influenza like illness	5 (<0.1)	4 (<0.1)	9 (<0.1)
Reactogenicity event	3 (<0.1)	4 (<0.1)	7 (<0.1)
Swelling face	2 (<0.1)	4 (<0.1)	6 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site lymphadenopathy	0	4 (<0.1)	4 (<0.1)
Injection site haematoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site reaction	1 (<0.1)	3 (<0.1)	4 (<0.1)
Non-cardiac chest pain	4 (<0.1)	3 (<0.1)	7 (<0.1)
Vaccination site erythema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vaccination site swelling	1 (<0.1)	3 (<0.1)	4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)	2 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site irritation	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	2 (<0.1)
Injection site nodule	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site paraesthesia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Injection site scab	0	2 (<0.1)	2 (<0.1)
Vaccination site pain	5 (<0.1)	2 (<0.1)	7 (<0.1)
Adverse drug reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Asthenia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Crying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst	4 (<0.1)	1 (<0.1)	5 (<0.1)
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Facial pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Feeling cold	0	1 (<0.1)	1 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
General disorders and administration site conditions (Cont.)			
Inflammation	0	1 (<0.1)	1 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Sensation of foreign body	0	1 (<0.1)	1 (<0.1)
Temperature intolerance	0	1 (<0.1)	1 (<0.1)
Vaccination site induration	0	1 (<0.1)	1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vaccination site rash	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Discomfort	2 (<0.1)	0	2 (<0.1)
Gait disturbance	1 (<0.1)	0	1 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site discolouration	2 (<0.1)	0	2 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Polyp	1 (<0.1)	0	1 (<0.1)
Precancerous condition	2 (<0.1)	0	2 (<0.1)
Thirst	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site bruising	2 (<0.1)	0	2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0	1 (<0.1)
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	0	1 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	81 (0.5)	96 (0.6)	177 (0.6)
Blood pressure increased	34 (0.2)	31 (0.2)	65 (0.2)
Blood pressure systolic increased	14 (<0.1)	17 (0.1)	31 (0.1)
Blood pressure diastolic increased	7 (<0.1)	9 (<0.1)	16 (<0.1)
Heart rate increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Body temperature increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hepatic enzyme increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Blood glucose increased	2 (<0.1)	2 (<0.1)	4 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)	2 (<0.1)
Transaminases increased	0	2 (<0.1)	2 (<0.1)
White blood cell count increased	0	2 (<0.1)	2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Blood cholesterol increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood creatine increased	0	1 (<0.1)	1 (<0.1)
Blood creatinine increased	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Investigations (Cont.)			
Blood glucose decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Blood testosterone decreased	0	1 (<0.1)	1 (<0.1)
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)	3 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Hepatitis B antibody positive	0	1 (<0.1)	1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Mammogram abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	0	1 (<0.1)	1 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
SARS-CoV-2 test positive	7 (<0.1)	1 (<0.1)	8 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)
Vitamin K	0	1 (<0.1)	1 (<0.1)
Weight decreased	0	1 (<0.1)	1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)
Biopsy skin	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Investigations (Cont.)			
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood potassium decreased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
C-reactive protein increased	1 (<0.1)	0	1 (<0.1)
Colonoscopy	1 (<0.1)	0	1 (<0.1)
Lipase increased	1 (<0.1)	0	1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0	1 (<0.1)
Vitamin D decreased	2 (<0.1)	0	2 (<0.1)
Weight increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	294 (1.9)	265 (1.7)	559 (1.8)
Muscle strain	26 (0.2)	32 (0.2)	58 (0.2)
Ligament sprain	25 (0.2)	24 (0.2)	49 (0.2)
Arthropod bite	22 (0.1)	21 (0.1)	43 (0.1)
Skin laceration	30 (0.2)	20 (0.1)	50 (0.2)
Contusion	27 (0.2)	15 (<0.1)	42 (0.1)
Tooth fracture	13 (<0.1)	14 (<0.1)	27 (<0.1)
Fall	15 (<0.1)	11 (<0.1)	26 (<0.1)
Limb injury	5 (<0.1)	11 (<0.1)	16 (<0.1)
Procedural pain	14 (<0.1)	10 (<0.1)	24 (<0.1)
Foot fracture	9 (<0.1)	9 (<0.1)	18 (<0.1)
Arthropod sting	14 (<0.1)	7 (<0.1)	21 (<0.1)
Concussion	3 (<0.1)	7 (<0.1)	10 (<0.1)
Joint injury	4 (<0.1)	6 (<0.1)	10 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Meniscus injury	3 (<0.1)	6 (<0.1)	9 (<0.1)
Road traffic accident	3 (<0.1)	6 (<0.1)	9 (<0.1)
Skin abrasion	19 (0.1)	6 (<0.1)	25 (<0.1)
Animal bite	8 (<0.1)	5 (<0.1)	13 (<0.1)
Hand fracture	1 (<0.1)	5 (<0.1)	6 (<0.1)
Head injury	1 (<0.1)	4 (<0.1)	5 (<0.1)
Epicondylitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Rib fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Thermal burn	1 (<0.1)	3 (<0.1)	4 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Back injury	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cartilage injury	0	2 (<0.1)	2 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Clavicle fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Facial bones fracture	0	2 (<0.1)	2 (<0.1)
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Humerus fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ligament rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Animal scratch	0	1 (<0.1)	1 (<0.1)
Ankle fracture	4 (<0.1)	1 (<0.1)	5 (<0.1)
Bone fragmentation	0	1 (<0.1)	1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Burns second degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)	1 (<0.1)
Exposure to SARS-CoV-2	2 (<0.1)	1 (<0.1)	3 (<0.1)
Face injury	0	1 (<0.1)	1 (<0.1)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)	1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypobarism	0	1 (<0.1)	1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	0	1 (<0.1)	1 (<0.1)
Ligament injury	0	1 (<0.1)	1 (<0.1)
Lip injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Nasal injury	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Post-traumatic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Procedural headache	0	1 (<0.1)	1 (<0.1)
Procedural nausea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Scar	0	1 (<0.1)	1 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Thoracic vertebral fracture	0	1 (<0.1)	1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	1 (<0.1)	1 (<0.1)
Wound	4 (<0.1)	1 (<0.1)	5 (<0.1)
Abdominal injury	1 (<0.1)	0	1 (<0.1)
Bone contusion	3 (<0.1)	0	3 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Exposure to toxic agent	1 (<0.1)	0	1 (<0.1)
Eye injury	2 (<0.1)	0	2 (<0.1)
Eyelid contusion	1 (<0.1)	0	1 (<0.1)
Foreign body	3 (<0.1)	0	3 (<0.1)
Foreign body in ear	1 (<0.1)	0	1 (<0.1)
Fracture	1 (<0.1)	0	1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Mouth injury	1 (<0.1)	0	1 (<0.1)
Muscle injury	1 (<0.1)	0	1 (<0.1)
Nail injury	1 (<0.1)	0	1 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	2 (<0.1)	0	2 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Stress fracture	3 (<0.1)	0	3 (<0.1)
Sunburn	1 (<0.1)	0	1 (<0.1)
Superficial injury of eye	2 (<0.1)	0	2 (<0.1)
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Venomous sting	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Surgical and medical procedures	13 (<0.1)	19 (0.1)	32 (0.1)
Axillary lymphadenectomy	0	2 (<0.1)	2 (<0.1)
Endodontic procedure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Thyroidectomy	0	2 (<0.1)	2 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curettage of chalazion	0	1 (<0.1)	1 (<0.1)
Cyst removal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dental operation	0	1 (<0.1)	1 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lipoma excision	0	1 (<0.1)	1 (<0.1)
Phlebectomy	0	1 (<0.1)	1 (<0.1)
Skin cyst excision	0	1 (<0.1)	1 (<0.1)
Skin neoplasm excision	0	1 (<0.1)	1 (<0.1)
Skin operation	0	1 (<0.1)	1 (<0.1)
Spinal fusion surgery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Transurethral prostatectomy	0	1 (<0.1)	1 (<0.1)
Artificial crown procedure	1 (<0.1)	0	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Cataract operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Knee arthroplasty	1 (<0.1)	0	1 (<0.1)
Liposuction	1 (<0.1)	0	1 (<0.1)
Tooth extraction	1 (<0.1)	0	1 (<0.1)
Tooth repair	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Surgical and medical procedures (Cont.)			
Umbilical hernia repair	1 (<0.1)	0	1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopause	0	1 (<0.1)	1 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	2 (<0.1)	4 (<0.1)	6 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Device dislocation	0	1 (<0.1)	1 (<0.1)
Embedded device	0	1 (<0.1)	1 (<0.1)
Lead dislodgement	1 (<0.1)	0	1 (<0.1)
Uncoded	179 (1.2)	263 (1.7)	442 (1.5)
Uncoded	179 (1.2)	263 (1.7)	442 (1.5)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2475 (21.7)	2615 (22.9)	5090 (22.3)
Number of Unsolicited Adverse Events	4734	5072	9806
Infections and infestations	643 (5.6)	489 (4.3)	1132 (5.0)
Urinary tract infection	67 (0.6)	63 (0.6)	130 (0.6)
Upper respiratory tract infection	76 (0.7)	56 (0.5)	132 (0.6)
Sinusitis	32 (0.3)	48 (0.4)	80 (0.4)
COVID-19	172 (1.5)	26 (0.2)	198 (0.9)
Viral infection	36 (0.3)	25 (0.2)	61 (0.3)
Pharyngitis streptococcal	17 (0.1)	14 (0.1)	31 (0.1)
Ear infection	7 (<0.1)	13 (0.1)	20 (<0.1)
Herpes zoster	11 (<0.1)	13 (0.1)	24 (0.1)
Pharyngitis	24 (0.2)	13 (0.1)	37 (0.2)
Gastroenteritis	14 (0.1)	12 (0.1)	26 (0.1)
Rhinovirus infection	4 (<0.1)	12 (0.1)	16 (<0.1)
Tooth abscess	12 (0.1)	12 (0.1)	24 (0.1)
Tooth infection	12 (0.1)	12 (0.1)	24 (0.1)
Conjunctivitis	4 (<0.1)	9 (<0.1)	13 (<0.1)
Cellulitis	10 (<0.1)	8 (<0.1)	18 (<0.1)
Hordeolum	9 (<0.1)	7 (<0.1)	16 (<0.1)
Oral herpes	5 (<0.1)	7 (<0.1)	12 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Infections and infestations (Cont.)			
Folliculitis	1 (<0.1)	6 (<0.1)	7 (<0.1)
Otitis media	8 (<0.1)	6 (<0.1)	14 (<0.1)
Viral upper respiratory tract infection	9 (<0.1)	6 (<0.1)	15 (<0.1)
Acute sinusitis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bacterial vaginosis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Bronchitis	8 (<0.1)	5 (<0.1)	13 (<0.1)
Diverticulitis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Fungal infection	8 (<0.1)	5 (<0.1)	13 (<0.1)
Respiratory tract infection	5 (<0.1)	5 (<0.1)	10 (<0.1)
Gingivitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Herpes simplex	1 (<0.1)	4 (<0.1)	5 (<0.1)
Paronychia	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pneumonia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Rhinitis	6 (<0.1)	4 (<0.1)	10 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gonorrhoea	1 (<0.1)	3 (<0.1)	4 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Lyme disease	0	3 (<0.1)	3 (<0.1)
Nasopharyngitis	9 (<0.1)	3 (<0.1)	12 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Infections and infestations (Cont.)			
Onychomycosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin infection	0	3 (<0.1)	3 (<0.1)
Vulvovaginal mycotic infection	10 (<0.1)	3 (<0.1)	13 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Gastroenteritis viral	7 (<0.1)	2 (<0.1)	9 (<0.1)
Impetigo	0	2 (<0.1)	2 (<0.1)
Kidney infection	0	2 (<0.1)	2 (<0.1)
Localised infection	5 (<0.1)	2 (<0.1)	7 (<0.1)
Oral candidiasis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Otitis externa	7 (<0.1)	2 (<0.1)	9 (<0.1)
Sinusitis bacterial	2 (<0.1)	2 (<0.1)	4 (<0.1)
Soft tissue infection	0	2 (<0.1)	2 (<0.1)
Staphylococcal skin infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Subcutaneous abscess	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tonsillitis	7 (<0.1)	2 (<0.1)	9 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)	2 (<0.1)
Viral rhinitis	0	2 (<0.1)	2 (<0.1)
Abscess jaw	0	1 (<0.1)	1 (<0.1)
Bacterial infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Body tinea	0	1 (<0.1)	1 (<0.1)
Candida infection	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Infections and infestations (Cont.)			
Cat scratch disease	0	1 (<0.1)	1 (<0.1)
Catheter site infection	0	1 (<0.1)	1 (<0.1)
Chronic sinusitis	0	1 (<0.1)	1 (<0.1)
Clostridium difficile colitis	0	1 (<0.1)	1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Coronavirus infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)
Enterovirus infection	0	1 (<0.1)	1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Furuncle	1 (<0.1)	1 (<0.1)	2 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected bite	0	1 (<0.1)	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Laryngitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Osteomyelitis	0	1 (<0.1)	1 (<0.1)
Otitis media acute	2 (<0.1)	1 (<0.1)	3 (<0.1)
Papilloma viral infection	0	1 (<0.1)	1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)
Parotitis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Infections and infestations (Cont.)			
Periodontitis	0	1 (<0.1)	1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)	1 (<0.1)
Postoperative wound infection	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Pyelonephritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory tract infection viral	5 (<0.1)	1 (<0.1)	6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Staphylococcal infection	0	1 (<0.1)	1 (<0.1)
Streptococcal infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Suspected COVID-19	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tinea pedis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abscess	1 (<0.1)	0	1 (<0.1)
Appendicitis	1 (<0.1)	0	1 (<0.1)
Breast abscess	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Cystitis	5 (<0.1)	0	5 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Infections and infestations (Cont.)			
Eye infection	4 (<0.1)	0	4 (<0.1)
Eye infection bacterial	1 (<0.1)	0	1 (<0.1)
Gardnerella infection	1 (<0.1)	0	1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0	1 (<0.1)
Herpes virus infection	1 (<0.1)	0	1 (<0.1)
Influenza	2 (<0.1)	0	2 (<0.1)
Latent tuberculosis	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Nasal abscess	1 (<0.1)	0	1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0	1 (<0.1)
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Perirectal abscess	1 (<0.1)	0	1 (<0.1)
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Pustule	1 (<0.1)	0	1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0	1 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Sepsis	1 (<0.1)	0	1 (<0.1)
Septic shock	1 (<0.1)	0	1 (<0.1)
Sialoadenitis	1 (<0.1)	0	1 (<0.1)
Skin candida	1 (<0.1)	0	1 (<0.1)
Syphilis	1 (<0.1)	0	1 (<0.1)
Tinea infection	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Infections and infestations (Cont.)			
Tinea versicolour	1 (<0.1)	0	1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (0.1)	22 (0.2)	35 (0.2)
Basal cell carcinoma	4 (<0.1)	2 (<0.1)	6 (<0.1)
Melanocytic naevus	0	2 (<0.1)	2 (<0.1)
Squamous cell carcinoma	0	2 (<0.1)	2 (<0.1)
Uterine leiomyoma	0	2 (<0.1)	2 (<0.1)
Breast neoplasm	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Gastric cancer	0	1 (<0.1)	1 (<0.1)
Haemangioma of liver	0	1 (<0.1)	1 (<0.1)
Lipoma of breast	0	1 (<0.1)	1 (<0.1)
Lung cancer metastatic	0	1 (<0.1)	1 (<0.1)
Malignant melanoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)	1 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Squamous cell carcinoma of skin	1 (<0.1)	1 (<0.1)	2 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Thyroid cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Chondromatosis	1 (<0.1)	0	1 (<0.1)
Colon cancer stage III	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Prostate cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	57 (0.5)	98 (0.9)	155 (0.7)
Lymphadenopathy	48 (0.4)	81 (0.7)	129 (0.6)
Anaemia	1 (<0.1)	6 (<0.1)	7 (<0.1)
Lymph node pain	2 (<0.1)	5 (<0.1)	7 (<0.1)
Lymphadenitis	0	5 (<0.1)	5 (<0.1)
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)
Iron deficiency anaemia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Increased tendency to bruise	1 (<0.1)	0	1 (<0.1)
Leukocytosis	1 (<0.1)	0	1 (<0.1)
Immune system disorders	27 (0.2)	22 (0.2)	49 (0.2)
Seasonal allergy	18 (0.2)	14 (0.1)	32 (0.1)

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MedDRA version 23.0.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Immune system disorders (Cont.)			
Hypersensitivity	2 (<0.1)	3 (<0.1)	5 (<0.1)
Drug hypersensitivity	2 (<0.1)	2 (<0.1)	4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Autoimmune disorder	0	1 (<0.1)	1 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	4 (<0.1)	7 (<0.1)	11 (<0.1)
Hypothyroidism	2 (<0.1)	5 (<0.1)	7 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Thyroid mass	0	1 (<0.1)	1 (<0.1)
Hypogonadism	1 (<0.1)	0	1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	58 (0.5)	49 (0.4)	107 (0.5)
Type 2 diabetes mellitus	2 (<0.1)	9 (<0.1)	11 (<0.1)
Decreased appetite	6 (<0.1)	8 (<0.1)	14 (<0.1)
Hyperlipidaemia	9 (<0.1)	6 (<0.1)	15 (<0.1)
Hypercholesterolaemia	12 (0.1)	5 (<0.1)	17 (<0.1)
Vitamin D deficiency	8 (<0.1)	5 (<0.1)	13 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Metabolism and nutrition disorders (Cont.)			
Dehydration	6 (<0.1)	3 (<0.1)	9 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Diabetes mellitus	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abnormal loss of weight	0	1 (<0.1)	1 (<0.1)
Food intolerance	0	1 (<0.1)	1 (<0.1)
Glucose tolerance impaired	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Gout	5 (<0.1)	1 (<0.1)	6 (<0.1)
Hypoglycaemia	0	1 (<0.1)	1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyponatraemia	0	1 (<0.1)	1 (<0.1)
Hypophosphataemia	0	1 (<0.1)	1 (<0.1)
Insulin resistance	0	1 (<0.1)	1 (<0.1)
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Abnormal weight gain	1 (<0.1)	0	1 (<0.1)
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	1 (<0.1)	0	1 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Increased appetite	1 (<0.1)	0	1 (<0.1)
Iron deficiency	1 (<0.1)	0	1 (<0.1)
Polydipsia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Metabolism and nutrition disorders (Cont.)			
Vitamin B12 deficiency	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	69 (0.6)	77 (0.7)	146 (0.6)
Depression	17 (0.1)	22 (0.2)	39 (0.2)
Anxiety	22 (0.2)	20 (0.2)	42 (0.2)
Insomnia	10 (<0.1)	11 (<0.1)	21 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<0.1)
Attention deficit hyperactivity disorder	7 (<0.1)	5 (<0.1)	12 (<0.1)
Sleep disorder	0	3 (<0.1)	3 (<0.1)
Bipolar disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Adjustment disorder with depressed mood	0	1 (<0.1)	1 (<0.1)
Affect lability	0	1 (<0.1)	1 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Intentional self-injury	0	1 (<0.1)	1 (<0.1)
Libido decreased	0	1 (<0.1)	1 (<0.1)
Major depression	1 (<0.1)	1 (<0.1)	2 (<0.1)
Panic attack	3 (<0.1)	1 (<0.1)	4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Psychiatric disorders (Cont.)			
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Stress	1 (<0.1)	1 (<0.1)	2 (<0.1)
Substance abuse	0	1 (<0.1)	1 (<0.1)
Confusional state	1 (<0.1)	0	1 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0	1 (<0.1)
Mental fatigue	1 (<0.1)	0	1 (<0.1)
Mental status changes	1 (<0.1)	0	1 (<0.1)
Nicotine dependence	1 (<0.1)	0	1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Suicidal ideation	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	500 (4.4)	525 (4.6)	1025 (4.5)
Headache	375 (3.3)	366 (3.2)	741 (3.2)
Dizziness	35 (0.3)	46 (0.4)	81 (0.4)
Paraesthesia	17 (0.1)	21 (0.2)	38 (0.2)
Presyncope	9 (<0.1)	12 (0.1)	21 (<0.1)
Migraine	20 (0.2)	10 (<0.1)	30 (0.1)
Ageusia	11 (<0.1)	9 (<0.1)	20 (<0.1)
Anosmia	9 (<0.1)	9 (<0.1)	18 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Nervous system disorders (Cont.)			
Dysgeusia	3 (<0.1)	9 (<0.1)	12 (<0.1)
Sciatica	4 (<0.1)	8 (<0.1)	12 (<0.1)
Syncope	14 (0.1)	7 (<0.1)	21 (<0.1)
Hypoaesthesia	4 (<0.1)	6 (<0.1)	10 (<0.1)
Tension headache	3 (<0.1)	6 (<0.1)	9 (<0.1)
Sinus headache	4 (<0.1)	5 (<0.1)	9 (<0.1)
Hyperaesthesia	0	4 (<0.1)	4 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mental impairment	0	3 (<0.1)	3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Burning sensation	0	2 (<0.1)	2 (<0.1)
Nerve compression	1 (<0.1)	2 (<0.1)	3 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)	3 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cerebrovascular accident	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)	1 (<0.1)
Disturbance in attention	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dizziness postural	0	1 (<0.1)	1 (<0.1)
Facial paralysis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Lethargy	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Nervous system disorders (Cont.)			
Memory impairment	0	1 (<0.1)	1 (<0.1)
Migraine with aura	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Neuralgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neuropathy peripheral	0	1 (<0.1)	1 (<0.1)
Parosmia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Post-traumatic headache	0	1 (<0.1)	1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)	1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Taste disorder	0	1 (<0.1)	1 (<0.1)
Thoracic outlet syndrome	0	1 (<0.1)	1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)	1 (<0.1)
Tremor	0	1 (<0.1)	1 (<0.1)
Visual field defect	0	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	2 (<0.1)	0	2 (<0.1)
Encephalitis autoimmune	1 (<0.1)	0	1 (<0.1)
Head discomfort	1 (<0.1)	0	1 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Nervous system disorders (Cont.)			
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Hyposmia	1 (<0.1)	0	1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	0	2 (<0.1)
Muscle contractions involuntary	2 (<0.1)	0	2 (<0.1)
Shift work disorder	1 (<0.1)	0	1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Eye disorders	28 (0.2)	34 (0.3)	62 (0.3)
Eye pruritus	3 (<0.1)	5 (<0.1)	8 (<0.1)
Eye irritation	0	3 (<0.1)	3 (<0.1)
Vision blurred	2 (<0.1)	3 (<0.1)	5 (<0.1)
Blepharitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lacrimation increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ocular hyperaemia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Blepharospasm	0	1 (<0.1)	1 (<0.1)
Blindness transient	0	1 (<0.1)	1 (<0.1)
Conjunctival haemorrhage	0	1 (<0.1)	1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Dry eye	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eye discharge	0	1 (<0.1)	1 (<0.1)
Eye inflammation	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Eye disorders (Cont.)			
Eye swelling	2 (<0.1)	1 (<0.1)	3 (<0.1)
Eyelid cyst	0	1 (<0.1)	1 (<0.1)
Iris disorder	0	1 (<0.1)	1 (<0.1)
Macular oedema	0	1 (<0.1)	1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Presbyopia	0	1 (<0.1)	1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)	2 (<0.1)
Swelling of eyelid	1 (<0.1)	1 (<0.1)	2 (<0.1)
Visual impairment	0	1 (<0.1)	1 (<0.1)
Vitreous floaters	2 (<0.1)	1 (<0.1)	3 (<0.1)
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0	1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0	1 (<0.1)
Eye ulcer	1 (<0.1)	0	1 (<0.1)
Eyelid ptosis	1 (<0.1)	0	1 (<0.1)
Macular degeneration	1 (<0.1)	0	1 (<0.1)
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Retinal tear	1 (<0.1)	0	1 (<0.1)
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Ear and labyrinth disorders	43 (0.4)	39 (0.3)	82 (0.4)
Vertigo	9 (<0.1)	11 (<0.1)	20 (<0.1)
Ear pain	10 (<0.1)	10 (<0.1)	20 (<0.1)
Tinnitus	7 (<0.1)	6 (<0.1)	13 (<0.1)
Ear discomfort	4 (<0.1)	3 (<0.1)	7 (<0.1)
Vertigo positional	0	3 (<0.1)	3 (<0.1)
Ear canal erythema	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cerumen impaction	2 (<0.1)	1 (<0.1)	3 (<0.1)
Deafness neurosensory	0	1 (<0.1)	1 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Middle ear effusion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Motion sickness	0	1 (<0.1)	1 (<0.1)
Otorrhoea	0	1 (<0.1)	1 (<0.1)
Deafness	1 (<0.1)	0	1 (<0.1)
Ear congestion	2 (<0.1)	0	2 (<0.1)
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Ear pruritus	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	3 (<0.1)	0	3 (<0.1)
Cardiac disorders	42 (0.4)	36 (0.3)	78 (0.3)
Tachycardia	10 (<0.1)	11 (<0.1)	21 (<0.1)
Bradycardia	14 (0.1)	9 (<0.1)	23 (0.1)
Palpitations	4 (<0.1)	5 (<0.1)	9 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Cardiac disorders (Cont.)			
Myocardial infarction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Angina pectoris	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atrial fibrillation	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cardiac failure	0	1 (<0.1)	1 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic left ventricular failure	0	1 (<0.1)	1 (<0.1)
Coronary artery disease	0	1 (<0.1)	1 (<0.1)
Sinus tachycardia	0	1 (<0.1)	1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0	1 (<0.1)
Arrhythmia	2 (<0.1)	0	2 (<0.1)
Atrial tachycardia	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0	1 (<0.1)
Cardiomyopathy	1 (<0.1)	0	1 (<0.1)
Pericarditis	1 (<0.1)	0	1 (<0.1)
Vascular disorders	106 (0.9)	109 (1.0)	215 (0.9)
Hypertension	82 (0.7)	89 (0.8)	171 (0.7)
Flushing	2 (<0.1)	5 (<0.1)	7 (<0.1)
Hot flush	3 (<0.1)	4 (<0.1)	7 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Vascular disorders (Cont.)			
Deep vein thrombosis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Haematoma	4 (<0.1)	2 (<0.1)	6 (<0.1)
Systolic hypertension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypotension	2 (<0.1)	1 (<0.1)	3 (<0.1)
Orthostatic hypotension	0	1 (<0.1)	1 (<0.1)
Pallor	0	1 (<0.1)	1 (<0.1)
Peripheral coldness	0	1 (<0.1)	1 (<0.1)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic aneurysm	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Diastolic hypertension	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	2 (<0.1)	0	2 (<0.1)
Ischaemia	1 (<0.1)	0	1 (<0.1)
Lymphoedema	1 (<0.1)	0	1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0	1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	473 (4.1)	426 (3.7)	899 (3.9)
Cough	144 (1.3)	144 (1.3)	288 (1.3)
Oropharyngeal pain	181 (1.6)	137 (1.2)	318 (1.4)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Nasal congestion	112 (1.0)	118 (1.0)	230 (1.0)
Rhinorrhoea	112 (1.0)	104 (0.9)	216 (0.9)
Dyspnoea	34 (0.3)	40 (0.4)	74 (0.3)
Tachypnoea	30 (0.3)	34 (0.3)	64 (0.3)
Throat irritation	9 (<0.1)	14 (0.1)	23 (0.1)
Epistaxis	4 (<0.1)	12 (0.1)	16 (<0.1)
Sinus congestion	25 (0.2)	11 (<0.1)	36 (0.2)
Asthma	9 (<0.1)	7 (<0.1)	16 (<0.1)
Respiratory tract congestion	8 (<0.1)	7 (<0.1)	15 (<0.1)
Rhinitis allergic	6 (<0.1)	7 (<0.1)	13 (<0.1)
Upper-airway cough syndrome	8 (<0.1)	6 (<0.1)	14 (<0.1)
Chronic obstructive pulmonary disease	4 (<0.1)	5 (<0.1)	9 (<0.1)
Productive cough	4 (<0.1)	4 (<0.1)	8 (<0.1)
Sneezing	10 (<0.1)	4 (<0.1)	14 (<0.1)
Dry throat	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dyspnoea exertional	1 (<0.1)	3 (<0.1)	4 (<0.1)
Paranasal sinus discomfort	2 (<0.1)	3 (<0.1)	5 (<0.1)
Pulmonary embolism	4 (<0.1)	3 (<0.1)	7 (<0.1)
Sinus pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Wheezing	3 (<0.1)	3 (<0.1)	6 (<0.1)
Pharyngeal erythema	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Acute respiratory failure	2 (<0.1)	1 (<0.1)	3 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Dysphonia	6 (<0.1)	1 (<0.1)	7 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal discomfort	0	1 (<0.1)	1 (<0.1)
Nasal dryness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)	4 (<0.1)
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Pleural effusion	1 (<0.1)	0	1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0	1 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Respiratory disorder	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Respiratory symptom	2 (<0.1)	0	2 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	319 (2.8)	345 (3.0)	664 (2.9)
Diarrhoea	114 (1.0)	148 (1.3)	262 (1.1)
Nausea	98 (0.9)	85 (0.7)	183 (0.8)
Vomiting	30 (0.3)	29 (0.3)	59 (0.3)
Toothache	16 (0.1)	19 (0.2)	35 (0.2)
Gastrooesophageal reflux disease	12 (0.1)	17 (0.1)	29 (0.1)
Abdominal pain	17 (0.1)	14 (0.1)	31 (0.1)
Constipation	9 (<0.1)	10 (<0.1)	19 (<0.1)
Food poisoning	6 (<0.1)	9 (<0.1)	15 (<0.1)
Abdominal pain upper	11 (<0.1)	7 (<0.1)	18 (<0.1)
Abdominal pain lower	5 (<0.1)	6 (<0.1)	11 (<0.1)
Abdominal discomfort	3 (<0.1)	5 (<0.1)	8 (<0.1)
Dental caries	4 (<0.1)	4 (<0.1)	8 (<0.1)
Gastric ulcer	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haematochezia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aphthous ulcer	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Gastrointestinal disorders (Cont.)			
Colitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dyspepsia	10 (<0.1)	3 (<0.1)	13 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Proctalgia	0	2 (<0.1)	2 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)
Diverticulum	0	1 (<0.1)	1 (<0.1)
Dry mouth	2 (<0.1)	1 (<0.1)	3 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Flatulence	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastric disorder	0	1 (<0.1)	1 (<0.1)
Gastritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Hiatus hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hyperchlorhydria	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Gastrointestinal disorders (Cont.)			
Inguinal hernia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Irritable bowel syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)	1 (<0.1)
Oral pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Peptic ulcer	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Saliva altered	1 (<0.1)	1 (<0.1)	2 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stomatitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)	1 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tongue discolouration	0	1 (<0.1)	1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth impacted	2 (<0.1)	1 (<0.1)	3 (<0.1)
Umbilical hernia	0	1 (<0.1)	1 (<0.1)
Dysphagia	2 (<0.1)	0	2 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorder	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Gastrointestinal disorders (Cont.)			
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0	1 (<0.1)
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Gingival pain	1 (<0.1)	0	1 (<0.1)
Glossitis	1 (<0.1)	0	1 (<0.1)
Glossodynia	1 (<0.1)	0	1 (<0.1)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Oral disorder	1 (<0.1)	0	1 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Paraesthesia oral	2 (<0.1)	0	2 (<0.1)
Regurgitation	1 (<0.1)	0	1 (<0.1)
Tongue coated	1 (<0.1)	0	1 (<0.1)
Tooth disorder	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	8 (<0.1)	9 (<0.1)
Cholelithiasis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Cholecystitis	0	2 (<0.1)	2 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	125 (1.1)	156 (1.4)	281 (1.2)
Rash	25 (0.2)	30 (0.3)	55 (0.2)
Dermatitis contact	15 (0.1)	13 (0.1)	28 (0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Pruritus	10 (<0.1)	12 (0.1)	22 (<0.1)
Urticaria	10 (<0.1)	12 (0.1)	22 (<0.1)
Hyperhidrosis	8 (<0.1)	10 (<0.1)	18 (<0.1)
Acne	2 (<0.1)	7 (<0.1)	9 (<0.1)
Night sweats	5 (<0.1)	7 (<0.1)	12 (<0.1)
Alopecia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Dermatitis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Rash erythematous	2 (<0.1)	5 (<0.1)	7 (<0.1)
Blister	2 (<0.1)	4 (<0.1)	6 (<0.1)
Ecchymosis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Erythema	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pityriasis rosea	0	3 (<0.1)	3 (<0.1)
Psoriasis	0	3 (<0.1)	3 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin lesion	1 (<0.1)	3 (<0.1)	4 (<0.1)
Dermatitis allergic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Eczema	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Rash pruritic	1 (<0.1)	2 (<0.1)	3 (<0.1)
Urticaria papular	3 (<0.1)	2 (<0.1)	5 (<0.1)
Angioedema	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cold sweat	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermal cyst	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dermatitis atopic	6 (<0.1)	1 (<0.1)	7 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)	2 (<0.1)
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	1 (<0.1)	1 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Macule	0	1 (<0.1)	1 (<0.1)
Pain of skin	0	1 (<0.1)	1 (<0.1)
Papule	2 (<0.1)	1 (<0.1)	3 (<0.1)
Petechiae	0	1 (<0.1)	1 (<0.1)
Rash maculo-papular	3 (<0.1)	1 (<0.1)	4 (<0.1)
Rash papular	0	1 (<0.1)	1 (<0.1)
Rash vesicular	0	1 (<0.1)	1 (<0.1)
Rosacea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Skin warm	0	1 (<0.1)	1 (<0.1)
Actinic keratosis	1 (<0.1)	0	1 (<0.1)
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Ingrown hair	1 (<0.1)	0	1 (<0.1)
Intertrigo	1 (<0.1)	0	1 (<0.1)
Livedo reticularis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Onychoclasia	1 (<0.1)	0	1 (<0.1)
Rash macular	1 (<0.1)	0	1 (<0.1)
Skin discolouration	2 (<0.1)	0	2 (<0.1)
Skin hyperpigmentation	1 (<0.1)	0	1 (<0.1)
Skin irritation	1 (<0.1)	0	1 (<0.1)
Umbilical erythema	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	405 (3.5)	450 (3.9)	855 (3.7)
Myalgia	118 (1.0)	139 (1.2)	257 (1.1)
Arthralgia	118 (1.0)	130 (1.1)	248 (1.1)
Back pain	66 (0.6)	58 (0.5)	124 (0.5)
Pain in extremity	43 (0.4)	39 (0.3)	82 (0.4)
Neck pain	18 (0.2)	26 (0.2)	44 (0.2)
Musculoskeletal pain	20 (0.2)	22 (0.2)	42 (0.2)
Muscle spasms	9 (<0.1)	19 (0.2)	28 (0.1)
Tendonitis	5 (<0.1)	11 (<0.1)	16 (<0.1)
Musculoskeletal chest pain	11 (<0.1)	9 (<0.1)	20 (<0.1)
Intervertebral disc protrusion	2 (<0.1)	6 (<0.1)	8 (<0.1)
Rotator cuff syndrome	2 (<0.1)	5 (<0.1)	7 (<0.1)
Bursitis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Groin pain	0	4 (<0.1)	4 (<0.1)
Musculoskeletal stiffness	9 (<0.1)	4 (<0.1)	13 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteoarthritis	5 (<0.1)	4 (<0.1)	9 (<0.1)
Pain in jaw	2 (<0.1)	4 (<0.1)	6 (<0.1)
Arthritis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Bone pain	0	3 (<0.1)	3 (<0.1)
Flank pain	0	3 (<0.1)	3 (<0.1)
Limb discomfort	3 (<0.1)	3 (<0.1)	6 (<0.1)
Axillary mass	2 (<0.1)	2 (<0.1)	4 (<0.1)
Costochondritis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Exostosis	0	2 (<0.1)	2 (<0.1)
Fibromyalgia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Joint range of motion decreased	0	2 (<0.1)	2 (<0.1)
Joint swelling	6 (<0.1)	2 (<0.1)	8 (<0.1)
Neck mass	0	2 (<0.1)	2 (<0.1)
Plantar fasciitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Spinal pain	0	2 (<0.1)	2 (<0.1)
Arthropathy	0	1 (<0.1)	1 (<0.1)
Bone lesion	0	1 (<0.1)	1 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	0	1 (<0.1)	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	1 (<0.1)
Floating patella	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Intervertebral disc degeneration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint stiffness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle tightness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle twitching	3 (<0.1)	1 (<0.1)	4 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteopenia	0	1 (<0.1)	1 (<0.1)
Osteoporosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthrititis	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spinal osteoarthritis	0	1 (<0.1)	1 (<0.1)
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Synovial cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Torticollis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Intervertebral disc disorder	1 (<0.1)	0	1 (<0.1)
Limb mass	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteitis	1 (<0.1)	0	1 (<0.1)
Spinal stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Undifferentiated connective tissue disease	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	25 (0.2)	25 (0.2)	50 (0.2)
Nephrolithiasis	16 (0.1)	10 (<0.1)	26 (0.1)
Dysuria	1 (<0.1)	4 (<0.1)	5 (<0.1)
Acute kidney injury	0	1 (<0.1)	1 (<0.1)
Bladder pain	0	1 (<0.1)	1 (<0.1)
Chronic kidney disease	0	1 (<0.1)	1 (<0.1)
End stage renal disease	0	1 (<0.1)	1 (<0.1)
Hydronephrosis	0	1 (<0.1)	1 (<0.1)
Nocturia	0	1 (<0.1)	1 (<0.1)
Polyuria	0	1 (<0.1)	1 (<0.1)
Renal mass	0	1 (<0.1)	1 (<0.1)
Renal pain	0	1 (<0.1)	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Urinary hesitation	0	1 (<0.1)	1 (<0.1)
Urinary incontinence	0	1 (<0.1)	1 (<0.1)
Urinary retention	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bladder prolapse	1 (<0.1)	0	1 (<0.1)
Haematuria	6 (<0.1)	0	6 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Renal and urinary disorders (Cont.)			
Pollakiuria	1 (<0.1)	0	1 (<0.1)
Renal colic	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pregnancy	0	2 (<0.1)	2 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)	1 (<0.1)
Morning sickness	0	1 (<0.1)	1 (<0.1)
Abortion spontaneous	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	33 (0.3)	28 (0.2)	61 (0.3)
Dysmenorrhoea	4 (<0.1)	4 (<0.1)	8 (<0.1)
Pelvic pain	0	4 (<0.1)	4 (<0.1)
Erectile dysfunction	2 (<0.1)	2 (<0.1)	4 (<0.1)
Menorrhagia	0	2 (<0.1)	2 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast disorder	0	1 (<0.1)	1 (<0.1)
Breast pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopausal symptoms	0	1 (<0.1)	1 (<0.1)
Menstrual disorder	0	1 (<0.1)	1 (<0.1)
Metrorrhagia	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Reproductive system and breast disorders (Cont.)			
Nipple exudate bloody	0	1 (<0.1)	1 (<0.1)
Ovarian mass	0	1 (<0.1)	1 (<0.1)
Prostatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Testicular pain	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
Uterine polyp	0	1 (<0.1)	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Vaginal haemorrhage	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Amenorrhoea	1 (<0.1)	0	1 (<0.1)
Bartholin's cyst	1 (<0.1)	0	1 (<0.1)
Benign prostatic hyperplasia	4 (<0.1)	0	4 (<0.1)
Breast mass	2 (<0.1)	0	2 (<0.1)
Cystocele	1 (<0.1)	0	1 (<0.1)
Endometriosis	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	1 (<0.1)	0	1 (<0.1)
Nipple pain	1 (<0.1)	0	1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0	1 (<0.1)
Ovarian cyst	1 (<0.1)	0	1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Testicular swelling	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Reproductive system and breast disorders (Cont.)			
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Uterine spasm	2 (<0.1)	0	2 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	1 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	473 (4.1)	711 (6.2)	1184 (5.2)
Fatigue	273 (2.4)	267 (2.3)	540 (2.4)
Injection site pain	38 (0.3)	123 (1.1)	161 (0.7)
Injection site erythema	6 (<0.1)	70 (0.6)	76 (0.3)
Chills	56 (0.5)	69 (0.6)	125 (0.5)
Pyrexia	48 (0.4)	57 (0.5)	105 (0.5)
Injection site swelling	7 (<0.1)	55 (0.5)	62 (0.3)
Pain	44 (0.4)	54 (0.5)	98 (0.4)
Injection site pruritus	10 (<0.1)	50 (0.4)	60 (0.3)
Injection site induration	4 (<0.1)	26 (0.2)	30 (0.1)
Injection site rash	1 (<0.1)	22 (0.2)	23 (0.1)
Axillary pain	8 (<0.1)	20 (0.2)	28 (0.1)
Malaise	5 (<0.1)	11 (<0.1)	16 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
General disorders and administration site conditions (Cont.)			
Chest discomfort	9 (<0.1)	10 (<0.1)	19 (<0.1)
Chest pain	8 (<0.1)	10 (<0.1)	18 (<0.1)
Swelling	3 (<0.1)	10 (<0.1)	13 (<0.1)
Injection site bruising	11 (<0.1)	9 (<0.1)	20 (<0.1)
Injection site urticaria	0	6 (<0.1)	6 (<0.1)
Injection site warmth	1 (<0.1)	6 (<0.1)	7 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	5 (<0.1)	6 (<0.1)
Feeling hot	3 (<0.1)	4 (<0.1)	7 (<0.1)
Influenza like illness	4 (<0.1)	4 (<0.1)	8 (<0.1)
Injection site haemorrhage	1 (<0.1)	4 (<0.1)	5 (<0.1)
Peripheral swelling	6 (<0.1)	4 (<0.1)	10 (<0.1)
Swelling face	2 (<0.1)	4 (<0.1)	6 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)
Injection site haematoma	1 (<0.1)	3 (<0.1)	4 (<0.1)
Non-cardiac chest pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Oedema peripheral	2 (<0.1)	3 (<0.1)	5 (<0.1)
Reactogenicity event	3 (<0.1)	3 (<0.1)	6 (<0.1)
Vaccination site erythema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vaccination site lymphadenopathy	0	3 (<0.1)	3 (<0.1)
Vaccination site swelling	0	3 (<0.1)	3 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
General disorders and administration site conditions (Cont.)			
Injection site irritation	0	2 (<0.1)	2 (<0.1)
Injection site nodule	0	2 (<0.1)	2 (<0.1)
Injection site reaction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Adverse drug reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Crying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst	3 (<0.1)	1 (<0.1)	4 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)	1 (<0.1)
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Facial pain	3 (<0.1)	1 (<0.1)	4 (<0.1)
Feeling abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Feeling cold	0	1 (<0.1)	1 (<0.1)
Granuloma	0	1 (<0.1)	1 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)	1 (<0.1)
Injection site joint pain	0	1 (<0.1)	1 (<0.1)
Injection site mass	0	1 (<0.1)	1 (<0.1)
Injection site paraesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site scab	0	1 (<0.1)	1 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Sensation of foreign body	0	1 (<0.1)	1 (<0.1)
Vaccination site induration	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site pruritus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vaccination site rash	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Asthenia	3 (<0.1)	0	3 (<0.1)
Discomfort	2 (<0.1)	0	2 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Injection site discolouration	1 (<0.1)	0	1 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Polyp	1 (<0.1)	0	1 (<0.1)
Precancerous condition	2 (<0.1)	0	2 (<0.1)
Vaccination site bruising	2 (<0.1)	0	2 (<0.1)
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Vaccination site pain	4 (<0.1)	0	4 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	62 (0.5)	59 (0.5)	121 (0.5)
Blood pressure increased	27 (0.2)	19 (0.2)	46 (0.2)
Blood pressure systolic increased	9 (<0.1)	10 (<0.1)	19 (<0.1)
Blood pressure diastolic increased	5 (<0.1)	7 (<0.1)	12 (<0.1)
Body temperature increased	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Investigations (Cont.)			
Heart rate increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hepatic enzyme increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Transaminases increased	0	2 (<0.1)	2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Blood cholesterol increased	0	1 (<0.1)	1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood testosterone decreased	0	1 (<0.1)	1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Mammogram abnormal	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	0	1 (<0.1)	1 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
SARS-CoV-2 test positive	7 (<0.1)	1 (<0.1)	8 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)
White blood cell count increased	0	1 (<0.1)	1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Investigations (Cont.)			
Biopsy skin	1 (<0.1)	0	1 (<0.1)
Blood glucose decreased	1 (<0.1)	0	1 (<0.1)
Blood potassium decreased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
C-reactive protein increased	1 (<0.1)	0	1 (<0.1)
Cardiac murmur	1 (<0.1)	0	1 (<0.1)
Colonoscopy	1 (<0.1)	0	1 (<0.1)
Lipase increased	1 (<0.1)	0	1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0	1 (<0.1)
Vitamin D decreased	2 (<0.1)	0	2 (<0.1)
Weight increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	202 (1.8)	171 (1.5)	373 (1.6)
Muscle strain	19 (0.2)	25 (0.2)	44 (0.2)
Ligament sprain	20 (0.2)	18 (0.2)	38 (0.2)
Skin laceration	23 (0.2)	13 (0.1)	36 (0.2)
Arthropod bite	16 (0.1)	11 (<0.1)	27 (0.1)
Tooth fracture	8 (<0.1)	8 (<0.1)	16 (<0.1)
Arthropod sting	8 (<0.1)	6 (<0.1)	14 (<0.1)
Concussion	2 (<0.1)	6 (<0.1)	8 (<0.1)
Foot fracture	7 (<0.1)	6 (<0.1)	13 (<0.1)
Limb injury	2 (<0.1)	6 (<0.1)	8 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Injury, poisoning and procedural complications (Cont.)			
Contusion	18 (0.2)	5 (<0.1)	23 (0.1)
Joint injury	3 (<0.1)	5 (<0.1)	8 (<0.1)
Meniscus injury	1 (<0.1)	5 (<0.1)	6 (<0.1)
Animal bite	6 (<0.1)	4 (<0.1)	10 (<0.1)
Road traffic accident	2 (<0.1)	4 (<0.1)	6 (<0.1)
Skin abrasion	13 (0.1)	4 (<0.1)	17 (<0.1)
Hand fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Head injury	0	3 (<0.1)	3 (<0.1)
Procedural pain	11 (<0.1)	3 (<0.1)	14 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Cartilage injury	0	2 (<0.1)	2 (<0.1)
Clavicle fracture	0	2 (<0.1)	2 (<0.1)
Epicondylitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fall	8 (<0.1)	2 (<0.1)	10 (<0.1)
Ligament rupture	0	2 (<0.1)	2 (<0.1)
Tendon injury	0	2 (<0.1)	2 (<0.1)
Thermal burn	1 (<0.1)	2 (<0.1)	3 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Ankle fracture	3 (<0.1)	1 (<0.1)	4 (<0.1)
Back injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bone fragmentation	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Injury, poisoning and procedural complications (Cont.)			
Burns second degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dislocation of vertebra	0	1 (<0.1)	1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)	2 (<0.1)
Face injury	0	1 (<0.1)	1 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)	1 (<0.1)
Hypobarism	0	1 (<0.1)	1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	0	1 (<0.1)	1 (<0.1)
Ligament injury	0	1 (<0.1)	1 (<0.1)
Lip injury	0	1 (<0.1)	1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)	1 (<0.1)
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Muscle rupture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Nasal injury	0	1 (<0.1)	1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)	1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post-traumatic pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Procedural headache	0	1 (<0.1)	1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rib fracture	0	1 (<0.1)	1 (<0.1)
Scar	0	1 (<0.1)	1 (<0.1)
Tendon rupture	0	1 (<0.1)	1 (<0.1)
Thoracic vertebral fracture	0	1 (<0.1)	1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	1 (<0.1)	1 (<0.1)
Wound	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bone contusion	1 (<0.1)	0	1 (<0.1)
Burns first degree	1 (<0.1)	0	1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0	1 (<0.1)
Eyelid contusion	1 (<0.1)	0	1 (<0.1)
Fibula fracture	1 (<0.1)	0	1 (<0.1)
Foreign body	2 (<0.1)	0	2 (<0.1)
Hip fracture	1 (<0.1)	0	1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Mouth injury	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Injury, poisoning and procedural complications (Cont.)			
Muscle injury	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Procedural nausea	1 (<0.1)	0	1 (<0.1)
Scratch	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Stress fracture	3 (<0.1)	0	3 (<0.1)
Sunburn	1 (<0.1)	0	1 (<0.1)
Superficial injury of eye	2 (<0.1)	0	2 (<0.1)
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Venomous sting	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	8 (<0.1)	9 (<0.1)	17 (<0.1)
Axillary lymphadenectomy	0	2 (<0.1)	2 (<0.1)
Thyroidectomy	0	2 (<0.1)	2 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Dental operation	0	1 (<0.1)	1 (<0.1)
Endodontic procedure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin neoplasm excision	0	1 (<0.1)	1 (<0.1)
Spinal fusion surgery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Artificial crown procedure	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11415) n (%)	mRNA-1273 (N=11414) n (%)	Total (N=22830) n (%)
Surgical and medical procedures (Cont.)			
Cataract operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Knee arthroplasty	1 (<0.1)	0	1 (<0.1)
Liposuction	1 (<0.1)	0	1 (<0.1)
Tooth repair	2 (<0.1)	0	2 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopause	0	1 (<0.1)	1 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	0	3 (<0.1)	3 (<0.1)
Device breakage	0	1 (<0.1)	1 (<0.1)
Device dislocation	0	1 (<0.1)	1 (<0.1)
Embedded device	0	1 (<0.1)	1 (<0.1)
Uncoded	123 (1.1)	197 (1.7)	320 (1.4)
Uncoded	123 (1.1)	197 (1.7)	320 (1.4)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	816 (21.8)	952 (25.3)	1768 (23.5)
Number of Unsolicited Adverse Events	1518	1850	3368
Infections and infestations	175 (4.7)	148 (3.9)	323 (4.3)
Urinary tract infection	36 (1.0)	26 (0.7)	62 (0.8)
Sinusitis	8 (0.2)	11 (0.3)	19 (0.3)
Upper respiratory tract infection	6 (0.2)	9 (0.2)	15 (0.2)
COVID-19	24 (0.6)	7 (0.2)	31 (0.4)
Herpes zoster	3 (<0.1)	7 (0.2)	10 (0.1)
Cellulitis	5 (0.1)	5 (0.1)	10 (0.1)
Gastroenteritis	3 (<0.1)	5 (0.1)	8 (0.1)
Gingivitis	2 (<0.1)	5 (0.1)	7 (<0.1)
Localised infection	3 (<0.1)	4 (0.1)	7 (<0.1)
Rhinovirus infection	1 (<0.1)	4 (0.1)	5 (<0.1)
Tooth infection	3 (<0.1)	4 (0.1)	7 (<0.1)
Viral infection	5 (0.1)	4 (0.1)	9 (0.1)
Conjunctivitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Diverticulitis	4 (0.1)	3 (<0.1)	7 (<0.1)
Enterovirus infection	0	3 (<0.1)	3 (<0.1)
Herpes simplex	0	3 (<0.1)	3 (<0.1)
Hordeolum	4 (0.1)	3 (<0.1)	7 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)			
Laryngitis	0	3 (<0.1)	3 (<0.1)
Pharyngitis	0	3 (<0.1)	3 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tooth abscess	10 (0.3)	3 (<0.1)	13 (0.2)
Acute sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Appendicitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cystitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ear infection	3 (<0.1)	2 (<0.1)	5 (<0.1)
Fungal infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oral herpes	1 (<0.1)	2 (<0.1)	3 (<0.1)
Paronychia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pneumonia	6 (0.2)	2 (<0.1)	8 (0.1)
Rhinitis	4 (0.1)	2 (<0.1)	6 (<0.1)
Subcutaneous abscess	0	2 (<0.1)	2 (<0.1)
Bronchitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Chronic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Clostridium difficile colitis	0	1 (<0.1)	1 (<0.1)
Colonic abscess	0	1 (<0.1)	1 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)
Folliculitis	4 (0.1)	1 (<0.1)	5 (<0.1)
Gastrointestinal infection	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)			
Impetigo	0	1 (<0.1)	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Joint abscess	0	1 (<0.1)	1 (<0.1)
Latent tuberculosis	0	1 (<0.1)	1 (<0.1)
Nasopharyngitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Onychomycosis	0	1 (<0.1)	1 (<0.1)
Otitis media acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Postoperative abscess	0	1 (<0.1)	1 (<0.1)
Postoperative wound infection	0	1 (<0.1)	1 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tinea infection	0	1 (<0.1)	1 (<0.1)
Tinea pedis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Viral upper respiratory tract infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Body tinea	1 (<0.1)	0	1 (<0.1)
Candida infection	2 (<0.1)	0	2 (<0.1)
Denture stomatitis	1 (<0.1)	0	1 (<0.1)
Fungal skin infection	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)			
Gardnerella infection	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	1 (<0.1)	0	1 (<0.1)
Kidney infection	1 (<0.1)	0	1 (<0.1)
Labyrinthitis	1 (<0.1)	0	1 (<0.1)
Oral candidiasis	1 (<0.1)	0	1 (<0.1)
Osteomyelitis	1 (<0.1)	0	1 (<0.1)
Otitis externa	3 (<0.1)	0	3 (<0.1)
Otitis media	1 (<0.1)	0	1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	0	2 (<0.1)
Respiratory tract infection	1 (<0.1)	0	1 (<0.1)
Skin infection	3 (<0.1)	0	3 (<0.1)
Soft tissue infection	1 (<0.1)	0	1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Tinea cruris	1 (<0.1)	0	1 (<0.1)
Viral rhinitis	1 (<0.1)	0	1 (<0.1)
Viral sinusitis	1 (<0.1)	0	1 (<0.1)
Vulvovaginal mycotic infection	1 (<0.1)	0	1 (<0.1)
Wound infection	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.6)	23 (0.6)	47 (0.6)
Basal cell carcinoma	7 (0.2)	5 (0.1)	12 (0.2)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Malignant melanoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)	5 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)	1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)	1 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	0	1 (<0.1)	1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meningioma	0	1 (<0.1)	1 (<0.1)
Meningioma benign	0	1 (<0.1)	1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Neoplasm malignant	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Squamous cell carcinoma	7 (0.2)	1 (<0.1)	8 (0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0	1 (<0.1)
Skin cancer	2 (<0.1)	0	2 (<0.1)
Squamous cell carcinoma of skin	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Blood and lymphatic system disorders	10 (0.3)	22 (0.6)	32 (0.4)
Lymphadenopathy	8 (0.2)	19 (0.5)	27 (0.4)
Anaemia	0	1 (<0.1)	1 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Leukocytosis	0	1 (<0.1)	1 (<0.1)
Lymph node pain	1 (<0.1)	0	1 (<0.1)
Lymphadenitis	1 (<0.1)	0	1 (<0.1)
Immune system disorders	7 (0.2)	7 (0.2)	14 (0.2)
Hypersensitivity	0	3 (<0.1)	3 (<0.1)
Seasonal allergy	5 (0.1)	2 (<0.1)	7 (<0.1)
Drug hypersensitivity	1 (<0.1)	1 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to chemicals	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	5 (0.1)	1 (<0.1)	6 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Addison's disease	1 (<0.1)	0	1 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Hypothyroidism	3 (<0.1)	0	3 (<0.1)
Metabolism and nutrition disorders	26 (0.7)	32 (0.8)	58 (0.8)
Hyperlipidaemia	3 (<0.1)	7 (0.2)	10 (0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypercholesterolaemia	3 (<0.1)	5 (0.1)	8 (0.1)
Dehydration	3 (<0.1)	4 (0.1)	7 (<0.1)
Gout	4 (0.1)	3 (<0.1)	7 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hyponatraemia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Vitamin D deficiency	0	2 (<0.1)	2 (<0.1)
Decreased appetite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetes mellitus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)	1 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)
Insulin resistance	0	1 (<0.1)	1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vitamin B12 deficiency	0	1 (<0.1)	1 (<0.1)
Abnormal loss of weight	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	1 (<0.1)	0	1 (<0.1)
Hypocalcaemia	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	2 (<0.1)	0	2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Psychiatric disorders	9 (0.2)	22 (0.6)	31 (0.4)
Anxiety	2 (<0.1)	7 (0.2)	9 (0.1)
Depression	0	3 (<0.1)	3 (<0.1)
Insomnia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Nightmare	0	3 (<0.1)	3 (<0.1)
Sleep disorder	0	2 (<0.1)	2 (<0.1)
Bruxism	0	1 (<0.1)	1 (<0.1)
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Mental fatigue	0	1 (<0.1)	1 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	0	1 (<0.1)
Confusional state	1 (<0.1)	0	1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0	1 (<0.1)
Mental status changes	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	120 (3.2)	147 (3.9)	267 (3.6)
Headache	78 (2.1)	96 (2.5)	174 (2.3)
Dizziness	14 (0.4)	16 (0.4)	30 (0.4)
Sinus headache	1 (<0.1)	6 (0.2)	7 (<0.1)
Cervical radiculopathy	0	4 (0.1)	4 (<0.1)
Paraesthesia	2 (<0.1)	4 (0.1)	6 (<0.1)
Sciatica	2 (<0.1)	4 (0.1)	6 (<0.1)
Ageusia	3 (<0.1)	2 (<0.1)	5 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)			
Dysgeusia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Hyperaesthesia	0	2 (<0.1)	2 (<0.1)
Hypoaesthesia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Syncope	6 (0.2)	2 (<0.1)	8 (0.1)
Tension headache	0	2 (<0.1)	2 (<0.1)
Amnesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anosmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Carpal tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)	1 (<0.1)
Disturbance in attention	0	1 (<0.1)	1 (<0.1)
Dizziness postural	0	1 (<0.1)	1 (<0.1)
Essential tremor	0	1 (<0.1)	1 (<0.1)
Facial paralysis	0	1 (<0.1)	1 (<0.1)
Hyposmia	0	1 (<0.1)	1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Migraine	3 (<0.1)	1 (<0.1)	4 (<0.1)
Neuralgia	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)			
Dysaesthesia	1 (<0.1)	0	1 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Nerve compression	1 (<0.1)	0	1 (<0.1)
Post-traumatic headache	1 (<0.1)	0	1 (<0.1)
Presyncope	2 (<0.1)	0	2 (<0.1)
Restless legs syndrome	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Taste disorder	1 (<0.1)	0	1 (<0.1)
Tremor	1 (<0.1)	0	1 (<0.1)
Eye disorders	20 (0.5)	21 (0.6)	41 (0.5)
Eye pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Eye irritation	0	2 (<0.1)	2 (<0.1)
Eye pruritus	1 (<0.1)	2 (<0.1)	3 (<0.1)
Glaucoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Accommodation disorder	0	1 (<0.1)	1 (<0.1)
Cataract	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry eye	2 (<0.1)	1 (<0.1)	3 (<0.1)
Eye inflammation	0	1 (<0.1)	1 (<0.1)
Eye swelling	0	1 (<0.1)	1 (<0.1)
Keratitis	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Eye disorders (Cont.)			
Retinal detachment	0	1 (<0.1)	1 (<0.1)
Swelling of eyelid	0	1 (<0.1)	1 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vitreous disorder	0	1 (<0.1)	1 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blepharitis	1 (<0.1)	0	1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Eye discharge	1 (<0.1)	0	1 (<0.1)
Macular hole	1 (<0.1)	0	1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Strabismus	1 (<0.1)	0	1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)
Vision blurred	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	20 (0.5)	17 (0.5)	37 (0.5)
Vertigo	7 (0.2)	6 (0.2)	13 (0.2)
Vertigo positional	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Ear and labyrinth disorders (Cont.)			
Tinnitus	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Deafness unilateral	0	1 (<0.1)	1 (<0.1)
Ear congestion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ear pain	4 (0.1)	1 (<0.1)	5 (<0.1)
Middle ear effusion	0	1 (<0.1)	1 (<0.1)
Motion sickness	0	1 (<0.1)	1 (<0.1)
Ear discomfort	2 (<0.1)	0	2 (<0.1)
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Otorrhoea	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	0	2 (<0.1)
Cardiac disorders	28 (0.7)	31 (0.8)	59 (0.8)
Atrial fibrillation	6 (0.2)	8 (0.2)	14 (0.2)
Coronary artery disease	4 (0.1)	5 (0.1)	9 (0.1)
Angina pectoris	0	3 (<0.1)	3 (<0.1)
Palpitations	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tachycardia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Arrhythmia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cardiac failure congestive	1 (<0.1)	2 (<0.1)	3 (<0.1)
Myocardial infarction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus tachycardia	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Cardiac disorders (Cont.)			
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute myocardial infarction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bradycardia	7 (0.2)	1 (<0.1)	8 (0.1)
Cardio-respiratory arrest	0	1 (<0.1)	1 (<0.1)
Cardiomyopathy	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	0	1 (<0.1)	1 (<0.1)
Tachyarrhythmia	0	1 (<0.1)	1 (<0.1)
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Cardiac failure	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	61 (1.6)	62 (1.6)	123 (1.6)
Hypertension	46 (1.2)	42 (1.1)	88 (1.2)
Hot flush	3 (<0.1)	7 (0.2)	10 (0.1)
Flushing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Orthostatic hypotension	0	2 (<0.1)	2 (<0.1)
Aortic aneurysm	3 (<0.1)	1 (<0.1)	4 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Haematoma	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Vascular disorders (Cont.)			
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)	1 (<0.1)
Systolic hypertension	2 (<0.1)	1 (<0.1)	3 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	124 (3.3)	120 (3.2)	244 (3.2)
Rhinorrhoea	33 (0.9)	43 (1.1)	76 (1.0)
Nasal congestion	26 (0.7)	34 (0.9)	60 (0.8)
Oropharyngeal pain	30 (0.8)	32 (0.8)	62 (0.8)
Cough	21 (0.6)	30 (0.8)	51 (0.7)
Dyspnoea	7 (0.2)	11 (0.3)	18 (0.2)
Asthma	2 (<0.1)	5 (0.1)	7 (<0.1)
Upper-airway cough syndrome	1 (<0.1)	5 (0.1)	6 (<0.1)
Sneezing	2 (<0.1)	4 (0.1)	6 (<0.1)
Tachypnoea	5 (0.1)	4 (0.1)	9 (0.1)
Dysphonia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Epistaxis	6 (0.2)	3 (<0.1)	9 (0.1)
Sinus congestion	6 (0.2)	3 (<0.1)	9 (0.1)
Chronic obstructive pulmonary disease	4 (0.1)	2 (<0.1)	6 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Respiratory tract congestion	0	2 (<0.1)	2 (<0.1)
Rhinitis allergic	4 (0.1)	2 (<0.1)	6 (<0.1)
Throat irritation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Bronchiectasis	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)	1 (<0.1)
Dry throat	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dyspnoea exertional	0	1 (<0.1)	1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)	1 (<0.1)
Pneumonia aspiration	0	1 (<0.1)	1 (<0.1)
Productive cough	2 (<0.1)	1 (<0.1)	3 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rhonchi	0	1 (<0.1)	1 (<0.1)
Sinus pain	0	1 (<0.1)	1 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)	1 (<0.1)
Wheezing	0	1 (<0.1)	1 (<0.1)
Nasal disorder	1 (<0.1)	0	1 (<0.1)
Nasal septum deviation	1 (<0.1)	0	1 (<0.1)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	0	1 (<0.1)
Pharyngeal erythema	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pleural effusion	2 (<0.1)	0	2 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Respiratory failure	1 (<0.1)	0	1 (<0.1)
Tonsillar exudate	1 (<0.1)	0	1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	106 (2.8)	126 (3.3)	232 (3.1)
Diarrhoea	46 (1.2)	43 (1.1)	89 (1.2)
Nausea	20 (0.5)	33 (0.9)	53 (0.7)
Gastroesophageal reflux disease	2 (<0.1)	14 (0.4)	16 (0.2)
Vomiting	7 (0.2)	13 (0.3)	20 (0.3)
Toothache	4 (0.1)	8 (0.2)	12 (0.2)
Dyspepsia	1 (<0.1)	5 (0.1)	6 (<0.1)
Abdominal pain upper	3 (<0.1)	4 (0.1)	7 (<0.1)
Abdominal pain	2 (<0.1)	3 (<0.1)	5 (<0.1)
Abdominal pain lower	1 (<0.1)	3 (<0.1)	4 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Dental caries	2 (<0.1)	3 (<0.1)	5 (<0.1)
Constipation	4 (0.1)	2 (<0.1)	6 (<0.1)
Inguinal hernia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abdominal discomfort	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)			
Diverticular perforation	0	1 (<0.1)	1 (<0.1)
Dry mouth	1 (<0.1)	1 (<0.1)	2 (<0.1)
Faeces soft	0	1 (<0.1)	1 (<0.1)
Food poisoning	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hiatus hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)	1 (<0.1)
Lip swelling	0	1 (<0.1)	1 (<0.1)
Oesophageal pain	0	1 (<0.1)	1 (<0.1)
Oral mucosal blistering	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Paraesthesia oral	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Salivary hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stomatitis	0	1 (<0.1)	1 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Aphthous ulcer	1 (<0.1)	0	1 (<0.1)
Diverticulum	1 (<0.1)	0	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)			
Gastritis	1 (<0.1)	0	1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0	1 (<0.1)
Gingival pain	2 (<0.1)	0	2 (<0.1)
Intestinal obstruction	1 (<0.1)	0	1 (<0.1)
Large intestine polyp	3 (<0.1)	0	3 (<0.1)
Oral discomfort	1 (<0.1)	0	1 (<0.1)
Oral pain	2 (<0.1)	0	2 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Umbilical hernia	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)	3 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Cholelithiasis	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	52 (1.4)	67 (1.8)	119 (1.6)
Rash	5 (0.1)	12 (0.3)	17 (0.2)
Pruritus	8 (0.2)	8 (0.2)	16 (0.2)
Erythema	3 (<0.1)	7 (0.2)	10 (0.1)
Urticaria	4 (0.1)	6 (0.2)	10 (0.1)
Hyperhidrosis	2 (<0.1)	4 (0.1)	6 (<0.1)
Actinic keratosis	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis atopic	0	3 (<0.1)	3 (<0.1)
Dermatitis contact	10 (0.3)	3 (<0.1)	13 (0.2)
Dermatitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Night sweats	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rash pruritic	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ecchymosis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eczema	0	1 (<0.1)	1 (<0.1)
Ingrowing nail	0	1 (<0.1)	1 (<0.1)
Macule	0	1 (<0.1)	1 (<0.1)
Nail disorder	0	1 (<0.1)	1 (<0.1)
Pityriasis rosea	0	1 (<0.1)	1 (<0.1)
Rash erythematous	0	1 (<0.1)	1 (<0.1)
Rash papular	0	1 (<0.1)	1 (<0.1)
Skin hypopigmentation	0	1 (<0.1)	1 (<0.1)
Skin lesion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Solar lentigo	0	1 (<0.1)	1 (<0.1)
Angioedema	1 (<0.1)	0	1 (<0.1)
Cold sweat	1 (<0.1)	0	1 (<0.1)
Dermal cyst	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Psoriasis	1 (<0.1)	0	1 (<0.1)
Scab	1 (<0.1)	0	1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0	1 (<0.1)
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Urticaria papular	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	157 (4.2)	173 (4.6)	330 (4.4)
Arthralgia	42 (1.1)	52 (1.4)	94 (1.3)
Myalgia	32 (0.9)	44 (1.2)	76 (1.0)
Back pain	26 (0.7)	22 (0.6)	48 (0.6)
Pain in extremity	19 (0.5)	16 (0.4)	35 (0.5)
Musculoskeletal pain	7 (0.2)	11 (0.3)	18 (0.2)
Neck pain	7 (0.2)	10 (0.3)	17 (0.2)
Muscle spasms	6 (0.2)	8 (0.2)	14 (0.2)
Musculoskeletal stiffness	1 (<0.1)	6 (0.2)	7 (<0.1)
Tendonitis	4 (0.1)	4 (0.1)	8 (0.1)
Arthritis	0	3 (<0.1)	3 (<0.1)
Joint swelling	0	3 (<0.1)	3 (<0.1)
Osteoporosis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Muscular weakness	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteoarthritis	8 (0.2)	2 (<0.1)	10 (0.1)
Rotator cuff syndrome	4 (0.1)	2 (<0.1)	6 (<0.1)
Spinal stenosis	0	2 (<0.1)	2 (<0.1)
Trigger finger	0	2 (<0.1)	2 (<0.1)
Bursitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Costochondritis	0	1 (<0.1)	1 (<0.1)
Flank pain	0	1 (<0.1)	1 (<0.1)
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Joint range of motion decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint stiffness	0	1 (<0.1)	1 (<0.1)
Limb discomfort	0	1 (<0.1)	1 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Muscle tightness	0	1 (<0.1)	1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neck mass	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal osteoarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spondylitis	0	1 (<0.1)	1 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Fibromyalgia	1 (<0.1)	0	1 (<0.1)
Foot deformity	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Groin pain	1 (<0.1)	0	1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	0	1 (<0.1)
Intervertebral disc protrusion	2 (<0.1)	0	2 (<0.1)
Lumbar spinal stenosis	1 (<0.1)	0	1 (<0.1)
Pain in jaw	2 (<0.1)	0	2 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	20 (0.5)	20 (0.5)	40 (0.5)
Nephrolithiasis	7 (0.2)	8 (0.2)	15 (0.2)
Chronic kidney disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Haematuria	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bladder prolapse	0	1 (<0.1)	1 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
Dysuria	0	1 (<0.1)	1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)
Pollakiuria	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyuria	0	1 (<0.1)	1 (<0.1)
Urinary hesitation	0	1 (<0.1)	1 (<0.1)
Urinary retention	1 (<0.1)	1 (<0.1)	2 (<0.1)
Acute kidney injury	3 (<0.1)	0	3 (<0.1)
Chromaturia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)			
Micturition urgency	1 (<0.1)	0	1 (<0.1)
Renal colic	1 (<0.1)	0	1 (<0.1)
Renal mass	1 (<0.1)	0	1 (<0.1)
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Urinary incontinence	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	3 (<0.1)	15 (0.4)	18 (0.2)
Benign prostatic hyperplasia	1 (<0.1)	6 (0.2)	7 (<0.1)
Erectile dysfunction	0	2 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Breast discharge	0	1 (<0.1)	1 (<0.1)
Breast mass	0	1 (<0.1)	1 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Ovarian cyst	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)	1 (<0.1)
Prostatitis	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	145 (3.9)	229 (6.1)	374 (5.0)
Fatigue	63 (1.7)	102 (2.7)	165 (2.2)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)			
Injection site erythema	7 (0.2)	32 (0.8)	39 (0.5)
Injection site pain	14 (0.4)	29 (0.8)	43 (0.6)
Chills	13 (0.3)	21 (0.6)	34 (0.5)
Pyrexia	8 (0.2)	20 (0.5)	28 (0.4)
Injection site pruritus	2 (<0.1)	18 (0.5)	20 (0.3)
Pain	11 (0.3)	18 (0.5)	29 (0.4)
Injection site swelling	5 (0.1)	12 (0.3)	17 (0.2)
Injection site rash	0	8 (0.2)	8 (0.1)
Injection site induration	3 (<0.1)	4 (0.1)	7 (<0.1)
Axillary pain	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site bruising	6 (0.2)	3 (<0.1)	9 (0.1)
Oedema peripheral	4 (0.1)	3 (<0.1)	7 (<0.1)
Chest discomfort	3 (<0.1)	2 (<0.1)	5 (<0.1)
Injection site warmth	0	2 (<0.1)	2 (<0.1)
Peripheral swelling	4 (0.1)	2 (<0.1)	6 (<0.1)
Vaccination site pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Asthenia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chest pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)	1 (<0.1)
Feeling abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Feeling hot	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)			
Inflammation	0	1 (<0.1)	1 (<0.1)
Injection site haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site joint pain	0	1 (<0.1)	1 (<0.1)
Injection site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Injection site paraesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site reaction	0	1 (<0.1)	1 (<0.1)
Injection site scab	0	1 (<0.1)	1 (<0.1)
Injection site urticaria	0	1 (<0.1)	1 (<0.1)
Malaise	5 (0.1)	1 (<0.1)	6 (<0.1)
Reactogenicity event	0	1 (<0.1)	1 (<0.1)
Swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Temperature intolerance	0	1 (<0.1)	1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst	1 (<0.1)	0	1 (<0.1)
Facial pain	1 (<0.1)	0	1 (<0.1)
Gait disturbance	1 (<0.1)	0	1 (<0.1)
Granuloma	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Influenza like illness	1 (<0.1)	0	1 (<0.1)
Injection site discolouration	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)			
Injection site haematoma	1 (<0.1)	0	1 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	0	1 (<0.1)
Injection site mass	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	0	1 (<0.1)
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Thirst	1 (<0.1)	0	1 (<0.1)
Vaccination site inflammation	1 (<0.1)	0	1 (<0.1)
Vaccination site swelling	1 (<0.1)	0	1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	0	1 (<0.1)
Investigations	19 (0.5)	37 (1.0)	56 (0.7)
Blood pressure increased	7 (0.2)	12 (0.3)	19 (0.3)
Blood pressure systolic increased	5 (0.1)	7 (0.2)	12 (0.2)
Blood pressure diastolic increased	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)	2 (<0.1)
Blood creatine increased	0	1 (<0.1)	1 (<0.1)
Blood creatinine increased	0	1 (<0.1)	1 (<0.1)
Blood glucose decreased	0	1 (<0.1)	1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Investigations (Cont.)			
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)	2 (<0.1)
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)
Heart rate increased	0	1 (<0.1)	1 (<0.1)
Hepatitis B antibody positive	0	1 (<0.1)	1 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Vitamin K	0	1 (<0.1)	1 (<0.1)
Weight decreased	0	1 (<0.1)	1 (<0.1)
White blood cell count increased	0	1 (<0.1)	1 (<0.1)
Blood cholesterol increased	1 (<0.1)	0	1 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Mammogram abnormal	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	92 (2.5)	94 (2.5)	186 (2.5)
Arthropod bite	6 (0.2)	10 (0.3)	16 (0.2)
Contusion	9 (0.2)	10 (0.3)	19 (0.3)
Fall	7 (0.2)	9 (0.2)	16 (0.2)
Muscle strain	7 (0.2)	7 (0.2)	14 (0.2)
Procedural pain	3 (<0.1)	7 (0.2)	10 (0.1)
Skin laceration	7 (0.2)	7 (0.2)	14 (0.2)
Ligament sprain	5 (0.1)	6 (0.2)	11 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)			
Tooth fracture	5 (0.1)	6 (0.2)	11 (0.1)
Limb injury	3 (<0.1)	5 (0.1)	8 (0.1)
Foot fracture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Facial bones fracture	0	2 (<0.1)	2 (<0.1)
Hand fracture	0	2 (<0.1)	2 (<0.1)
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Humerus fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rib fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Road traffic accident	1 (<0.1)	2 (<0.1)	3 (<0.1)
Skin abrasion	6 (0.2)	2 (<0.1)	8 (0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Animal bite	2 (<0.1)	1 (<0.1)	3 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<0.1)
Arthropod sting	6 (0.2)	1 (<0.1)	7 (<0.1)
Back injury	0	1 (<0.1)	1 (<0.1)
Burns first degree	0	1 (<0.1)	1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Epicondylitis	0	1 (<0.1)	1 (<0.1)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)			
Femur fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fibula fracture	0	1 (<0.1)	1 (<0.1)
Head injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Muscle rupture	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Procedural nausea	0	1 (<0.1)	1 (<0.1)
Scratch	0	1 (<0.1)	1 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thermal burn	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Abdominal injury	1 (<0.1)	0	1 (<0.1)
Ankle fracture	1 (<0.1)	0	1 (<0.1)
Bone contusion	2 (<0.1)	0	2 (<0.1)
Clavicle fracture	1 (<0.1)	0	1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0	1 (<0.1)
Eye injury	2 (<0.1)	0	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)			
Foreign body	1 (<0.1)	0	1 (<0.1)
Foreign body in ear	1 (<0.1)	0	1 (<0.1)
Fracture	1 (<0.1)	0	1 (<0.1)
Ligament rupture	1 (<0.1)	0	1 (<0.1)
Lip injury	2 (<0.1)	0	2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0	1 (<0.1)
Nail injury	1 (<0.1)	0	1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	0	1 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Post-traumatic pain	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Tendon injury	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Wound	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	5 (0.1)	10 (0.3)	15 (0.2)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Curettage of chalazion	0	1 (<0.1)	1 (<0.1)
Cyst removal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Endodontic procedure	0	1 (<0.1)	1 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.6
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Surgical and medical procedures (Cont.)			
Lipoma excision	0	1 (<0.1)	1 (<0.1)
Phlebectomy	0	1 (<0.1)	1 (<0.1)
Skin cyst excision	0	1 (<0.1)	1 (<0.1)
Skin operation	0	1 (<0.1)	1 (<0.1)
Transurethral prostatectomy	0	1 (<0.1)	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Tooth extraction	1 (<0.1)	0	1 (<0.1)
Umbilical hernia repair	1 (<0.1)	0	1 (<0.1)
Product issues	2 (<0.1)	1 (<0.1)	3 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lead dislodgement	1 (<0.1)	0	1 (<0.1)
Uncoded	56 (1.5)	66 (1.8)	122 (1.6)
Uncoded	56 (1.5)	66 (1.8)	122 (1.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2846 (19.8)	3204 (22.4)	6050 (21.1)
Number of Unsolicited Adverse Events	5172	5902	11074
Infections and infestations	609 (4.2)	496 (3.5)	1105 (3.9)
Urinary tract infection	84 (0.6)	68 (0.5)	152 (0.5)
Sinusitis	27 (0.2)	51 (0.4)	78 (0.3)
Upper respiratory tract infection	59 (0.4)	38 (0.3)	97 (0.3)
Viral infection	30 (0.2)	20 (0.1)	50 (0.2)
Herpes zoster	10 (<0.1)	17 (0.1)	27 (<0.1)
Gastroenteritis	14 (<0.1)	16 (0.1)	30 (0.1)
Tooth infection	11 (<0.1)	16 (0.1)	27 (<0.1)
COVID-19	101 (0.7)	15 (0.1)	116 (0.4)
Rhinovirus infection	4 (<0.1)	15 (0.1)	19 (<0.1)
Tooth abscess	22 (0.2)	15 (0.1)	37 (0.1)
Pharyngitis	18 (0.1)	13 (<0.1)	31 (0.1)
Cellulitis	11 (<0.1)	12 (<0.1)	23 (<0.1)
Ear infection	7 (<0.1)	12 (<0.1)	19 (<0.1)
Conjunctivitis	5 (<0.1)	11 (<0.1)	16 (<0.1)
Pharyngitis streptococcal	16 (0.1)	11 (<0.1)	27 (<0.1)
Gingivitis	4 (<0.1)	9 (<0.1)	13 (<0.1)
Hordeolum	9 (<0.1)	8 (<0.1)	17 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Oral herpes	5 (<0.1)	8 (<0.1)	13 (<0.1)
Fungal infection	8 (<0.1)	7 (<0.1)	15 (<0.1)
Diverticulitis	8 (<0.1)	6 (<0.1)	14 (<0.1)
Pneumonia	8 (<0.1)	6 (<0.1)	14 (<0.1)
Viral upper respiratory tract infection	9 (<0.1)	6 (<0.1)	15 (<0.1)
Acute sinusitis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bacterial vaginosis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Herpes simplex	1 (<0.1)	5 (<0.1)	6 (<0.1)
Localised infection	8 (<0.1)	5 (<0.1)	13 (<0.1)
Otitis media	6 (<0.1)	5 (<0.1)	11 (<0.1)
Vulvovaginal candidiasis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Enterovirus infection	0	4 (<0.1)	4 (<0.1)
Folliculitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Paronychia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Respiratory tract infection	4 (<0.1)	4 (<0.1)	8 (<0.1)
Rhinitis	9 (<0.1)	4 (<0.1)	13 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	3 (<0.1)	4 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Impetigo	0	3 (<0.1)	3 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Nasopharyngitis	9 (<0.1)	3 (<0.1)	12 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Onychomycosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vulvovaginal mycotic infection	9 (<0.1)	3 (<0.1)	12 (<0.1)
Bronchitis	5 (<0.1)	2 (<0.1)	7 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Laryngitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Otitis media acute	3 (<0.1)	2 (<0.1)	5 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Staphylococcal skin infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Subcutaneous abscess	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tinea pedis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Tonsillitis	6 (<0.1)	2 (<0.1)	8 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)	2 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abscess jaw	0	1 (<0.1)	1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bacterial infection	0	1 (<0.1)	1 (<0.1)
Body tinea	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Candida infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cat scratch disease	0	1 (<0.1)	1 (<0.1)
Catheter site infection	0	1 (<0.1)	1 (<0.1)
Clostridium difficile colitis	0	1 (<0.1)	1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cystitis	6 (<0.1)	1 (<0.1)	7 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Furuncle	0	1 (<0.1)	1 (<0.1)
Gastroenteritis viral	6 (<0.1)	1 (<0.1)	7 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gonorrhoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected bite	0	1 (<0.1)	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Joint abscess	0	1 (<0.1)	1 (<0.1)
Kidney infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lyme disease	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Osteomyelitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Otitis externa	10 (<0.1)	1 (<0.1)	11 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)
Parotitis	0	1 (<0.1)	1 (<0.1)
Periodontitis	0	1 (<0.1)	1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)	1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Respiratory tract infection viral	3 (<0.1)	1 (<0.1)	4 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Breast abscess	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Denture stomatitis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Eye infection	4 (<0.1)	0	4 (<0.1)
Fungal skin infection	1 (<0.1)	0	1 (<0.1)
Gardnerella infection	2 (<0.1)	0	2 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	1 (<0.1)	0	1 (<0.1)
Herpes virus infection	1 (<0.1)	0	1 (<0.1)
Influenza	1 (<0.1)	0	1 (<0.1)
Labyrinthitis	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Nasal abscess	1 (<0.1)	0	1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0	1 (<0.1)
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Pustule	1 (<0.1)	0	1 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0	1 (<0.1)
Skin candida	1 (<0.1)	0	1 (<0.1)
Streptococcal infection	1 (<0.1)	0	1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Suspected COVID-19	2 (<0.1)	0	2 (<0.1)
Syphilis	1 (<0.1)	0	1 (<0.1)
Tinea cruris	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Tinea infection	1 (<0.1)	0	1 (<0.1)
Tinea versicolour	1 (<0.1)	0	1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	32 (0.2)	36 (0.3)	68 (0.2)
Basal cell carcinoma	11 (<0.1)	6 (<0.1)	17 (<0.1)
Squamous cell carcinoma	6 (<0.1)	3 (<0.1)	9 (<0.1)
Malignant melanoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Melanocytic naevus	0	2 (<0.1)	2 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)	5 (<0.1)
Uterine leiomyoma	0	2 (<0.1)	2 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)	1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)	1 (<0.1)
Breast neoplasm	0	1 (<0.1)	1 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Haemangioma of liver	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	0	1 (<0.1)	1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Lipoma of breast	0	1 (<0.1)	1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)	1 (<0.1)
Meningioma benign	0	1 (<0.1)	1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Neoplasm malignant	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Thyroid cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Chondromatosis	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Skin cancer	1 (<0.1)	0	1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	0	2 (<0.1)
Blood and lymphatic system disorders	57 (0.4)	111 (0.8)	168 (0.6)
Lymphadenopathy	49 (0.3)	92 (0.6)	141 (0.5)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Blood and lymphatic system disorders (Cont.)			
Anaemia	0	7 (<0.1)	7 (<0.1)
Lymph node pain	3 (<0.1)	5 (<0.1)	8 (<0.1)
Lymphadenitis	0	5 (<0.1)	5 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Thrombocytopenia	0	1 (<0.1)	1 (<0.1)
Increased tendency to bruise	1 (<0.1)	0	1 (<0.1)
Immune system disorders	30 (0.2)	25 (0.2)	55 (0.2)
Seasonal allergy	20 (0.1)	14 (<0.1)	34 (0.1)
Hypersensitivity	1 (<0.1)	6 (<0.1)	7 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Autoimmune disorder	0	1 (<0.1)	1 (<0.1)
Drug hypersensitivity	3 (<0.1)	1 (<0.1)	4 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to chemicals	1 (<0.1)	0	1 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Endocrine disorders	9 (<0.1)	5 (<0.1)	14 (<0.1)
Hypothyroidism	5 (<0.1)	4 (<0.1)	9 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Addison's disease	1 (<0.1)	0	1 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Hypogonadism	1 (<0.1)	0	1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	60 (0.4)	68 (0.5)	128 (0.4)
Hyperlipidaemia	9 (<0.1)	11 (<0.1)	20 (<0.1)
Decreased appetite	6 (<0.1)	9 (<0.1)	15 (<0.1)
Type 2 diabetes mellitus	3 (<0.1)	9 (<0.1)	12 (<0.1)
Dehydration	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hypercholesterolaemia	10 (<0.1)	7 (<0.1)	17 (<0.1)
Vitamin D deficiency	7 (<0.1)	6 (<0.1)	13 (<0.1)
Diabetes mellitus	0	3 (<0.1)	3 (<0.1)
Hyperglycaemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Gout	6 (<0.1)	2 (<0.1)	8 (<0.1)
Hyponatraemia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abnormal loss of weight	0	1 (<0.1)	1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Food intolerance	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Metabolism and nutrition disorders (Cont.)			
Glucose tolerance impaired	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Insulin resistance	0	1 (<0.1)	1 (<0.1)
Iron deficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abnormal weight gain	1 (<0.1)	0	1 (<0.1)
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	1 (<0.1)	0	1 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hypocalcaemia	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	2 (<0.1)	0	2 (<0.1)
Polydipsia	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	69 (0.5)	89 (0.6)	158 (0.6)
Anxiety	23 (0.2)	24 (0.2)	47 (0.2)
Depression	15 (0.1)	22 (0.2)	37 (0.1)
Insomnia	13 (<0.1)	14 (<0.1)	27 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<0.1)
Sleep disorder	0	5 (<0.1)	5 (<0.1)
Attention deficit hyperactivity disorder	4 (<0.1)	4 (<0.1)	8 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Psychiatric disorders (Cont.)			
Nightmare	0	3 (<0.1)	3 (<0.1)
Bipolar disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	1 (<0.1)	2 (<0.1)
Affect lability	0	1 (<0.1)	1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	0	1 (<0.1)	1 (<0.1)
Bruxism	0	1 (<0.1)	1 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Libido decreased	0	1 (<0.1)	1 (<0.1)
Major depression	1 (<0.1)	1 (<0.1)	2 (<0.1)
Panic attack	3 (<0.1)	1 (<0.1)	4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Stress	1 (<0.1)	1 (<0.1)	2 (<0.1)
Substance abuse	0	1 (<0.1)	1 (<0.1)
Alcohol abuse	1 (<0.1)	0	1 (<0.1)
Confusional state	1 (<0.1)	0	1 (<0.1)
Generalised anxiety disorder	2 (<0.1)	0	2 (<0.1)
Mental fatigue	1 (<0.1)	0	1 (<0.1)
Mental status changes	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Psychiatric disorders (Cont.)			
Persistent depressive disorder	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Suicidal ideation	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	522 (3.6)	597 (4.2)	1119 (3.9)
Headache	386 (2.7)	417 (2.9)	803 (2.8)
Dizziness	44 (0.3)	58 (0.4)	102 (0.4)
Paraesthesia	18 (0.1)	24 (0.2)	42 (0.1)
Dysgeusia	6 (<0.1)	11 (<0.1)	17 (<0.1)
Sinus headache	5 (<0.1)	10 (<0.1)	15 (<0.1)
Ageusia	6 (<0.1)	9 (<0.1)	15 (<0.1)
Migraine	17 (0.1)	9 (<0.1)	26 (<0.1)
Hypoaesthesia	4 (<0.1)	8 (<0.1)	12 (<0.1)
Sciatica	5 (<0.1)	8 (<0.1)	13 (<0.1)
Syncope	10 (<0.1)	8 (<0.1)	18 (<0.1)
Anosmia	5 (<0.1)	6 (<0.1)	11 (<0.1)
Presyncope	10 (<0.1)	6 (<0.1)	16 (<0.1)
Tension headache	2 (<0.1)	6 (<0.1)	8 (<0.1)
Hyperaesthesia	0	5 (<0.1)	5 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	4 (<0.1)	6 (<0.1)
Cervical radiculopathy	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Nervous system disorders (Cont.)			
Mental impairment	0	3 (<0.1)	3 (<0.1)
Burning sensation	0	2 (<0.1)	2 (<0.1)
Disturbance in attention	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neuralgia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Seizure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Somnolence	0	2 (<0.1)	2 (<0.1)
Transient ischaemic attack	0	2 (<0.1)	2 (<0.1)
Amnesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)	1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)	1 (<0.1)
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Lethargy	0	1 (<0.1)	1 (<0.1)
Memory impairment	0	1 (<0.1)	1 (<0.1)
Migraine with aura	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Nerve compression	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Nervous system disorders (Cont.)			
Neuropathy peripheral	0	1 (<0.1)	1 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Post-traumatic headache	1 (<0.1)	1 (<0.1)	2 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)	1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thoracic outlet syndrome	0	1 (<0.1)	1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Visual field defect	0	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Encephalitis autoimmune	1 (<0.1)	0	1 (<0.1)
Facial paralysis	1 (<0.1)	0	1 (<0.1)
Head discomfort	1 (<0.1)	0	1 (<0.1)
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Lumbar radiculopathy	3 (<0.1)	0	3 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0	1 (<0.1)
Restless legs syndrome	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Nervous system disorders (Cont.)			
Speech disorder	1 (<0.1)	0	1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Tremor	1 (<0.1)	0	1 (<0.1)
Eye disorders	46 (0.3)	46 (0.3)	92 (0.3)
Eye pruritus	4 (<0.1)	7 (<0.1)	11 (<0.1)
Eye irritation	0	5 (<0.1)	5 (<0.1)
Dry eye	5 (<0.1)	2 (<0.1)	7 (<0.1)
Eye inflammation	0	2 (<0.1)	2 (<0.1)
Eye pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Eye swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lacrimation increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ocular hyperaemia	6 (<0.1)	2 (<0.1)	8 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)	3 (<0.1)
Visual impairment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vitreous floaters	3 (<0.1)	2 (<0.1)	5 (<0.1)
Accommodation disorder	0	1 (<0.1)	1 (<0.1)
Blepharitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blepharospasm	0	1 (<0.1)	1 (<0.1)
Blindness transient	0	1 (<0.1)	1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Eye disorders (Cont.)			
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Eye discharge	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eyelid cyst	0	1 (<0.1)	1 (<0.1)
Glaucoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Iris disorder	0	1 (<0.1)	1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Vision blurred	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vitreous disorder	0	1 (<0.1)	1 (<0.1)
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	0	2 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0	1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Eyelid ptosis	1 (<0.1)	0	1 (<0.1)
Macular degeneration	1 (<0.1)	0	1 (<0.1)
Macular hole	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	0	1 (<0.1)
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Eye disorders (Cont.)			
Strabismus	1 (<0.1)	0	1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	50 (0.3)	50 (0.3)	100 (0.3)
Vertigo	14 (<0.1)	14 (<0.1)	28 (<0.1)
Ear pain	9 (<0.1)	11 (<0.1)	20 (<0.1)
Tinnitus	7 (<0.1)	8 (<0.1)	15 (<0.1)
Vertigo positional	0	5 (<0.1)	5 (<0.1)
Ear canal erythema	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ear discomfort	4 (<0.1)	2 (<0.1)	6 (<0.1)
Middle ear effusion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Motion sickness	0	2 (<0.1)	2 (<0.1)
Cerumen impaction	2 (<0.1)	1 (<0.1)	3 (<0.1)
Deafness neurosensory	0	1 (<0.1)	1 (<0.1)
Deafness unilateral	0	1 (<0.1)	1 (<0.1)
Ear congestion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Otorrhoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Deafness	1 (<0.1)	0	1 (<0.1)
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Ear and labyrinth disorders (Cont.)			
Tympanic membrane perforation	4 (<0.1)	0	4 (<0.1)
Cardiac disorders	54 (0.4)	53 (0.4)	107 (0.4)
Tachycardia	10 (<0.1)	12 (<0.1)	22 (<0.1)
Bradycardia	17 (0.1)	10 (<0.1)	27 (<0.1)
Atrial fibrillation	6 (<0.1)	9 (<0.1)	15 (<0.1)
Palpitations	5 (<0.1)	6 (<0.1)	11 (<0.1)
Angina pectoris	1 (<0.1)	3 (<0.1)	4 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)	6 (<0.1)
Myocardial infarction	0	3 (<0.1)	3 (<0.1)
Cardiac failure congestive	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus tachycardia	0	2 (<0.1)	2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute myocardial infarction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arrhythmia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Cardiac failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic left ventricular failure	0	1 (<0.1)	1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Atrial tachycardia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Cardiac disorders (Cont.)			
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	135 (0.9)	144 (1.0)	279 (1.0)
Hypertension	103 (0.7)	108 (0.8)	211 (0.7)
Hot flush	6 (<0.1)	11 (<0.1)	17 (<0.1)
Flushing	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hypertensive urgency	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypotension	1 (<0.1)	3 (<0.1)	4 (<0.1)
Systolic hypertension	4 (<0.1)	3 (<0.1)	7 (<0.1)
Haematoma	3 (<0.1)	2 (<0.1)	5 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Deep vein thrombosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)	1 (<0.1)
Pallor	0	1 (<0.1)	1 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
Peripheral coldness	0	1 (<0.1)	1 (<0.1)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Vascular disorders (Cont.)			
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	2 (<0.1)	0	2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0	1 (<0.1)
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	504 (3.5)	459 (3.2)	963 (3.4)
Cough	141 (1.0)	142 (1.0)	283 (1.0)
Oropharyngeal pain	178 (1.2)	125 (0.9)	303 (1.1)
Nasal congestion	114 (0.8)	118 (0.8)	232 (0.8)
Rhinorrhoea	117 (0.8)	113 (0.8)	230 (0.8)
Dyspnoea	35 (0.2)	39 (0.3)	74 (0.3)
Tachypnoea	31 (0.2)	35 (0.2)	66 (0.2)
Throat irritation	12 (<0.1)	15 (0.1)	27 (<0.1)
Epistaxis	8 (<0.1)	13 (<0.1)	21 (<0.1)
Sinus congestion	22 (0.2)	12 (<0.1)	34 (0.1)
Asthma	10 (<0.1)	11 (<0.1)	21 (<0.1)
Upper-airway cough syndrome	7 (<0.1)	9 (<0.1)	16 (<0.1)
Sneezing	10 (<0.1)	8 (<0.1)	18 (<0.1)
Rhinitis allergic	9 (<0.1)	7 (<0.1)	16 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	6 (<0.1)	14 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Respiratory tract congestion	8 (<0.1)	6 (<0.1)	14 (<0.1)
Dyspnoea exertional	1 (<0.1)	4 (<0.1)	5 (<0.1)
Paranasal sinus discomfort	2 (<0.1)	4 (<0.1)	6 (<0.1)
Productive cough	6 (<0.1)	4 (<0.1)	10 (<0.1)
Dry throat	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dysphonia	7 (<0.1)	3 (<0.1)	10 (<0.1)
Sinus pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Wheezing	3 (<0.1)	3 (<0.1)	6 (<0.1)
Pharyngeal erythema	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)	5 (<0.1)
Acute respiratory failure	0	1 (<0.1)	1 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchiectasis	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)	1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal discomfort	0	1 (<0.1)	1 (<0.1)
Nasal dryness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pleuritic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)	1 (<0.1)
Tonsillolith	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Nasal septum deviation	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Pleural effusion	3 (<0.1)	0	3 (<0.1)
Pneumonia aspiration	1 (<0.1)	0	1 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Respiratory symptom	2 (<0.1)	0	2 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Tonsillar exudate	1 (<0.1)	0	1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	374 (2.6)	412 (2.9)	786 (2.7)
Diarrhoea	143 (1.0)	170 (1.2)	313 (1.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Gastrointestinal disorders (Cont.)			
Nausea	104 (0.7)	100 (0.7)	204 (0.7)
Vomiting	29 (0.2)	35 (0.2)	64 (0.2)
Gastroesophageal reflux disease	9 (<0.1)	27 (0.2)	36 (0.1)
Toothache	18 (0.1)	26 (0.2)	44 (0.2)
Abdominal pain	14 (<0.1)	17 (0.1)	31 (0.1)
Constipation	11 (<0.1)	10 (<0.1)	21 (<0.1)
Food poisoning	6 (<0.1)	10 (<0.1)	16 (<0.1)
Abdominal pain upper	14 (<0.1)	9 (<0.1)	23 (<0.1)
Dental caries	6 (<0.1)	7 (<0.1)	13 (<0.1)
Dyspepsia	10 (<0.1)	7 (<0.1)	17 (<0.1)
Abdominal discomfort	5 (<0.1)	6 (<0.1)	11 (<0.1)
Abdominal pain lower	6 (<0.1)	6 (<0.1)	12 (<0.1)
Colitis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aphthous ulcer	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematochezia	0	3 (<0.1)	3 (<0.1)
Haemorrhoids	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	3 (<0.1)	5 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)	5 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Gastrointestinal disorders (Cont.)			
Gastric ulcer	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mouth ulceration	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Proctalgia	0	2 (<0.1)	2 (<0.1)
Stomatitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swollen tongue	0	2 (<0.1)	2 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)
Diverticulum	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Flatulence	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastric disorder	0	1 (<0.1)	1 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Hiatus hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hyperchlorhydria	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Oesophageal pain	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Gastrointestinal disorders (Cont.)			
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Paraesthesia oral	3 (<0.1)	1 (<0.1)	4 (<0.1)
Peptic ulcer	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Salivary hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)	1 (<0.1)
Tongue discolouration	0	1 (<0.1)	1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Tooth impacted	2 (<0.1)	1 (<0.1)	3 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysphagia	2 (<0.1)	0	2 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastritis	2 (<0.1)	0	2 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Gastrointestinal disorders (Cont.)			
Gastrointestinal motility disorder	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0	1 (<0.1)
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Gingival pain	3 (<0.1)	0	3 (<0.1)
Glossitis	1 (<0.1)	0	1 (<0.1)
Glossodynia	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	1 (<0.1)	0	1 (<0.1)
Large intestine polyp	2 (<0.1)	0	2 (<0.1)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Oral discomfort	1 (<0.1)	0	1 (<0.1)
Oral disorder	1 (<0.1)	0	1 (<0.1)
Oral pain	4 (<0.1)	0	4 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Regurgitation	1 (<0.1)	0	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Saliva altered	1 (<0.1)	0	1 (<0.1)
Tongue coated	1 (<0.1)	0	1 (<0.1)
Tooth disorder	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	10 (<0.1)	10 (<0.1)
Cholelithiasis	0	6 (<0.1)	6 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Hepatobiliary disorders (Cont.)			
Cholecystitis	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	152 (1.1)	203 (1.4)	355 (1.2)
Rash	24 (0.2)	40 (0.3)	64 (0.2)
Pruritus	16 (0.1)	19 (0.1)	35 (0.1)
Urticaria	12 (<0.1)	16 (0.1)	28 (<0.1)
Dermatitis contact	22 (0.2)	15 (0.1)	37 (0.1)
Hyperhidrosis	10 (<0.1)	11 (<0.1)	21 (<0.1)
Erythema	4 (<0.1)	10 (<0.1)	14 (<0.1)
Night sweats	6 (<0.1)	9 (<0.1)	15 (<0.1)
Dermatitis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Acne	1 (<0.1)	6 (<0.1)	7 (<0.1)
Alopecia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Rash erythematous	2 (<0.1)	5 (<0.1)	7 (<0.1)
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Rash pruritic	2 (<0.1)	4 (<0.1)	6 (<0.1)
Actinic keratosis	0	3 (<0.1)	3 (<0.1)
Blister	1 (<0.1)	3 (<0.1)	4 (<0.1)
Dermatitis atopic	4 (<0.1)	3 (<0.1)	7 (<0.1)
Ecchymosis	4 (<0.1)	3 (<0.1)	7 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Eczema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Psoriasis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)	5 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin lesion	4 (<0.1)	3 (<0.1)	7 (<0.1)
Dermatitis allergic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Macule	0	2 (<0.1)	2 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Rash papular	0	2 (<0.1)	2 (<0.1)
Urticaria papular	4 (<0.1)	2 (<0.1)	6 (<0.1)
Angioedema	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dermal cyst	4 (<0.1)	1 (<0.1)	5 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)	2 (<0.1)
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	1 (<0.1)	1 (<0.1)
Ingrowing nail	0	1 (<0.1)	1 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Pain of skin	0	1 (<0.1)	1 (<0.1)
Papule	1 (<0.1)	1 (<0.1)	2 (<0.1)
Petechiae	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash maculo-papular	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin warm	0	1 (<0.1)	1 (<0.1)
Solar lentigo	0	1 (<0.1)	1 (<0.1)
Dermatitis bullous	2 (<0.1)	0	2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Ingrown hair	1 (<0.1)	0	1 (<0.1)
Intertrigo	1 (<0.1)	0	1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Livedo reticularis	1 (<0.1)	0	1 (<0.1)
Onychoclasia	1 (<0.1)	0	1 (<0.1)
Rash macular	1 (<0.1)	0	1 (<0.1)
Scab	1 (<0.1)	0	1 (<0.1)
Seborrheic dermatitis	1 (<0.1)	0	1 (<0.1)
Skin discolouration	2 (<0.1)	0	2 (<0.1)
Skin hyperpigmentation	1 (<0.1)	0	1 (<0.1)
Skin irritation	1 (<0.1)	0	1 (<0.1)
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Umbilical erythema	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Musculoskeletal and connective tissue disorders	503 (3.5)	566 (4.0)	1069 (3.7)
Arthralgia	147 (1.0)	172 (1.2)	319 (1.1)
Myalgia	136 (0.9)	164 (1.1)	300 (1.0)
Back pain	87 (0.6)	68 (0.5)	155 (0.5)
Pain in extremity	59 (0.4)	49 (0.3)	108 (0.4)
Neck pain	23 (0.2)	33 (0.2)	56 (0.2)
Musculoskeletal pain	23 (0.2)	30 (0.2)	53 (0.2)
Muscle spasms	11 (<0.1)	26 (0.2)	37 (0.1)
Tendonitis	9 (<0.1)	14 (<0.1)	23 (<0.1)
Musculoskeletal chest pain	10 (<0.1)	10 (<0.1)	20 (<0.1)
Musculoskeletal stiffness	8 (<0.1)	10 (<0.1)	18 (<0.1)
Rotator cuff syndrome	5 (<0.1)	7 (<0.1)	12 (<0.1)
Arthritis	0	6 (<0.1)	6 (<0.1)
Intervertebral disc protrusion	2 (<0.1)	5 (<0.1)	7 (<0.1)
Osteoarthritis	11 (<0.1)	5 (<0.1)	16 (<0.1)
Bursitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Groin pain	1 (<0.1)	4 (<0.1)	5 (<0.1)
Joint swelling	6 (<0.1)	4 (<0.1)	10 (<0.1)
Pain in jaw	3 (<0.1)	4 (<0.1)	7 (<0.1)
Bone pain	0	3 (<0.1)	3 (<0.1)
Costochondritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Flank pain	0	3 (<0.1)	3 (<0.1)
Joint range of motion decreased	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Limb discomfort	3 (<0.1)	3 (<0.1)	6 (<0.1)
Osteoporosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Axillary mass	0	2 (<0.1)	2 (<0.1)
Exostosis	0	2 (<0.1)	2 (<0.1)
Fibromyalgia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Joint stiffness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle tightness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscular weakness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neck mass	0	2 (<0.1)	2 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Spinal osteoarthritis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Spinal pain	0	2 (<0.1)	2 (<0.1)
Spinal stenosis	0	2 (<0.1)	2 (<0.1)
Trigger finger	0	2 (<0.1)	2 (<0.1)
Arthropathy	0	1 (<0.1)	1 (<0.1)
Bone lesion	0	1 (<0.1)	1 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Floating patella	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Muscle twitching	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteopenia	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthrititis	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spondylitis	0	1 (<0.1)	1 (<0.1)
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Torticollis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Foot deformity	1 (<0.1)	0	1 (<0.1)
Intervertebral disc disorder	1 (<0.1)	0	1 (<0.1)
Limb mass	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteitis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Synovial cyst	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Renal and urinary disorders	36 (0.3)	35 (0.2)	71 (0.2)
Nephrolithiasis	20 (0.1)	13 (<0.1)	33 (0.1)
Dysuria	1 (<0.1)	5 (<0.1)	6 (<0.1)
Haematuria	6 (<0.1)	2 (<0.1)	8 (<0.1)
Polyuria	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Acute kidney injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bladder pain	0	1 (<0.1)	1 (<0.1)
Chronic kidney disease	0	1 (<0.1)	1 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
End stage renal disease	0	1 (<0.1)	1 (<0.1)
Hydronephrosis	0	1 (<0.1)	1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)
Nocturia	0	1 (<0.1)	1 (<0.1)
Pollakiuria	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal pain	0	1 (<0.1)	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urinary retention	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bladder prolapse	1 (<0.1)	0	1 (<0.1)
Chromaturia	1 (<0.1)	0	1 (<0.1)
Renal colic	1 (<0.1)	0	1 (<0.1)
Renal mass	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Renal and urinary disorders (Cont.)			
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	0	1 (<0.1)	1 (<0.1)
Pregnancy	0	1 (<0.1)	1 (<0.1)
Reproductive system and breast disorders	30 (0.2)	39 (0.3)	69 (0.2)
Benign prostatic hyperplasia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Dysmenorrhoea	3 (<0.1)	4 (<0.1)	7 (<0.1)
Pelvic pain	0	4 (<0.1)	4 (<0.1)
Erectile dysfunction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Menorrhagia	0	2 (<0.1)	2 (<0.1)
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast discharge	0	1 (<0.1)	1 (<0.1)
Breast disorder	0	1 (<0.1)	1 (<0.1)
Breast mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopausal symptoms	0	1 (<0.1)	1 (<0.1)
Menstrual disorder	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Reproductive system and breast disorders (Cont.)			
Metrorrhagia	0	1 (<0.1)	1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)	1 (<0.1)
Ovarian cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ovarian mass	0	1 (<0.1)	1 (<0.1)
Prostatitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Testicular pain	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
Uterine polyp	0	1 (<0.1)	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Vaginal haemorrhage	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Amenorrhoea	1 (<0.1)	0	1 (<0.1)
Bartholin's cyst	1 (<0.1)	0	1 (<0.1)
Cystocele	1 (<0.1)	0	1 (<0.1)
Endometriosis	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	1 (<0.1)	0	1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0	1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	1 (<0.1)	0	1 (<0.1)
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Uterine spasm	2 (<0.1)	0	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Congenital, familial and genetic disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	1 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	542 (3.8)	856 (6.0)	1398 (4.9)
Fatigue	300 (2.1)	331 (2.3)	631 (2.2)
Injection site pain	47 (0.3)	139 (1.0)	186 (0.6)
Injection site erythema	12 (<0.1)	98 (0.7)	110 (0.4)
Chills	59 (0.4)	73 (0.5)	132 (0.5)
Injection site pruritus	12 (<0.1)	65 (0.5)	77 (0.3)
Injection site swelling	11 (<0.1)	65 (0.5)	76 (0.3)
Pyrexia	37 (0.3)	58 (0.4)	95 (0.3)
Pain	43 (0.3)	52 (0.4)	95 (0.3)
Injection site rash	1 (<0.1)	30 (0.2)	31 (0.1)
Injection site induration	7 (<0.1)	28 (0.2)	35 (0.1)
Axillary pain	8 (<0.1)	23 (0.2)	31 (0.1)
Malaise	9 (<0.1)	12 (<0.1)	21 (<0.1)
Injection site bruising	16 (0.1)	11 (<0.1)	27 (<0.1)
Swelling	4 (<0.1)	11 (<0.1)	15 (<0.1)
Chest discomfort	9 (<0.1)	10 (<0.1)	19 (<0.1)
Chest pain	9 (<0.1)	7 (<0.1)	16 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Injection site urticaria	0	7 (<0.1)	7 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	8 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	6 (<0.1)	7 (<0.1)
Injection site haemorrhage	2 (<0.1)	5 (<0.1)	7 (<0.1)
Oedema peripheral	4 (<0.1)	5 (<0.1)	9 (<0.1)
Peripheral swelling	9 (<0.1)	5 (<0.1)	14 (<0.1)
Reactogenicity event	3 (<0.1)	4 (<0.1)	7 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)
Feeling hot	3 (<0.1)	3 (<0.1)	6 (<0.1)
Influenza like illness	4 (<0.1)	3 (<0.1)	7 (<0.1)
Injection site haematoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site reaction	1 (<0.1)	3 (<0.1)	4 (<0.1)
Non-cardiac chest pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Vaccination site erythema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vaccination site lymphadenopathy	0	3 (<0.1)	3 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)	2 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site irritation	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	2 (<0.1)
Injection site nodule	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Injection site scab	0	2 (<0.1)	2 (<0.1)
Swelling face	2 (<0.1)	2 (<0.1)	4 (<0.1)
Vaccination site pain	4 (<0.1)	2 (<0.1)	6 (<0.1)
Vaccination site swelling	0	2 (<0.1)	2 (<0.1)
Asthenia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Crying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Facial pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Feeling cold	0	1 (<0.1)	1 (<0.1)
Granuloma	0	1 (<0.1)	1 (<0.1)
Inflammation	0	1 (<0.1)	1 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site paraesthesia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Sensation of foreign body	0	1 (<0.1)	1 (<0.1)
Temperature intolerance	0	1 (<0.1)	1 (<0.1)
Vaccination site induration	0	1 (<0.1)	1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site rash	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)	1 (<0.1)
Adverse drug reaction	1 (<0.1)	0	1 (<0.1)
Discomfort	2 (<0.1)	0	2 (<0.1)
Gait disturbance	1 (<0.1)	0	1 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site discolouration	2 (<0.1)	0	2 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Polyp	1 (<0.1)	0	1 (<0.1)
Precancerous condition	2 (<0.1)	0	2 (<0.1)
Thirst	1 (<0.1)	0	1 (<0.1)
Vaccination site bruising	2 (<0.1)	0	2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0	1 (<0.1)
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	0	1 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Investigations	57 (0.4)	78 (0.5)	135 (0.5)
Blood pressure increased	22 (0.2)	21 (0.1)	43 (0.1)
Blood pressure systolic increased	9 (<0.1)	15 (0.1)	24 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	8 (<0.1)	10 (<0.1)
Body temperature increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Heart rate increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hepatic enzyme increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Blood glucose increased	2 (<0.1)	2 (<0.1)	4 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Transaminases increased	0	2 (<0.1)	2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Blood cholesterol increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood creatine increased	0	1 (<0.1)	1 (<0.1)
Blood creatinine increased	0	1 (<0.1)	1 (<0.1)
Blood glucose decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Blood testosterone decreased	0	1 (<0.1)	1 (<0.1)
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)	2 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Investigations (Cont.)			
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Mammogram abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	0	1 (<0.1)	1 (<0.1)
Prostatic specific antigen increased	0	1 (<0.1)	1 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)
Weight decreased	0	1 (<0.1)	1 (<0.1)
White blood cell count increased	0	1 (<0.1)	1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)
Biopsy skin	1 (<0.1)	0	1 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood potassium decreased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
C-reactive protein increased	1 (<0.1)	0	1 (<0.1)
Colonoscopy	1 (<0.1)	0	1 (<0.1)
Lipase increased	1 (<0.1)	0	1 (<0.1)
SARS-CoV-2 test positive	3 (<0.1)	0	3 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Investigations (Cont.)			
Vitamin B12 decreased	1 (<0.1)	0	1 (<0.1)
Vitamin D decreased	2 (<0.1)	0	2 (<0.1)
Weight increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	257 (1.8)	233 (1.6)	490 (1.7)
Muscle strain	24 (0.2)	31 (0.2)	55 (0.2)
Ligament sprain	21 (0.1)	21 (0.1)	42 (0.1)
Skin laceration	25 (0.2)	20 (0.1)	45 (0.2)
Arthropod bite	21 (0.1)	19 (0.1)	40 (0.1)
Contusion	26 (0.2)	14 (<0.1)	40 (0.1)
Fall	13 (<0.1)	10 (<0.1)	23 (<0.1)
Limb injury	4 (<0.1)	10 (<0.1)	14 (<0.1)
Tooth fracture	12 (<0.1)	10 (<0.1)	22 (<0.1)
Foot fracture	8 (<0.1)	9 (<0.1)	17 (<0.1)
Procedural pain	11 (<0.1)	8 (<0.1)	19 (<0.1)
Arthropod sting	13 (<0.1)	7 (<0.1)	20 (<0.1)
Skin abrasion	17 (0.1)	6 (<0.1)	23 (<0.1)
Animal bite	7 (<0.1)	5 (<0.1)	12 (<0.1)
Concussion	3 (<0.1)	5 (<0.1)	8 (<0.1)
Hand fracture	1 (<0.1)	5 (<0.1)	6 (<0.1)
Road traffic accident	2 (<0.1)	5 (<0.1)	7 (<0.1)
Meniscus injury	3 (<0.1)	4 (<0.1)	7 (<0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Epicondylitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Rib fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Back injury	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cartilage injury	0	2 (<0.1)	2 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Facial bones fracture	0	2 (<0.1)	2 (<0.1)
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Joint injury	4 (<0.1)	2 (<0.1)	6 (<0.1)
Ligament rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Thermal burn	1 (<0.1)	2 (<0.1)	3 (<0.1)
Upper limb fracture	0	2 (<0.1)	2 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<0.1)
Ankle fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bone fragmentation	0	1 (<0.1)	1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Burns second degree	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010807.sas 20NOV2020 06:55

Table 14.3.1.8.7
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Clavicle fracture	0	1 (<0.1)	1 (<0.1)
Corneal abrasion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Exposure to SARS-CoV-2	2 (<0.1)	1 (<0.1)	3 (<0.1)
Face injury	0	1 (<0.1)	1 (<0.1)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Head injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypobarism	0	1 (<0.1)	1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	0	1 (<0.1)	1 (<0.1)
Ligament injury	0	1 (<0.1)	1 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Nasal injury	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010807.sas 20NOV2020 06:55

Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Periorbital haemorrhage	0	1 (<0.1)	1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Post-traumatic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Procedural headache	0	1 (<0.1)	1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	1 (<0.1)	1 (<0.1)
Wound	2 (<0.1)	1 (<0.1)	3 (<0.1)
Abdominal injury	1 (<0.1)	0	1 (<0.1)
Bone contusion	2 (<0.1)	0	2 (<0.1)
Exposure to toxic agent	1 (<0.1)	0	1 (<0.1)
Eye injury	1 (<0.1)	0	1 (<0.1)
Eyelid contusion	1 (<0.1)	0	1 (<0.1)
Foreign body	2 (<0.1)	0	2 (<0.1)
Foreign body in ear	1 (<0.1)	0	1 (<0.1)
Humerus fracture	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Iliotibial band syndrome	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Lip injury	1 (<0.1)	0	1 (<0.1)
Mouth injury	1 (<0.1)	0	1 (<0.1)
Muscle injury	1 (<0.1)	0	1 (<0.1)
Nail injury	1 (<0.1)	0	1 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Procedural nausea	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Stress fracture	3 (<0.1)	0	3 (<0.1)
Sunburn	1 (<0.1)	0	1 (<0.1)
Superficial injury of eye	1 (<0.1)	0	1 (<0.1)
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Venomous sting	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	10 (<0.1)	15 (0.1)	25 (<0.1)
Axillary lymphadenectomy	0	2 (<0.1)	2 (<0.1)
Endodontic procedure	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Surgical and medical procedures (Cont.)			
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curettage of chalazion	0	1 (<0.1)	1 (<0.1)
Cyst removal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dental operation	0	1 (<0.1)	1 (<0.1)
Lipoma excision	0	1 (<0.1)	1 (<0.1)
Phlebectomy	0	1 (<0.1)	1 (<0.1)
Skin neoplasm excision	0	1 (<0.1)	1 (<0.1)
Skin operation	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Transurethral prostatectomy	0	1 (<0.1)	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Cataract operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Hip arthroplasty	1 (<0.1)	0	1 (<0.1)
Tooth extraction	1 (<0.1)	0	1 (<0.1)
Tooth repair	2 (<0.1)	0	2 (<0.1)
Umbilical hernia repair	1 (<0.1)	0	1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopause	0	1 (<0.1)	1 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Product issues	2 (<0.1)	4 (<0.1)	6 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Device dislocation	0	1 (<0.1)	1 (<0.1)
Embedded device	0	1 (<0.1)	1 (<0.1)
Lead dislodgement	1 (<0.1)	0	1 (<0.1)
Uncoded	141 (1.0)	234 (1.6)	375 (1.3)
Uncoded	141 (1.0)	234 (1.6)	375 (1.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	56 (16.8)	49 (14.4)	105 (15.6)
Number of Unsolicited Adverse Events	100	95	195
Infections and infestations	7 (2.1)	11 (3.2)	18 (2.7)
COVID-19	3 (0.9)	3 (0.9)	6 (0.9)
Viral infection	1 (0.3)	2 (0.6)	3 (0.4)
Cystitis	0	1 (0.3)	1 (0.1)
Otitis externa	0	1 (0.3)	1 (0.1)
Paronychia	0	1 (0.3)	1 (0.1)
Sinusitis	0	1 (0.3)	1 (0.1)
Subcutaneous abscess	0	1 (0.3)	1 (0.1)
Upper respiratory tract infection	2 (0.6)	1 (0.3)	3 (0.4)
Vaginal infection	0	1 (0.3)	1 (0.1)
Pyelonephritis acute	1 (0.3)	0	1 (0.1)
Septic shock	1 (0.3)	0	1 (0.1)
Blood and lymphatic system disorders	2 (0.6)	0	2 (0.3)
Lymphadenopathy	2 (0.6)	0	2 (0.3)
Metabolism and nutrition disorders	4 (1.2)	2 (0.6)	6 (0.9)
Hyperlipidaemia	0	1 (0.3)	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypoglycaemia	0	1 (0.3)	1 (0.1)
Type 2 diabetes mellitus	0	1 (0.3)	1 (0.1)
Vitamin D deficiency	0	1 (0.3)	1 (0.1)
Dehydration	1 (0.3)	0	1 (0.1)
Diabetes mellitus	1 (0.3)	0	1 (0.1)
Hypercholesterolaemia	1 (0.3)	0	1 (0.1)
Increased appetite	1 (0.3)	0	1 (0.1)
Psychiatric disorders	0	1 (0.3)	1 (0.1)
Depression	0	1 (0.3)	1 (0.1)
Nervous system disorders	17 (5.1)	9 (2.6)	26 (3.9)
Headache	13 (3.9)	7 (2.1)	20 (3.0)
Dizziness	0	2 (0.6)	2 (0.3)
Ageusia	0	1 (0.3)	1 (0.1)
Sciatica	0	1 (0.3)	1 (0.1)
Migraine	2 (0.6)	0	2 (0.3)
Paraesthesia	1 (0.3)	0	1 (0.1)
Parosmia	1 (0.3)	0	1 (0.1)
Somnolence	1 (0.3)	0	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Eye disorders	0	1 (0.3)	1 (0.1)
Vision blurred	0	1 (0.3)	1 (0.1)
Ear and labyrinth disorders	3 (0.9)	1 (0.3)	4 (0.6)
Cerumen impaction	0	1 (0.3)	1 (0.1)
Ear pruritus	1 (0.3)	0	1 (0.1)
Tinnitus	1 (0.3)	0	1 (0.1)
Tympanic membrane perforation	1 (0.3)	0	1 (0.1)
Cardiac disorders	1 (0.3)	0	1 (0.1)
Acute left ventricular failure	1 (0.3)	0	1 (0.1)
Atrial fibrillation	1 (0.3)	0	1 (0.1)
Vascular disorders	1 (0.3)	2 (0.6)	3 (0.4)
Hypertension	1 (0.3)	2 (0.6)	3 (0.4)
Respiratory, thoracic and mediastinal disorders	9 (2.7)	7 (2.1)	16 (2.4)
Rhinorrhoea	1 (0.3)	3 (0.9)	4 (0.6)
Nasal congestion	2 (0.6)	2 (0.6)	4 (0.6)
Oropharyngeal pain	3 (0.9)	2 (0.6)	5 (0.7)
Cough	1 (0.3)	1 (0.3)	2 (0.3)
Dyspnoea	0	1 (0.3)	1 (0.1)
Epistaxis	1 (0.3)	1 (0.3)	2 (0.3)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Productive cough	0	1 (0.3)	1 (0.1)
Acute respiratory failure	1 (0.3)	0	1 (0.1)
Sinus congestion	1 (0.3)	0	1 (0.1)
Gastrointestinal disorders	5 (1.5)	5 (1.5)	10 (1.5)
Diarrhoea	0	3 (0.9)	3 (0.4)
Gastrooesophageal reflux disease	2 (0.6)	2 (0.6)	4 (0.6)
Gastric ulcer	0	1 (0.3)	1 (0.1)
Nausea	0	1 (0.3)	1 (0.1)
Oesophageal ulcer	0	1 (0.3)	1 (0.1)
Abdominal pain	1 (0.3)	0	1 (0.1)
Dyspepsia	1 (0.3)	0	1 (0.1)
Vomiting	1 (0.3)	0	1 (0.1)
Hepatobiliary disorders	1 (0.3)	0	1 (0.1)
Cholelithiasis	1 (0.3)	0	1 (0.1)
Skin and subcutaneous tissue disorders	5 (1.5)	4 (1.2)	9 (1.3)
Acne	0	1 (0.3)	1 (0.1)
Ecchymosis	0	1 (0.3)	1 (0.1)
Hyperhidrosis	0	1 (0.3)	1 (0.1)

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Urticaria	0	1 (0.3)	1 (0.1)
Blister	1 (0.3)	0	1 (0.1)
Dermatitis contact	1 (0.3)	0	1 (0.1)
Night sweats	1 (0.3)	0	1 (0.1)
Rash	2 (0.6)	0	2 (0.3)
Musculoskeletal and connective tissue disorders	12 (3.6)	10 (2.9)	22 (3.3)
Myalgia	2 (0.6)	3 (0.9)	5 (0.7)
Back pain	1 (0.3)	2 (0.6)	3 (0.4)
Pain in extremity	0	2 (0.6)	2 (0.3)
Arthralgia	2 (0.6)	1 (0.3)	3 (0.4)
Limb discomfort	0	1 (0.3)	1 (0.1)
Neck pain	1 (0.3)	1 (0.3)	2 (0.3)
Arthritis	1 (0.3)	0	1 (0.1)
Axillary mass	1 (0.3)	0	1 (0.1)
Muscle twitching	1 (0.3)	0	1 (0.1)
Musculoskeletal pain	2 (0.6)	0	2 (0.3)
Musculoskeletal stiffness	1 (0.3)	0	1 (0.1)
Plantar fasciitis	1 (0.3)	0	1 (0.1)
Spinal stenosis	1 (0.3)	0	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Renal and urinary disorders	2 (0.6)	0	2 (0.3)
Micturition urgency	1 (0.3)	0	1 (0.1)
Nephrolithiasis	1 (0.3)	0	1 (0.1)
Renal colic	1 (0.3)	0	1 (0.1)
General disorders and administration site conditions	9 (2.7)	15 (4.4)	24 (3.6)
Fatigue	4 (1.2)	3 (0.9)	7 (1.0)
Injection site pain	1 (0.3)	3 (0.9)	4 (0.6)
Chest pain	0	2 (0.6)	2 (0.3)
Feeling hot	0	2 (0.6)	2 (0.3)
Injection site induration	0	2 (0.6)	2 (0.3)
Injection site bruising	1 (0.3)	1 (0.3)	2 (0.3)
Injection site erythema	0	1 (0.3)	1 (0.1)
Oedema peripheral	0	1 (0.3)	1 (0.1)
Pyrexia	0	1 (0.3)	1 (0.1)
Swelling face	0	1 (0.3)	1 (0.1)
Chills	1 (0.3)	0	1 (0.1)
Non-cardiac chest pain	1 (0.3)	0	1 (0.1)
Pain	1 (0.3)	0	1 (0.1)
Investigations	2 (0.6)	3 (0.9)	5 (0.7)
Blood pressure increased	0	1 (0.3)	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Investigations (Cont.)			
Heart rate increased	0	1 (0.3)	1 (0.1)
SARS-CoV-2 test positive	1 (0.3)	1 (0.3)	2 (0.3)
Blood pressure systolic increased	1 (0.3)	0	1 (0.1)
Injury, poisoning and procedural complications	3 (0.9)	3 (0.9)	6 (0.9)
Fall	0	1 (0.3)	1 (0.1)
Head injury	0	1 (0.3)	1 (0.1)
Road traffic accident	1 (0.3)	1 (0.3)	2 (0.3)
Ligament sprain	2 (0.6)	0	2 (0.3)
Uncoded	7 (2.1)	5 (1.5)	12 (1.8)
Uncoded	7 (2.1)	5 (1.5)	12 (1.8)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	47 (10.1)	72 (13.7)	119 (12.0)
Number of Unsolicited Adverse Events	76	160	236
Infections and infestations	5 (1.1)	14 (2.7)	19 (1.9)
Urinary tract infection	1 (0.2)	2 (0.4)	3 (0.3)
COVID-19	1 (0.2)	1 (0.2)	2 (0.2)
Conjunctivitis	1 (0.2)	1 (0.2)	2 (0.2)
Folliculitis	0	1 (0.2)	1 (0.1)
Herpes simplex	0	1 (0.2)	1 (0.1)
Herpes zoster	0	1 (0.2)	1 (0.1)
Kidney infection	0	1 (0.2)	1 (0.1)
Laryngitis	0	1 (0.2)	1 (0.1)
Lyme disease	0	1 (0.2)	1 (0.1)
Pharyngitis	0	1 (0.2)	1 (0.1)
Staphylococcal infection	0	1 (0.2)	1 (0.1)
Subcutaneous abscess	0	1 (0.2)	1 (0.1)
Upper respiratory tract infection	1 (0.2)	1 (0.2)	2 (0.2)
Tonsillitis	1 (0.2)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.2)	1 (0.1)
Lung cancer metastatic	0	1 (0.2)	1 (0.1)
Blood and lymphatic system disorders	3 (0.6)	0	3 (0.3)
Lymphadenitis	1 (0.2)	0	1 (0.1)
Lymphadenopathy	2 (0.4)	0	2 (0.2)
Immune system disorders	0	1 (0.2)	1 (0.1)
Seasonal allergy	0	1 (0.2)	1 (0.1)
Metabolism and nutrition disorders	1 (0.2)	0	1 (0.1)
Gout	1 (0.2)	0	1 (0.1)
Psychiatric disorders	0	1 (0.2)	1 (0.1)
Depression	0	1 (0.2)	1 (0.1)
Nervous system disorders	13 (2.8)	18 (3.4)	31 (3.1)
Headache	10 (2.2)	11 (2.1)	21 (2.1)
Anosmia	0	1 (0.2)	1 (0.1)
Dizziness	0	1 (0.2)	1 (0.1)
Dizziness postural	0	1 (0.2)	1 (0.1)
Essential tremor	0	1 (0.2)	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Nervous system disorders (Cont.)			
Hyperaesthesia	0	1 (0.2)	1 (0.1)
Migraine	0	1 (0.2)	1 (0.1)
Sciatica	0	1 (0.2)	1 (0.1)
Sinus headache	0	1 (0.2)	1 (0.1)
Tension headache	0	1 (0.2)	1 (0.1)
Horner's syndrome	1 (0.2)	0	1 (0.1)
Nerve compression	1 (0.2)	0	1 (0.1)
Syncope	1 (0.2)	0	1 (0.1)
Ear and labyrinth disorders	1 (0.2)	2 (0.4)	3 (0.3)
Vertigo	0	1 (0.2)	1 (0.1)
Vertigo positional	0	1 (0.2)	1 (0.1)
Ear discomfort	1 (0.2)	0	1 (0.1)
Cardiac disorders	0	2 (0.4)	2 (0.2)
Arrhythmia	0	1 (0.2)	1 (0.1)
Cardiac failure congestive	0	1 (0.2)	1 (0.1)
Vascular disorders	2 (0.4)	3 (0.6)	5 (0.5)
Hypertension	1 (0.2)	2 (0.4)	3 (0.3)
Haematoma	0	1 (0.2)	1 (0.1)
Hypotension	1 (0.2)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Respiratory, thoracic and mediastinal disorders	9 (1.9)	14 (2.7)	23 (2.3)
Oropharyngeal pain	3 (0.6)	10 (1.9)	13 (1.3)
Cough	1 (0.2)	5 (0.9)	6 (0.6)
Nasal congestion	3 (0.6)	5 (0.9)	8 (0.8)
Dyspnoea	0	2 (0.4)	2 (0.2)
Rhinorrhoea	3 (0.6)	2 (0.4)	5 (0.5)
Dry throat	0	1 (0.2)	1 (0.1)
Dysphonia	0	1 (0.2)	1 (0.1)
Respiratory tract congestion	0	1 (0.2)	1 (0.1)
Upper-airway cough syndrome	0	1 (0.2)	1 (0.1)
Oropharyngeal discomfort	1 (0.2)	0	1 (0.1)
Sinus congestion	2 (0.4)	0	2 (0.2)
Tachypnoea	1 (0.2)	0	1 (0.1)
Gastrointestinal disorders	8 (1.7)	9 (1.7)	17 (1.7)
Diarrhoea	4 (0.9)	5 (0.9)	9 (0.9)
Nausea	3 (0.6)	2 (0.4)	5 (0.5)
Abdominal pain upper	0	1 (0.2)	1 (0.1)
Dyspepsia	0	1 (0.2)	1 (0.1)
Vomiting	2 (0.4)	1 (0.2)	3 (0.3)
Constipation	1 (0.2)	0	1 (0.1)
Toothache	1 (0.2)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Skin and subcutaneous tissue disorders	1 (0.2)	6 (1.1)	7 (0.7)
Ecchymosis	0	1 (0.2)	1 (0.1)
Erythema	0	1 (0.2)	1 (0.1)
Nail disorder	0	1 (0.2)	1 (0.1)
Pruritus	0	1 (0.2)	1 (0.1)
Rash erythematous	0	1 (0.2)	1 (0.1)
Urticaria	0	1 (0.2)	1 (0.1)
Papule	1 (0.2)	0	1 (0.1)
Musculoskeletal and connective tissue disorders	6 (1.3)	10 (1.9)	16 (1.6)
Myalgia	0	5 (0.9)	5 (0.5)
Back pain	0	3 (0.6)	3 (0.3)
Arthralgia	3 (0.6)	1 (0.2)	4 (0.4)
Joint swelling	0	1 (0.2)	1 (0.1)
Muscular weakness	0	1 (0.2)	1 (0.1)
Musculoskeletal pain	0	1 (0.2)	1 (0.1)
Neck mass	0	1 (0.2)	1 (0.1)
Axillary mass	1 (0.2)	0	1 (0.1)
Musculoskeletal stiffness	1 (0.2)	0	1 (0.1)
Pain in jaw	1 (0.2)	0	1 (0.1)
Reproductive system and breast disorders	0	2 (0.4)	2 (0.2)
Adenomyosis	0	1 (0.2)	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Reproductive system and breast disorders (Cont.)			
Erectile dysfunction	0	1 (0.2)	1 (0.1)
General disorders and administration site conditions	9 (1.9)	23 (4.4)	32 (3.2)
Fatigue	3 (0.6)	10 (1.9)	13 (1.3)
Injection site pain	1 (0.2)	5 (0.9)	6 (0.6)
Pain	0	5 (0.9)	5 (0.5)
Chills	0	4 (0.8)	4 (0.4)
Injection site erythema	1 (0.2)	3 (0.6)	4 (0.4)
Injection site pruritus	0	3 (0.6)	3 (0.3)
Pyrexia	2 (0.4)	3 (0.6)	5 (0.5)
Injection site swelling	1 (0.2)	2 (0.4)	3 (0.3)
Adverse drug reaction	0	1 (0.2)	1 (0.1)
Chest pain	0	1 (0.2)	1 (0.1)
Injection site paraesthesia	0	1 (0.2)	1 (0.1)
Injection site warmth	0	1 (0.2)	1 (0.1)
Vaccination site lymphadenopathy	0	1 (0.2)	1 (0.1)
Vaccination site swelling	0	1 (0.2)	1 (0.1)
Axillary pain	1 (0.2)	0	1 (0.1)
Investigations	0	1 (0.2)	1 (0.1)
Blood pressure increased	0	1 (0.2)	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.7
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Injury, poisoning and procedural complications	2 (0.4)	2 (0.4)	4 (0.4)
Joint injury	0	1 (0.2)	1 (0.1)
Scar	0	1 (0.2)	1 (0.1)
Corneal abrasion	1 (0.2)	0	1 (0.1)
Limb injury	1 (0.2)	0	1 (0.1)
Uncoded	5 (1.1)	5 (0.9)	10 (1.0)
Uncoded	5 (1.1)	5 (0.9)	10 (1.0)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3167 (22.0)	3436 (24.0)	6603 (23.0)
Number of Unsolicited Adverse Events	6044	6647	12691
Infections and infestations	799 (5.6)	609 (4.3)	1408 (4.9)
Urinary tract infection	100 (0.7)	87 (0.6)	187 (0.7)
Upper respiratory tract infection	77 (0.5)	62 (0.4)	139 (0.5)
Sinusitis	40 (0.3)	58 (0.4)	98 (0.3)
COVID-19	191 (1.3)	29 (0.2)	220 (0.8)
Viral infection	39 (0.3)	27 (0.2)	66 (0.2)
Herpes zoster	14 (<0.1)	19 (0.1)	33 (0.1)
Gastroenteritis	17 (0.1)	17 (0.1)	34 (0.1)
Rhinovirus infection	5 (<0.1)	16 (0.1)	21 (<0.1)
Tooth infection	15 (0.1)	16 (0.1)	31 (0.1)
Ear infection	10 (<0.1)	15 (0.1)	25 (<0.1)
Pharyngitis	24 (0.2)	15 (0.1)	39 (0.1)
Tooth abscess	22 (0.2)	15 (0.1)	37 (0.1)
Cellulitis	15 (0.1)	13 (<0.1)	28 (<0.1)
Pharyngitis streptococcal	18 (0.1)	13 (<0.1)	31 (0.1)
Conjunctivitis	5 (<0.1)	11 (<0.1)	16 (<0.1)
Hordeolum	13 (<0.1)	10 (<0.1)	23 (<0.1)
Gingivitis	6 (<0.1)	9 (<0.1)	15 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Infections and infestations (Cont.)			
Oral herpes	6 (<0.1)	9 (<0.1)	15 (<0.1)
Diverticulitis	9 (<0.1)	8 (<0.1)	17 (<0.1)
Acute sinusitis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Fungal infection	10 (<0.1)	7 (<0.1)	17 (<0.1)
Viral upper respiratory tract infection	11 (<0.1)	7 (<0.1)	18 (<0.1)
Bronchitis	9 (<0.1)	6 (<0.1)	15 (<0.1)
Herpes simplex	1 (<0.1)	6 (<0.1)	7 (<0.1)
Localised infection	8 (<0.1)	6 (<0.1)	14 (<0.1)
Otitis media	9 (<0.1)	6 (<0.1)	15 (<0.1)
Pneumonia	10 (<0.1)	6 (<0.1)	16 (<0.1)
Rhinitis	10 (<0.1)	6 (<0.1)	16 (<0.1)
Bacterial vaginosis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Folliculitis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Paronychia	2 (<0.1)	5 (<0.1)	7 (<0.1)
Respiratory tract infection	6 (<0.1)	5 (<0.1)	11 (<0.1)
Vulvovaginal candidiasis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Enterovirus infection	0	4 (<0.1)	4 (<0.1)
Nasopharyngitis	11 (<0.1)	4 (<0.1)	15 (<0.1)
Onychomycosis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gonorrhoea	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Helicobacter infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Impetigo	0	3 (<0.1)	3 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Laryngitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Skin infection	3 (<0.1)	3 (<0.1)	6 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vulvovaginal mycotic infection	11 (<0.1)	3 (<0.1)	14 (<0.1)
Appendicitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Clostridium difficile colitis	0	2 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Lyme disease	0	2 (<0.1)	2 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Otitis media acute	3 (<0.1)	2 (<0.1)	5 (<0.1)
Postoperative wound infection	0	2 (<0.1)	2 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Staphylococcal skin infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Subcutaneous abscess	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tinea pedis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Tonsillitis	6 (<0.1)	2 (<0.1)	8 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Infections and infestations (Cont.)			
Viral rhinitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abscess jaw	0	1 (<0.1)	1 (<0.1)
Bacterial infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Candida infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cat scratch disease	0	1 (<0.1)	1 (<0.1)
Catheter site infection	0	1 (<0.1)	1 (<0.1)
Colonic abscess	0	1 (<0.1)	1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Coronavirus infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cystitis	6 (<0.1)	1 (<0.1)	7 (<0.1)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Furuncle	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastroenteritis viral	7 (<0.1)	1 (<0.1)	8 (<0.1)
Gastrointestinal infection	0	1 (<0.1)	1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected bite	0	1 (<0.1)	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Joint abscess	0	1 (<0.1)	1 (<0.1)
Kidney infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Otitis externa	10 (<0.1)	1 (<0.1)	11 (<0.1)
Papilloma viral infection	0	1 (<0.1)	1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)
Parotitis	0	1 (<0.1)	1 (<0.1)
Periodontitis	0	1 (<0.1)	1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)	1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Postoperative abscess	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Pyelonephritis	0	1 (<0.1)	1 (<0.1)
Respiratory tract infection viral	5 (<0.1)	1 (<0.1)	6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Infections and infestations (Cont.)			
Sinusitis bacterial	2 (<0.1)	1 (<0.1)	3 (<0.1)
Streptococcal infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Suspected COVID-19	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tinea infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Abscess	1 (<0.1)	0	1 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Breast abscess	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Denture stomatitis	1 (<0.1)	0	1 (<0.1)
Eye infection	4 (<0.1)	0	4 (<0.1)
Eye infection bacterial	1 (<0.1)	0	1 (<0.1)
Fungal skin infection	1 (<0.1)	0	1 (<0.1)
Gardnerella infection	2 (<0.1)	0	2 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	1 (<0.1)	0	1 (<0.1)
Herpes virus infection	1 (<0.1)	0	1 (<0.1)
Influenza	2 (<0.1)	0	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Infections and infestations (Cont.)			
Labyrinthitis	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Nasal abscess	1 (<0.1)	0	1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0	1 (<0.1)
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Perirectal abscess	1 (<0.1)	0	1 (<0.1)
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Pustule	1 (<0.1)	0	1 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Skin candida	1 (<0.1)	0	1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Syphilis	1 (<0.1)	0	1 (<0.1)
Tinea cruris	1 (<0.1)	0	1 (<0.1)
Tinea versicolour	1 (<0.1)	0	1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Viral sinusitis	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	37 (0.3)	43 (0.3)	80 (0.3)
Basal cell carcinoma	11 (<0.1)	7 (<0.1)	18 (<0.1)
Malignant melanoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Squamous cell carcinoma	7 (<0.1)	3 (<0.1)	10 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Melanocytic naevus	0	2 (<0.1)	2 (<0.1)
Prostate cancer	4 (<0.1)	2 (<0.1)	6 (<0.1)
Uterine leiomyoma	0	2 (<0.1)	2 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)	1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)	1 (<0.1)
Breast neoplasm	0	1 (<0.1)	1 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Gastric cancer	0	1 (<0.1)	1 (<0.1)
Haemangioma of liver	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	0	1 (<0.1)	1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lipoma of breast	0	1 (<0.1)	1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)	1 (<0.1)
Meningioma	0	1 (<0.1)	1 (<0.1)
Meningioma benign	0	1 (<0.1)	1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Neoplasm malignant	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Oesophageal carcinoma	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Thyroid cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Chondromatosis	1 (<0.1)	0	1 (<0.1)
Colon cancer stage III	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Skin cancer	2 (<0.1)	0	2 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	0	2 (<0.1)
Blood and lymphatic system disorders	62 (0.4)	120 (0.8)	182 (0.6)
Lymphadenopathy	52 (0.4)	100 (0.7)	152 (0.5)
Anaemia	1 (<0.1)	7 (<0.1)	8 (<0.1)
Lymph node pain	3 (<0.1)	5 (<0.1)	8 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Blood and lymphatic system disorders (Cont.)			
Lymphadenitis	0	5 (<0.1)	5 (<0.1)
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Increased tendency to bruise	1 (<0.1)	0	1 (<0.1)
Immune system disorders	33 (0.2)	28 (0.2)	61 (0.2)
Seasonal allergy	22 (0.2)	15 (0.1)	37 (0.1)
Hypersensitivity	2 (<0.1)	6 (<0.1)	8 (<0.1)
Drug hypersensitivity	3 (<0.1)	3 (<0.1)	6 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Autoimmune disorder	0	1 (<0.1)	1 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to chemicals	1 (<0.1)	0	1 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Endocrine disorders	9 (<0.1)	8 (<0.1)	17 (<0.1)
Hypothyroidism	5 (<0.1)	5 (<0.1)	10 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Thyroid mass	0	1 (<0.1)	1 (<0.1)
Addison's disease	1 (<0.1)	0	1 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Hypogonadism	1 (<0.1)	0	1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	78 (0.5)	79 (0.6)	157 (0.5)
Hyperlipidaemia	12 (<0.1)	12 (<0.1)	24 (<0.1)
Type 2 diabetes mellitus	3 (<0.1)	11 (<0.1)	14 (<0.1)
Hypercholesterolaemia	13 (<0.1)	10 (<0.1)	23 (<0.1)
Decreased appetite	7 (<0.1)	9 (<0.1)	16 (<0.1)
Dehydration	8 (<0.1)	7 (<0.1)	15 (<0.1)
Vitamin D deficiency	8 (<0.1)	6 (<0.1)	14 (<0.1)
Gout	8 (<0.1)	4 (<0.1)	12 (<0.1)
Diabetes mellitus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hyperglycaemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Insulin resistance	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Metabolism and nutrition disorders (Cont.)			
Abnormal loss of weight	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)	1 (<0.1)
Food intolerance	0	1 (<0.1)	1 (<0.1)
Glucose tolerance impaired	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypophosphataemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abnormal weight gain	1 (<0.1)	0	1 (<0.1)
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	2 (<0.1)	0	2 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hypocalcaemia	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	2 (<0.1)	0	2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Polydipsia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Psychiatric disorders	78 (0.5)	96 (0.7)	174 (0.6)
Anxiety	24 (0.2)	27 (0.2)	51 (0.2)
Depression	17 (0.1)	23 (0.2)	40 (0.1)
Insomnia	13 (<0.1)	14 (<0.1)	27 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<0.1)
Attention deficit hyperactivity disorder	7 (<0.1)	5 (<0.1)	12 (<0.1)
Sleep disorder	0	5 (<0.1)	5 (<0.1)
Nightmare	0	3 (<0.1)	3 (<0.1)
Bipolar disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	1 (<0.1)	2 (<0.1)
Affect lability	0	1 (<0.1)	1 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bruxism	0	1 (<0.1)	1 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Intentional self-injury	0	1 (<0.1)	1 (<0.1)
Libido decreased	0	1 (<0.1)	1 (<0.1)
Major depression	1 (<0.1)	1 (<0.1)	2 (<0.1)
Panic attack	3 (<0.1)	1 (<0.1)	4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Psychiatric disorders (Cont.)			
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)	1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Stress	1 (<0.1)	1 (<0.1)	2 (<0.1)
Substance abuse	0	1 (<0.1)	1 (<0.1)
Confusional state	2 (<0.1)	0	2 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Generalised anxiety disorder	2 (<0.1)	0	2 (<0.1)
Mental fatigue	1 (<0.1)	0	1 (<0.1)
Mental status changes	2 (<0.1)	0	2 (<0.1)
Nicotine dependence	1 (<0.1)	0	1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Suicidal ideation	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	587 (4.1)	642 (4.5)	1229 (4.3)
Headache	429 (3.0)	443 (3.1)	872 (3.0)
Dizziness	49 (0.3)	59 (0.4)	108 (0.4)
Paraesthesia	18 (0.1)	25 (0.2)	43 (0.1)
Presyncope	11 (<0.1)	12 (<0.1)	23 (<0.1)
Dysgeusia	6 (<0.1)	11 (<0.1)	17 (<0.1)
Ageusia	13 (<0.1)	10 (<0.1)	23 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Nervous system disorders (Cont.)			
Migraine	20 (0.1)	10 (<0.1)	30 (0.1)
Sciatica	6 (<0.1)	10 (<0.1)	16 (<0.1)
Sinus headache	5 (<0.1)	10 (<0.1)	15 (<0.1)
Anosmia	9 (<0.1)	9 (<0.1)	18 (<0.1)
Hypoaesthesia	5 (<0.1)	8 (<0.1)	13 (<0.1)
Syncope	19 (0.1)	8 (<0.1)	27 (<0.1)
Tension headache	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hyperaesthesia	0	5 (<0.1)	5 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	4 (<0.1)	6 (<0.1)
Cervical radiculopathy	0	4 (<0.1)	4 (<0.1)
Mental impairment	0	3 (<0.1)	3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Burning sensation	0	2 (<0.1)	2 (<0.1)
Cerebrovascular accident	1 (<0.1)	2 (<0.1)	3 (<0.1)
Disturbance in attention	1 (<0.1)	2 (<0.1)	3 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neuralgia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Somnolence	0	2 (<0.1)	2 (<0.1)
Transient ischaemic attack	0	2 (<0.1)	2 (<0.1)
Amnesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Nervous system disorders (Cont.)			
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)	1 (<0.1)
Dizziness postural	0	1 (<0.1)	1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Lethargy	0	1 (<0.1)	1 (<0.1)
Lumbar radiculopathy	4 (<0.1)	1 (<0.1)	5 (<0.1)
Memory impairment	0	1 (<0.1)	1 (<0.1)
Migraine with aura	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Nerve compression	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neuropathy peripheral	0	1 (<0.1)	1 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Post-traumatic headache	1 (<0.1)	1 (<0.1)	2 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)	1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Nervous system disorders (Cont.)			
Thoracic outlet syndrome	0	1 (<0.1)	1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Tremor	1 (<0.1)	1 (<0.1)	2 (<0.1)
Visual field defect	0	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Encephalitis autoimmune	1 (<0.1)	0	1 (<0.1)
Head discomfort	1 (<0.1)	0	1 (<0.1)
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Muscle contractions involuntary	2 (<0.1)	0	2 (<0.1)
Restless legs syndrome	1 (<0.1)	0	1 (<0.1)
Shift work disorder	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Eye disorders	48 (0.3)	54 (0.4)	102 (0.4)
Eye pruritus	4 (<0.1)	7 (<0.1)	11 (<0.1)
Eye irritation	0	5 (<0.1)	5 (<0.1)
Eye pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Blepharitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Dry eye	5 (<0.1)	2 (<0.1)	7 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Eye disorders (Cont.)			
Eye inflammation	0	2 (<0.1)	2 (<0.1)
Eye swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)
Glaucoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lacrimation increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ocular hyperaemia	6 (<0.1)	2 (<0.1)	8 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vision blurred	3 (<0.1)	2 (<0.1)	5 (<0.1)
Visual impairment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vitreous floaters	3 (<0.1)	2 (<0.1)	5 (<0.1)
Accommodation disorder	0	1 (<0.1)	1 (<0.1)
Blepharospasm	0	1 (<0.1)	1 (<0.1)
Blindness transient	0	1 (<0.1)	1 (<0.1)
Cataract	0	1 (<0.1)	1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Eye discharge	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eyelid cyst	0	1 (<0.1)	1 (<0.1)
Iris disorder	0	1 (<0.1)	1 (<0.1)
Keratitis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Eye disorders (Cont.)			
Macular oedema	0	1 (<0.1)	1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Presbyopia	0	1 (<0.1)	1 (<0.1)
Vitreous disorder	0	1 (<0.1)	1 (<0.1)
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0	1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Eye ulcer	1 (<0.1)	0	1 (<0.1)
Eyelid ptosis	1 (<0.1)	0	1 (<0.1)
Macular degeneration	1 (<0.1)	0	1 (<0.1)
Macular hole	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	0	1 (<0.1)
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	2 (<0.1)	0	2 (<0.1)
Retinal tear	1 (<0.1)	0	1 (<0.1)
Strabismus	1 (<0.1)	0	1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Ear and labyrinth disorders	59 (0.4)	52 (0.4)	111 (0.4)
Vertigo	16 (0.1)	15 (0.1)	31 (0.1)
Ear pain	14 (<0.1)	11 (<0.1)	25 (<0.1)
Tinnitus	7 (<0.1)	8 (<0.1)	15 (<0.1)
Vertigo positional	0	5 (<0.1)	5 (<0.1)
Ear discomfort	5 (<0.1)	3 (<0.1)	8 (<0.1)
Ear canal erythema	1 (<0.1)	2 (<0.1)	3 (<0.1)
Middle ear effusion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Motion sickness	0	2 (<0.1)	2 (<0.1)
Cerumen impaction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Deafness neurosensory	0	1 (<0.1)	1 (<0.1)
Deafness unilateral	0	1 (<0.1)	1 (<0.1)
Ear congestion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Otorrhoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Deafness	1 (<0.1)	0	1 (<0.1)
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	0	4 (<0.1)
Cardiac disorders	69 (0.5)	65 (0.5)	134 (0.5)
Tachycardia	11 (<0.1)	14 (<0.1)	25 (<0.1)
Bradycardia	21 (0.1)	10 (<0.1)	31 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Cardiac disorders (Cont.)			
Atrial fibrillation	8 (<0.1)	9 (<0.1)	17 (<0.1)
Palpitations	5 (<0.1)	8 (<0.1)	13 (<0.1)
Coronary artery disease	4 (<0.1)	6 (<0.1)	10 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Angina pectoris	1 (<0.1)	4 (<0.1)	5 (<0.1)
Sinus tachycardia	0	3 (<0.1)	3 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute myocardial infarction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Arrhythmia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Cardiac failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic left ventricular failure	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	0	1 (<0.1)	1 (<0.1)
Tachyarrhythmia	0	1 (<0.1)	1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	1 (<0.1)
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Atrial tachycardia	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Cardiac disorders (Cont.)			
Pericarditis	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	163 (1.1)	166 (1.2)	329 (1.1)
Hypertension	125 (0.9)	127 (0.9)	252 (0.9)
Hot flush	6 (<0.1)	11 (<0.1)	17 (<0.1)
Flushing	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hypertensive urgency	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypotension	3 (<0.1)	3 (<0.1)	6 (<0.1)
Orthostatic hypotension	0	3 (<0.1)	3 (<0.1)
Systolic hypertension	4 (<0.1)	3 (<0.1)	7 (<0.1)
Deep vein thrombosis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Haematoma	4 (<0.1)	2 (<0.1)	6 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Pallor	0	1 (<0.1)	1 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
Peripheral coldness	0	1 (<0.1)	1 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)	1 (<0.1)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Vascular disorders (Cont.)			
Diastolic hypertension	1 (<0.1)	0	1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	2 (<0.1)	0	2 (<0.1)
Ischaemia	1 (<0.1)	0	1 (<0.1)
Lymphoedema	1 (<0.1)	0	1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0	1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0	1 (<0.1)
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	577 (4.0)	525 (3.7)	1102 (3.8)
Cough	162 (1.1)	168 (1.2)	330 (1.2)
Oropharyngeal pain	205 (1.4)	157 (1.1)	362 (1.3)
Nasal congestion	132 (0.9)	145 (1.0)	277 (1.0)
Rhinorrhoea	140 (1.0)	142 (1.0)	282 (1.0)
Dyspnoea	41 (0.3)	48 (0.3)	89 (0.3)
Tachypnoea	34 (0.2)	38 (0.3)	72 (0.3)
Throat irritation	12 (<0.1)	16 (0.1)	28 (<0.1)
Epistaxis	9 (<0.1)	14 (<0.1)	23 (<0.1)
Sinus congestion	28 (0.2)	13 (<0.1)	41 (0.1)
Asthma	11 (<0.1)	12 (<0.1)	23 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Upper-airway cough syndrome	9 (<0.1)	10 (<0.1)	19 (<0.1)
Rhinitis allergic	10 (<0.1)	9 (<0.1)	19 (<0.1)
Respiratory tract congestion	8 (<0.1)	8 (<0.1)	16 (<0.1)
Sneezing	12 (<0.1)	8 (<0.1)	20 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	7 (<0.1)	15 (<0.1)
Dyspnoea exertional	1 (<0.1)	4 (<0.1)	5 (<0.1)
Paranasal sinus discomfort	2 (<0.1)	4 (<0.1)	6 (<0.1)
Productive cough	6 (<0.1)	4 (<0.1)	10 (<0.1)
Sinus pain	3 (<0.1)	4 (<0.1)	7 (<0.1)
Wheezing	3 (<0.1)	4 (<0.1)	7 (<0.1)
Dry throat	3 (<0.1)	3 (<0.1)	6 (<0.1)
Dysphonia	8 (<0.1)	3 (<0.1)	11 (<0.1)
Pulmonary embolism	4 (<0.1)	3 (<0.1)	7 (<0.1)
Pharyngeal erythema	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute respiratory failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchiectasis	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)	1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal discomfort	0	1 (<0.1)	1 (<0.1)
Nasal dryness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rhonchi	0	1 (<0.1)	1 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)	1 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)	4 (<0.1)
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Nasal disorder	1 (<0.1)	0	1 (<0.1)
Nasal septum deviation	1 (<0.1)	0	1 (<0.1)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Pleural effusion	3 (<0.1)	0	3 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Respiratory failure	1 (<0.1)	0	1 (<0.1)
Respiratory symptom	2 (<0.1)	0	2 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Tonsillar exudate	1 (<0.1)	0	1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	411 (2.9)	455 (3.2)	866 (3.0)
Diarrhoea	155 (1.1)	181 (1.3)	336 (1.2)
Nausea	115 (0.8)	114 (0.8)	229 (0.8)
Vomiting	34 (0.2)	41 (0.3)	75 (0.3)
Gastroesophageal reflux disease	12 (<0.1)	29 (0.2)	41 (0.1)
Toothache	19 (0.1)	27 (0.2)	46 (0.2)
Abdominal pain	17 (0.1)	17 (0.1)	34 (0.1)
Constipation	12 (<0.1)	12 (<0.1)	24 (<0.1)
Abdominal pain upper	14 (<0.1)	10 (<0.1)	24 (<0.1)
Food poisoning	8 (<0.1)	10 (<0.1)	18 (<0.1)
Abdominal pain lower	6 (<0.1)	9 (<0.1)	15 (<0.1)
Dental caries	6 (<0.1)	7 (<0.1)	13 (<0.1)
Dyspepsia	10 (<0.1)	7 (<0.1)	17 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Gastrointestinal disorders (Cont.)			
Abdominal discomfort	5 (<0.1)	6 (<0.1)	11 (<0.1)
Colitis	3 (<0.1)	6 (<0.1)	9 (<0.1)
Haematochezia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aphthous ulcer	1 (<0.1)	3 (<0.1)	4 (<0.1)
Gastric ulcer	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	3 (<0.1)	5 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hiatus hernia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Proctalgia	0	2 (<0.1)	2 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Swollen tongue	0	2 (<0.1)	2 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)
Diverticular perforation	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Gastrointestinal disorders (Cont.)			
Diverticulum	1 (<0.1)	1 (<0.1)	2 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Faeces soft	0	1 (<0.1)	1 (<0.1)
Flatulence	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastric disorder	0	1 (<0.1)	1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Hyperchlorhydria	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Oesophageal pain	0	1 (<0.1)	1 (<0.1)
Oral mucosal blistering	0	1 (<0.1)	1 (<0.1)
Oral pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Paraesthesia oral	3 (<0.1)	1 (<0.1)	4 (<0.1)
Peptic ulcer	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Gastrointestinal disorders (Cont.)			
Saliva altered	1 (<0.1)	1 (<0.1)	2 (<0.1)
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Salivary hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)	1 (<0.1)
Tongue discolouration	0	1 (<0.1)	1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Tooth impacted	2 (<0.1)	1 (<0.1)	3 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysphagia	2 (<0.1)	0	2 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorder	1 (<0.1)	0	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0	1 (<0.1)
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Gingival pain	3 (<0.1)	0	3 (<0.1)
Glossitis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Gastrointestinal disorders (Cont.)			
Glossodynia	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	1 (<0.1)	0	1 (<0.1)
Large intestine polyp	3 (<0.1)	0	3 (<0.1)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Oral discomfort	1 (<0.1)	0	1 (<0.1)
Oral disorder	1 (<0.1)	0	1 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Regurgitation	1 (<0.1)	0	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Tongue coated	1 (<0.1)	0	1 (<0.1)
Tooth disorder	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	11 (<0.1)	11 (<0.1)
Cholelithiasis	0	6 (<0.1)	6 (<0.1)
Cholecystitis	0	2 (<0.1)	2 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	171 (1.2)	213 (1.5)	384 (1.3)
Rash	28 (0.2)	42 (0.3)	70 (0.2)
Pruritus	18 (0.1)	19 (0.1)	37 (0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis contact	24 (0.2)	16 (0.1)	40 (0.1)
Urticaria	14 (<0.1)	16 (0.1)	30 (0.1)
Hyperhidrosis	10 (<0.1)	13 (<0.1)	23 (<0.1)
Erythema	4 (<0.1)	10 (<0.1)	14 (<0.1)
Night sweats	6 (<0.1)	9 (<0.1)	15 (<0.1)
Dermatitis	5 (<0.1)	7 (<0.1)	12 (<0.1)
Acne	2 (<0.1)	6 (<0.1)	8 (<0.1)
Alopecia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Rash erythematous	2 (<0.1)	5 (<0.1)	7 (<0.1)
Blister	1 (<0.1)	4 (<0.1)	5 (<0.1)
Dermatitis atopic	6 (<0.1)	4 (<0.1)	10 (<0.1)
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Rash pruritic	2 (<0.1)	4 (<0.1)	6 (<0.1)
Skin lesion	4 (<0.1)	4 (<0.1)	8 (<0.1)
Actinic keratosis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Ecchymosis	7 (<0.1)	3 (<0.1)	10 (<0.1)
Eczema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Psoriasis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)	5 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Dermatitis allergic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Macule	0	2 (<0.1)	2 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Rash papular	0	2 (<0.1)	2 (<0.1)
Urticaria papular	4 (<0.1)	2 (<0.1)	6 (<0.1)
Angioedema	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dermal cyst	4 (<0.1)	1 (<0.1)	5 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)	2 (<0.1)
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	1 (<0.1)	1 (<0.1)
Ingrowing nail	0	1 (<0.1)	1 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Pain of skin	0	1 (<0.1)	1 (<0.1)
Papule	1 (<0.1)	1 (<0.1)	2 (<0.1)
Petechiae	0	1 (<0.1)	1 (<0.1)
Rash maculo-papular	3 (<0.1)	1 (<0.1)	4 (<0.1)
Rash vesicular	0	1 (<0.1)	1 (<0.1)
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Skin hypopigmentation	0	1 (<0.1)	1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin warm	0	1 (<0.1)	1 (<0.1)
Solar lentigo	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis bullous	2 (<0.1)	0	2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Ingrown hair	1 (<0.1)	0	1 (<0.1)
Intertrigo	1 (<0.1)	0	1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Livedo reticularis	1 (<0.1)	0	1 (<0.1)
Onychoclasia	1 (<0.1)	0	1 (<0.1)
Rash macular	1 (<0.1)	0	1 (<0.1)
Scab	1 (<0.1)	0	1 (<0.1)
Seborrheic dermatitis	1 (<0.1)	0	1 (<0.1)
Skin discolouration	2 (<0.1)	0	2 (<0.1)
Skin hyperpigmentation	1 (<0.1)	0	1 (<0.1)
Skin irritation	1 (<0.1)	0	1 (<0.1)
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Umbilical erythema	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	543 (3.8)	602 (4.2)	1145 (4.0)
Arthralgia	155 (1.1)	180 (1.3)	335 (1.2)
Myalgia	148 (1.0)	175 (1.2)	323 (1.1)
Back pain	91 (0.6)	75 (0.5)	166 (0.6)
Pain in extremity	62 (0.4)	52 (0.4)	114 (0.4)
Neck pain	24 (0.2)	35 (0.2)	59 (0.2)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Musculoskeletal pain	25 (0.2)	32 (0.2)	57 (0.2)
Muscle spasms	14 (<0.1)	27 (0.2)	41 (0.1)
Tendonitis	9 (<0.1)	15 (0.1)	24 (<0.1)
Musculoskeletal chest pain	12 (<0.1)	10 (<0.1)	22 (<0.1)
Musculoskeletal stiffness	8 (<0.1)	10 (<0.1)	18 (<0.1)
Rotator cuff syndrome	6 (<0.1)	7 (<0.1)	13 (<0.1)
Arthritis	0	6 (<0.1)	6 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	6 (<0.1)	10 (<0.1)
Osteoarthritis	13 (<0.1)	6 (<0.1)	19 (<0.1)
Bursitis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Flank pain	0	4 (<0.1)	4 (<0.1)
Groin pain	1 (<0.1)	4 (<0.1)	5 (<0.1)
Joint swelling	6 (<0.1)	4 (<0.1)	10 (<0.1)
Osteoporosis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Pain in jaw	3 (<0.1)	4 (<0.1)	7 (<0.1)
Bone pain	0	3 (<0.1)	3 (<0.1)
Costochondritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Joint range of motion decreased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Limb discomfort	3 (<0.1)	3 (<0.1)	6 (<0.1)
Axillary mass	0	2 (<0.1)	2 (<0.1)
Exostosis	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Fibromyalgia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Joint stiffness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle tightness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscular weakness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neck mass	0	2 (<0.1)	2 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Spinal osteoarthritis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Spinal pain	0	2 (<0.1)	2 (<0.1)
Spinal stenosis	0	2 (<0.1)	2 (<0.1)
Trigger finger	0	2 (<0.1)	2 (<0.1)
Arthropathy	0	1 (<0.1)	1 (<0.1)
Bone lesion	0	1 (<0.1)	1 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	0	1 (<0.1)	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	1 (<0.1)
Floating patella	0	1 (<0.1)	1 (<0.1)
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Muscle twitching	2 (<0.1)	1 (<0.1)	3 (<0.1)
Osteopenia	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthritis	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spondylitis	0	1 (<0.1)	1 (<0.1)
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Synovial cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Torticollis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Foot deformity	1 (<0.1)	0	1 (<0.1)
Intervertebral disc disorder	1 (<0.1)	0	1 (<0.1)
Limb mass	1 (<0.1)	0	1 (<0.1)
Lumbar spinal stenosis	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteitis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Renal and urinary disorders	42 (0.3)	45 (0.3)	87 (0.3)
Nephrolithiasis	22 (0.2)	18 (0.1)	40 (0.1)
Dysuria	1 (<0.1)	5 (<0.1)	6 (<0.1)
Chronic kidney disease	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematuria	8 (<0.1)	2 (<0.1)	10 (<0.1)
Polyuria	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute kidney injury	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bladder pain	0	1 (<0.1)	1 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
End stage renal disease	0	1 (<0.1)	1 (<0.1)
Hydronephrosis	0	1 (<0.1)	1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)
Nocturia	0	1 (<0.1)	1 (<0.1)
Pollakiuria	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal pain	0	1 (<0.1)	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chromaturia	1 (<0.1)	0	1 (<0.1)
Renal colic	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Renal and urinary disorders (Cont.)			
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pregnancy	0	2 (<0.1)	2 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)	1 (<0.1)
Morning sickness	0	1 (<0.1)	1 (<0.1)
Abortion spontaneous	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	35 (0.2)	41 (0.3)	76 (0.3)
Benign prostatic hyperplasia	5 (<0.1)	6 (<0.1)	11 (<0.1)
Dysmenorrhoea	4 (<0.1)	4 (<0.1)	8 (<0.1)
Pelvic pain	0	4 (<0.1)	4 (<0.1)
Erectile dysfunction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Menorrhagia	0	2 (<0.1)	2 (<0.1)
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast discharge	0	1 (<0.1)	1 (<0.1)
Breast disorder	0	1 (<0.1)	1 (<0.1)
Breast mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Reproductive system and breast disorders (Cont.)			
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopausal symptoms	0	1 (<0.1)	1 (<0.1)
Menstrual disorder	0	1 (<0.1)	1 (<0.1)
Metrorrhagia	0	1 (<0.1)	1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)	1 (<0.1)
Ovarian cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ovarian mass	0	1 (<0.1)	1 (<0.1)
Prostatitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Testicular pain	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
Uterine polyp	0	1 (<0.1)	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Vaginal haemorrhage	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)	1 (<0.1)
Amenorrhoea	1 (<0.1)	0	1 (<0.1)
Bartholin's cyst	1 (<0.1)	0	1 (<0.1)
Cystocele	1 (<0.1)	0	1 (<0.1)
Endometriosis	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	1 (<0.1)	0	1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0	1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Reproductive system and breast disorders (Cont.)			
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	1 (<0.1)	0	1 (<0.1)
Testicular swelling	1 (<0.1)	0	1 (<0.1)
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Uterine spasm	2 (<0.1)	0	2 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	1 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	600 (4.2)	900 (6.3)	1500 (5.2)
Fatigue	329 (2.3)	356 (2.5)	685 (2.4)
Injection site pain	50 (0.3)	144 (1.0)	194 (0.7)
Injection site erythema	12 (<0.1)	98 (0.7)	110 (0.4)
Chills	68 (0.5)	85 (0.6)	153 (0.5)
Pyrexia	54 (0.4)	72 (0.5)	126 (0.4)
Pain	54 (0.4)	67 (0.5)	121 (0.4)
Injection site pruritus	12 (<0.1)	65 (0.5)	77 (0.3)
Injection site swelling	11 (<0.1)	65 (0.5)	76 (0.3)
Injection site rash	1 (<0.1)	30 (0.2)	31 (0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Injection site induration	7 (<0.1)	28 (0.2)	35 (0.1)
Axillary pain	9 (<0.1)	23 (0.2)	32 (0.1)
Malaise	10 (<0.1)	12 (<0.1)	22 (<0.1)
Chest discomfort	12 (<0.1)	11 (<0.1)	23 (<0.1)
Injection site bruising	16 (0.1)	11 (<0.1)	27 (<0.1)
Swelling	4 (<0.1)	11 (<0.1)	15 (<0.1)
Chest pain	10 (<0.1)	8 (<0.1)	18 (<0.1)
Injection site urticaria	0	7 (<0.1)	7 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	8 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	6 (<0.1)	7 (<0.1)
Peripheral swelling	10 (<0.1)	6 (<0.1)	16 (<0.1)
Injection site haemorrhage	2 (<0.1)	5 (<0.1)	7 (<0.1)
Oedema peripheral	6 (<0.1)	5 (<0.1)	11 (<0.1)
Influenza like illness	5 (<0.1)	4 (<0.1)	9 (<0.1)
Reactogenicity event	3 (<0.1)	4 (<0.1)	7 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)
Feeling hot	3 (<0.1)	3 (<0.1)	6 (<0.1)
Injection site haematoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site reaction	1 (<0.1)	3 (<0.1)	4 (<0.1)
Non-cardiac chest pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Swelling face	2 (<0.1)	3 (<0.1)	5 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site erythema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vaccination site lymphadenopathy	0	3 (<0.1)	3 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)	2 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site irritation	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	2 (<0.1)
Injection site nodule	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site scab	0	2 (<0.1)	2 (<0.1)
Vaccination site pain	5 (<0.1)	2 (<0.1)	7 (<0.1)
Vaccination site swelling	1 (<0.1)	2 (<0.1)	3 (<0.1)
Asthenia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Crying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst	4 (<0.1)	1 (<0.1)	5 (<0.1)
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Facial pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Feeling cold	0	1 (<0.1)	1 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Inflammation	0	1 (<0.1)	1 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Injection site paraesthesia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Sensation of foreign body	0	1 (<0.1)	1 (<0.1)
Temperature intolerance	0	1 (<0.1)	1 (<0.1)
Vaccination site induration	0	1 (<0.1)	1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vaccination site rash	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Adverse drug reaction	1 (<0.1)	0	1 (<0.1)
Discomfort	2 (<0.1)	0	2 (<0.1)
Gait disturbance	1 (<0.1)	0	1 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site discolouration	2 (<0.1)	0	2 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Polyp	1 (<0.1)	0	1 (<0.1)
Precancerous condition	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Thirst	1 (<0.1)	0	1 (<0.1)
Vaccination site bruising	2 (<0.1)	0	2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0	1 (<0.1)
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	0	1 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	77 (0.5)	92 (0.6)	169 (0.6)
Blood pressure increased	32 (0.2)	29 (0.2)	61 (0.2)
Blood pressure systolic increased	13 (<0.1)	17 (0.1)	30 (0.1)
Blood pressure diastolic increased	7 (<0.1)	9 (<0.1)	16 (<0.1)
Body temperature increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Heart rate increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hepatic enzyme increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Blood glucose increased	2 (<0.1)	2 (<0.1)	4 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)	2 (<0.1)
Transaminases increased	0	2 (<0.1)	2 (<0.1)
White blood cell count increased	0	2 (<0.1)	2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Investigations (Cont.)			
Blood cholesterol increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood creatine increased	0	1 (<0.1)	1 (<0.1)
Blood creatinine increased	0	1 (<0.1)	1 (<0.1)
Blood glucose decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Blood testosterone decreased	0	1 (<0.1)	1 (<0.1)
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)	3 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Hepatitis B antibody positive	0	1 (<0.1)	1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Mammogram abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	0	1 (<0.1)	1 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Investigations (Cont.)			
Vitamin K	0	1 (<0.1)	1 (<0.1)
Weight decreased	0	1 (<0.1)	1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)
Biopsy skin	1 (<0.1)	0	1 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood potassium decreased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
C-reactive protein increased	1 (<0.1)	0	1 (<0.1)
Colonoscopy	1 (<0.1)	0	1 (<0.1)
Lipase increased	1 (<0.1)	0	1 (<0.1)
SARS-CoV-2 test positive	6 (<0.1)	0	6 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0	1 (<0.1)
Vitamin D decreased	2 (<0.1)	0	2 (<0.1)
Weight increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	288 (2.0)	259 (1.8)	547 (1.9)
Muscle strain	26 (0.2)	32 (0.2)	58 (0.2)
Ligament sprain	23 (0.2)	23 (0.2)	46 (0.2)
Arthropod bite	22 (0.2)	21 (0.1)	43 (0.1)
Skin laceration	30 (0.2)	20 (0.1)	50 (0.2)
Contusion	27 (0.2)	15 (0.1)	42 (0.1)
Tooth fracture	13 (<0.1)	14 (<0.1)	27 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Limb injury	4 (<0.1)	11 (<0.1)	15 (<0.1)
Fall	15 (0.1)	10 (<0.1)	25 (<0.1)
Procedural pain	14 (<0.1)	10 (<0.1)	24 (<0.1)
Foot fracture	9 (<0.1)	9 (<0.1)	18 (<0.1)
Arthropod sting	14 (<0.1)	7 (<0.1)	21 (<0.1)
Concussion	3 (<0.1)	7 (<0.1)	10 (<0.1)
Meniscus injury	3 (<0.1)	6 (<0.1)	9 (<0.1)
Skin abrasion	19 (0.1)	6 (<0.1)	25 (<0.1)
Animal bite	8 (<0.1)	5 (<0.1)	13 (<0.1)
Hand fracture	1 (<0.1)	5 (<0.1)	6 (<0.1)
Joint injury	4 (<0.1)	5 (<0.1)	9 (<0.1)
Road traffic accident	2 (<0.1)	5 (<0.1)	7 (<0.1)
Epicondylitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Head injury	1 (<0.1)	3 (<0.1)	4 (<0.1)
Rib fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Thermal burn	1 (<0.1)	3 (<0.1)	4 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Back injury	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cartilage injury	0	2 (<0.1)	2 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Clavicle fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Facial bones fracture	0	2 (<0.1)	2 (<0.1)
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Humerus fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ligament rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<0.1)
Ankle fracture	4 (<0.1)	1 (<0.1)	5 (<0.1)
Bone fragmentation	0	1 (<0.1)	1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Burns second degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Corneal abrasion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)	1 (<0.1)
Exposure to SARS-CoV-2	2 (<0.1)	1 (<0.1)	3 (<0.1)
Face injury	0	1 (<0.1)	1 (<0.1)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class	Placebo (N=14366)	mRNA-1273 (N=14316)	Total (N=28682)
Preferred Term	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications (Cont.)			
Fibula fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)	1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypobarism	0	1 (<0.1)	1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	0	1 (<0.1)	1 (<0.1)
Ligament injury	0	1 (<0.1)	1 (<0.1)
Lip injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Nasal injury	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Post-traumatic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Procedural headache	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Procedural nausea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Thoracic vertebral fracture	0	1 (<0.1)	1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	1 (<0.1)	1 (<0.1)
Wound	4 (<0.1)	1 (<0.1)	5 (<0.1)
Abdominal injury	1 (<0.1)	0	1 (<0.1)
Bone contusion	3 (<0.1)	0	3 (<0.1)
Exposure to toxic agent	1 (<0.1)	0	1 (<0.1)
Eye injury	2 (<0.1)	0	2 (<0.1)
Eyelid contusion	1 (<0.1)	0	1 (<0.1)
Foreign body	3 (<0.1)	0	3 (<0.1)
Foreign body in ear	1 (<0.1)	0	1 (<0.1)
Fracture	1 (<0.1)	0	1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Mouth injury	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Muscle injury	1 (<0.1)	0	1 (<0.1)
Nail injury	1 (<0.1)	0	1 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	2 (<0.1)	0	2 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Stress fracture	3 (<0.1)	0	3 (<0.1)
Sunburn	1 (<0.1)	0	1 (<0.1)
Superficial injury of eye	1 (<0.1)	0	1 (<0.1)
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Venomous sting	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	12 (<0.1)	19 (0.1)	31 (0.1)
Axillary lymphadenectomy	0	2 (<0.1)	2 (<0.1)
Endodontic procedure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Thyroidectomy	0	2 (<0.1)	2 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curettage of chalazion	0	1 (<0.1)	1 (<0.1)
Cyst removal	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Surgical and medical procedures (Cont.)			
Dental operation	0	1 (<0.1)	1 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lipoma excision	0	1 (<0.1)	1 (<0.1)
Phlebectomy	0	1 (<0.1)	1 (<0.1)
Skin cyst excision	0	1 (<0.1)	1 (<0.1)
Skin neoplasm excision	0	1 (<0.1)	1 (<0.1)
Skin operation	0	1 (<0.1)	1 (<0.1)
Spinal fusion surgery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Transurethral prostatectomy	0	1 (<0.1)	1 (<0.1)
Artificial crown procedure	1 (<0.1)	0	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Cataract operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Liposuction	1 (<0.1)	0	1 (<0.1)
Tooth extraction	1 (<0.1)	0	1 (<0.1)
Tooth repair	2 (<0.1)	0	2 (<0.1)
Umbilical hernia repair	1 (<0.1)	0	1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopause	0	1 (<0.1)	1 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Product issues	2 (<0.1)	4 (<0.1)	6 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Device dislocation	0	1 (<0.1)	1 (<0.1)
Embedded device	0	1 (<0.1)	1 (<0.1)
Lead dislodgement	1 (<0.1)	0	1 (<0.1)
Uncoded	164 (1.1)	253 (1.8)	417 (1.5)
Uncoded	164 (1.1)	253 (1.8)	417 (1.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	68 (20.4)	55 (16.1)	123 (18.2)
Number of Unsolicited Adverse Events	121	102	223
Infections and infestations	11 (3.3)	13 (3.8)	24 (3.6)
COVID-19	3 (0.9)	3 (0.9)	6 (0.9)
Upper respiratory tract infection	3 (0.9)	2 (0.6)	5 (0.7)
Viral infection	2 (0.6)	2 (0.6)	4 (0.6)
Cystitis	0	1 (0.3)	1 (0.1)
Folliculitis	0	1 (0.3)	1 (0.1)
Otitis externa	0	1 (0.3)	1 (0.1)
Paronychia	0	1 (0.3)	1 (0.1)
Sinusitis	0	1 (0.3)	1 (0.1)
Subcutaneous abscess	0	1 (0.3)	1 (0.1)
Vaginal infection	0	1 (0.3)	1 (0.1)
Pyelonephritis	1 (0.3)	0	1 (0.1)
Pyelonephritis acute	1 (0.3)	0	1 (0.1)
Septic shock	1 (0.3)	0	1 (0.1)
Urinary tract infection	2 (0.6)	0	2 (0.3)
Blood and lymphatic system disorders	2 (0.6)	0	2 (0.3)
Lymphadenopathy	2 (0.6)	0	2 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Immune system disorders	1 (0.3)	0	1 (0.1)
Seasonal allergy	1 (0.3)	0	1 (0.1)
Metabolism and nutrition disorders	5 (1.5)	2 (0.6)	7 (1.0)
Hyperlipidaemia	0	1 (0.3)	1 (0.1)
Hypoglycaemia	0	1 (0.3)	1 (0.1)
Type 2 diabetes mellitus	0	1 (0.3)	1 (0.1)
Vitamin D deficiency	0	1 (0.3)	1 (0.1)
Dehydration	1 (0.3)	0	1 (0.1)
Diabetes mellitus	1 (0.3)	0	1 (0.1)
Hypercholesterolaemia	2 (0.6)	0	2 (0.3)
Increased appetite	1 (0.3)	0	1 (0.1)
Psychiatric disorders	0	1 (0.3)	1 (0.1)
Depression	0	1 (0.3)	1 (0.1)
Nervous system disorders	19 (5.7)	11 (3.2)	30 (4.4)
Headache	14 (4.2)	8 (2.3)	22 (3.3)
Dizziness	0	2 (0.6)	2 (0.3)
Ageusia	1 (0.3)	1 (0.3)	2 (0.3)
Sciatica	0	1 (0.3)	1 (0.1)
Syncope	0	1 (0.3)	1 (0.1)
Anosmia	1 (0.3)	0	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Nervous system disorders (Cont.)			
Migraine	2 (0.6)	0	2 (0.3)
Paraesthesia	1 (0.3)	0	1 (0.1)
Parosmia	1 (0.3)	0	1 (0.1)
Somnolence	1 (0.3)	0	1 (0.1)
Eye disorders	0	1 (0.3)	1 (0.1)
Vision blurred	0	1 (0.3)	1 (0.1)
Ear and labyrinth disorders	3 (0.9)	1 (0.3)	4 (0.6)
Cerumen impaction	0	1 (0.3)	1 (0.1)
Ear pruritus	1 (0.3)	0	1 (0.1)
Tinnitus	1 (0.3)	0	1 (0.1)
Tympanic membrane perforation	1 (0.3)	0	1 (0.1)
Cardiac disorders	1 (0.3)	0	1 (0.1)
Acute left ventricular failure	1 (0.3)	0	1 (0.1)
Atrial fibrillation	1 (0.3)	0	1 (0.1)
Vascular disorders	2 (0.6)	2 (0.6)	4 (0.6)
Hypertension	2 (0.6)	2 (0.6)	4 (0.6)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Respiratory, thoracic and mediastinal disorders	11 (3.3)	7 (2.1)	18 (2.7)
Rhinorrhoea	2 (0.6)	3 (0.9)	5 (0.7)
Nasal congestion	3 (0.9)	2 (0.6)	5 (0.7)
Oropharyngeal pain	3 (0.9)	2 (0.6)	5 (0.7)
Cough	2 (0.6)	1 (0.3)	3 (0.4)
Dyspnoea	0	1 (0.3)	1 (0.1)
Epistaxis	1 (0.3)	1 (0.3)	2 (0.3)
Productive cough	0	1 (0.3)	1 (0.1)
Acute respiratory failure	1 (0.3)	0	1 (0.1)
Sinus congestion	1 (0.3)	0	1 (0.1)
Gastrointestinal disorders	5 (1.5)	6 (1.8)	11 (1.6)
Diarrhoea	1 (0.3)	4 (1.2)	5 (0.7)
Gastrooesophageal reflux disease	2 (0.6)	2 (0.6)	4 (0.6)
Gastric ulcer	0	1 (0.3)	1 (0.1)
Nausea	0	1 (0.3)	1 (0.1)
Oesophageal ulcer	0	1 (0.3)	1 (0.1)
Abdominal pain	1 (0.3)	0	1 (0.1)
Dyspepsia	1 (0.3)	0	1 (0.1)
Vomiting	1 (0.3)	0	1 (0.1)
Hepatobiliary disorders	1 (0.3)	0	1 (0.1)
Cholelithiasis	1 (0.3)	0	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Skin and subcutaneous tissue disorders	5 (1.5)	4 (1.2)	9 (1.3)
Acne	0	1 (0.3)	1 (0.1)
Ecchymosis	0	1 (0.3)	1 (0.1)
Hyperhidrosis	0	1 (0.3)	1 (0.1)
Urticaria	0	1 (0.3)	1 (0.1)
Blister	1 (0.3)	0	1 (0.1)
Dermatitis contact	1 (0.3)	0	1 (0.1)
Night sweats	1 (0.3)	0	1 (0.1)
Rash	2 (0.6)	0	2 (0.3)
Musculoskeletal and connective tissue disorders	12 (3.6)	10 (2.9)	22 (3.3)
Myalgia	2 (0.6)	3 (0.9)	5 (0.7)
Back pain	1 (0.3)	2 (0.6)	3 (0.4)
Pain in extremity	0	2 (0.6)	2 (0.3)
Arthralgia	2 (0.6)	1 (0.3)	3 (0.4)
Limb discomfort	0	1 (0.3)	1 (0.1)
Neck pain	1 (0.3)	1 (0.3)	2 (0.3)
Arthritis	1 (0.3)	0	1 (0.1)
Axillary mass	1 (0.3)	0	1 (0.1)
Muscle twitching	1 (0.3)	0	1 (0.1)
Musculoskeletal pain	2 (0.6)	0	2 (0.3)
Musculoskeletal stiffness	1 (0.3)	0	1 (0.1)
Plantar fasciitis	1 (0.3)	0	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Spinal stenosis	1 (0.3)	0	1 (0.1)
Renal and urinary disorders	3 (0.9)	0	3 (0.4)
Micturition urgency	1 (0.3)	0	1 (0.1)
Nephrolithiasis	1 (0.3)	0	1 (0.1)
Pollakiuria	1 (0.3)	0	1 (0.1)
Renal colic	1 (0.3)	0	1 (0.1)
Reproductive system and breast disorders	1 (0.3)	0	1 (0.1)
Nipple pain	1 (0.3)	0	1 (0.1)
General disorders and administration site conditions	9 (2.7)	16 (4.7)	25 (3.7)
Fatigue	4 (1.2)	3 (0.9)	7 (1.0)
Injection site pain	1 (0.3)	3 (0.9)	4 (0.6)
Chest pain	0	2 (0.6)	2 (0.3)
Feeling hot	0	2 (0.6)	2 (0.3)
Injection site induration	0	2 (0.6)	2 (0.3)
Chest discomfort	0	1 (0.3)	1 (0.1)
Injection site bruising	1 (0.3)	1 (0.3)	2 (0.3)
Injection site erythema	0	1 (0.3)	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
General disorders and administration site conditions (Cont.)			
Oedema peripheral	0	1 (0.3)	1 (0.1)
Pyrexia	0	1 (0.3)	1 (0.1)
Swelling face	0	1 (0.3)	1 (0.1)
Chills	1 (0.3)	0	1 (0.1)
Non-cardiac chest pain	1 (0.3)	0	1 (0.1)
Pain	1 (0.3)	0	1 (0.1)
Investigations	3 (0.9)	3 (0.9)	6 (0.9)
Blood pressure increased	1 (0.3)	1 (0.3)	2 (0.3)
Heart rate increased	0	1 (0.3)	1 (0.1)
SARS-CoV-2 test positive	1 (0.3)	1 (0.3)	2 (0.3)
Blood pressure systolic increased	1 (0.3)	0	1 (0.1)
Injury, poisoning and procedural complications	3 (0.9)	4 (1.2)	7 (1.0)
Fall	0	1 (0.3)	1 (0.1)
Head injury	0	1 (0.3)	1 (0.1)
Ligament sprain	2 (0.6)	1 (0.3)	3 (0.4)
Road traffic accident	1 (0.3)	1 (0.3)	2 (0.3)
Surgical and medical procedures	1 (0.3)	0	1 (0.1)
Knee arthroplasty	1 (0.3)	0	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Uncoded	8 (2.4)	5 (1.5)	13 (1.9)
Uncoded	8 (2.4)	5 (1.5)	13 (1.9)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	56 (12.0)	76 (14.4)	132 (13.3)
Number of Unsolicited Adverse Events	87	173	260
Infections and infestations	8 (1.7)	15 (2.8)	23 (2.3)
Urinary tract infection	1 (0.2)	2 (0.4)	3 (0.3)
COVID-19	2 (0.4)	1 (0.2)	3 (0.3)
Conjunctivitis	1 (0.2)	1 (0.2)	2 (0.2)
Folliculitis	0	1 (0.2)	1 (0.1)
Gastroenteritis viral	0	1 (0.2)	1 (0.1)
Herpes simplex	0	1 (0.2)	1 (0.1)
Herpes zoster	0	1 (0.2)	1 (0.1)
Kidney infection	0	1 (0.2)	1 (0.1)
Laryngitis	0	1 (0.2)	1 (0.1)
Lyme disease	0	1 (0.2)	1 (0.1)
Pharyngitis	0	1 (0.2)	1 (0.1)
Pharyngitis streptococcal	1 (0.2)	1 (0.2)	2 (0.2)
Sinusitis bacterial	0	1 (0.2)	1 (0.1)
Staphylococcal infection	0	1 (0.2)	1 (0.1)
Subcutaneous abscess	0	1 (0.2)	1 (0.1)
Upper respiratory tract infection	2 (0.4)	1 (0.2)	3 (0.3)
Tonsillitis	1 (0.2)	0	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (0.4)	2 (0.2)
Lung cancer metastatic	0	1 (0.2)	1 (0.1)
Squamous cell carcinoma of skin	0	1 (0.2)	1 (0.1)
Blood and lymphatic system disorders	3 (0.6)	0	3 (0.3)
Lymphadenitis	1 (0.2)	0	1 (0.1)
Lymphadenopathy	2 (0.4)	0	2 (0.2)
Immune system disorders	0	1 (0.2)	1 (0.1)
Seasonal allergy	0	1 (0.2)	1 (0.1)
Metabolism and nutrition disorders	1 (0.2)	0	1 (0.1)
Gout	1 (0.2)	0	1 (0.1)
Psychiatric disorders	0	2 (0.4)	2 (0.2)
Depression	0	1 (0.2)	1 (0.1)
Mental fatigue	0	1 (0.2)	1 (0.1)
Nervous system disorders	14 (3.0)	19 (3.6)	33 (3.3)
Headache	10 (2.2)	11 (2.1)	21 (2.1)
Anosmia	0	1 (0.2)	1 (0.1)
Dizziness	0	1 (0.2)	1 (0.1)

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Nervous system disorders (Cont.)			
Dizziness postural	0	1 (0.2)	1 (0.1)
Essential tremor	0	1 (0.2)	1 (0.1)
Hyperaesthesia	0	1 (0.2)	1 (0.1)
Migraine	1 (0.2)	1 (0.2)	2 (0.2)
Nerve compression	1 (0.2)	1 (0.2)	2 (0.2)
Sciatica	0	1 (0.2)	1 (0.1)
Sinus headache	0	1 (0.2)	1 (0.1)
Tension headache	0	1 (0.2)	1 (0.1)
Horner's syndrome	1 (0.2)	0	1 (0.1)
Syncope	1 (0.2)	0	1 (0.1)
Ear and labyrinth disorders	1 (0.2)	3 (0.6)	4 (0.4)
Vertigo	0	2 (0.4)	2 (0.2)
Vertigo positional	0	1 (0.2)	1 (0.1)
Ear discomfort	1 (0.2)	0	1 (0.1)
Cardiac disorders	0	2 (0.4)	2 (0.2)
Arrhythmia	0	1 (0.2)	1 (0.1)
Cardiac failure congestive	0	1 (0.2)	1 (0.1)
Vascular disorders	2 (0.4)	3 (0.6)	5 (0.5)
Hypertension	1 (0.2)	2 (0.4)	3 (0.3)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Vascular disorders (Cont.)			
Haematoma	0	1 (0.2)	1 (0.1)
Hypotension	1 (0.2)	0	1 (0.1)
Respiratory, thoracic and mediastinal disorders	9 (1.9)	14 (2.7)	23 (2.3)
Oropharyngeal pain	3 (0.6)	10 (1.9)	13 (1.3)
Cough	1 (0.2)	5 (0.9)	6 (0.6)
Nasal congestion	3 (0.6)	5 (0.9)	8 (0.8)
Dyspnoea	0	2 (0.4)	2 (0.2)
Rhinorrhoea	3 (0.6)	2 (0.4)	5 (0.5)
Dry throat	0	1 (0.2)	1 (0.1)
Dysphonia	0	1 (0.2)	1 (0.1)
Respiratory tract congestion	0	1 (0.2)	1 (0.1)
Sinus congestion	2 (0.4)	1 (0.2)	3 (0.3)
Upper-airway cough syndrome	0	1 (0.2)	1 (0.1)
Oropharyngeal discomfort	1 (0.2)	0	1 (0.1)
Tachypnoea	1 (0.2)	0	1 (0.1)
Gastrointestinal disorders	9 (1.9)	10 (1.9)	19 (1.9)
Diarrhoea	4 (0.9)	6 (1.1)	10 (1.0)
Nausea	3 (0.6)	3 (0.6)	6 (0.6)
Abdominal pain upper	0	1 (0.2)	1 (0.1)
Dyspepsia	0	1 (0.2)	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Gastrointestinal disorders (Cont.)			
Vomiting	2 (0.4)	1 (0.2)	3 (0.3)
Abdominal pain	1 (0.2)	0	1 (0.1)
Constipation	1 (0.2)	0	1 (0.1)
Toothache	1 (0.2)	0	1 (0.1)
Skin and subcutaneous tissue disorders	1 (0.2)	6 (1.1)	7 (0.7)
Ecchymosis	0	1 (0.2)	1 (0.1)
Erythema	0	1 (0.2)	1 (0.1)
Nail disorder	0	1 (0.2)	1 (0.1)
Pruritus	0	1 (0.2)	1 (0.1)
Rash erythematous	0	1 (0.2)	1 (0.1)
Urticaria	0	1 (0.2)	1 (0.1)
Papule	1 (0.2)	0	1 (0.1)
Musculoskeletal and connective tissue disorders	7 (1.5)	11 (2.1)	18 (1.8)
Myalgia	0	5 (0.9)	5 (0.5)
Back pain	0	3 (0.6)	3 (0.3)
Arthralgia	3 (0.6)	1 (0.2)	4 (0.4)
Joint swelling	0	1 (0.2)	1 (0.1)
Muscular weakness	0	1 (0.2)	1 (0.1)
Musculoskeletal pain	0	1 (0.2)	1 (0.1)
Neck mass	0	1 (0.2)	1 (0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Pain in extremity	0	1 (0.2)	1 (0.1)
Axillary mass	1 (0.2)	0	1 (0.1)
Muscle spasms	1 (0.2)	0	1 (0.1)
Musculoskeletal stiffness	1 (0.2)	0	1 (0.1)
Pain in jaw	1 (0.2)	0	1 (0.1)
Reproductive system and breast disorders	0	2 (0.4)	2 (0.2)
Adenomyosis	0	1 (0.2)	1 (0.1)
Erectile dysfunction	0	1 (0.2)	1 (0.1)
General disorders and administration site conditions	9 (1.9)	24 (4.6)	33 (3.3)
Fatigue	3 (0.6)	10 (1.9)	13 (1.3)
Chills	0	5 (0.9)	5 (0.5)
Injection site pain	1 (0.2)	5 (0.9)	6 (0.6)
Pain	0	5 (0.9)	5 (0.5)
Pyrexia	2 (0.4)	4 (0.8)	6 (0.6)
Injection site erythema	1 (0.2)	3 (0.6)	4 (0.4)
Injection site pruritus	0	3 (0.6)	3 (0.3)
Injection site swelling	1 (0.2)	2 (0.4)	3 (0.3)
Adverse drug reaction	0	1 (0.2)	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.9

Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
General disorders and administration site conditions (Cont.)			
Chest pain	0	1 (0.2)	1 (0.1)
Injection site paraesthesia	0	1 (0.2)	1 (0.1)
Injection site warmth	0	1 (0.2)	1 (0.1)
Vaccination site lymphadenopathy	0	1 (0.2)	1 (0.1)
Vaccination site swelling	0	1 (0.2)	1 (0.1)
Axillary pain	1 (0.2)	0	1 (0.1)
Investigations	1 (0.2)	1 (0.2)	2 (0.2)
Blood pressure increased	1 (0.2)	1 (0.2)	2 (0.2)
Injury, poisoning and procedural complications	3 (0.6)	2 (0.4)	5 (0.5)
Joint injury	0	1 (0.2)	1 (0.1)
Scar	0	1 (0.2)	1 (0.1)
Corneal abrasion	1 (0.2)	0	1 (0.1)
Limb injury	1 (0.2)	0	1 (0.1)
Superficial injury of eye	1 (0.2)	0	1 (0.1)
Uncoded	7 (1.5)	5 (0.9)	12 (1.2)
Uncoded	7 (1.5)	5 (0.9)	12 (1.2)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	585 (4.1)	1095 (7.6)	1680 (5.9)
Number of Unsolicited Adverse Events	933	1790	2723
Infections and infestations	15 (0.1)	8 (<0.1)	23 (<0.1)
Injection site cellulitis	0	2 (<0.1)	2 (<0.1)
COVID-19	1 (<0.1)	1 (<0.1)	2 (<0.1)
Conjunctivitis	0	1 (<0.1)	1 (<0.1)
Ear infection	0	1 (<0.1)	1 (<0.1)
Herpes zoster	0	1 (<0.1)	1 (<0.1)
Sinusitis	0	1 (<0.1)	1 (<0.1)
Viral infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cellulitis	1 (<0.1)	0	1 (<0.1)
Gingivitis	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Onychomycosis	1 (<0.1)	0	1 (<0.1)
Oral herpes	1 (<0.1)	0	1 (<0.1)
Rhinitis	2 (<0.1)	0	2 (<0.1)
Tinea pedis	1 (<0.1)	0	1 (<0.1)
Upper respiratory tract infection	4 (<0.1)	0	4 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3

Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Blood and lymphatic system disorders	35 (0.2)	73 (0.5)	108 (0.4)
Lymphadenopathy	32 (0.2)	66 (0.5)	98 (0.3)
Lymphadenitis	0	5 (<0.1)	5 (<0.1)
Lymph node pain	3 (<0.1)	4 (<0.1)	7 (<0.1)
Anaemia	0	1 (<0.1)	1 (<0.1)
Immune system disorders	0	2 (<0.1)	2 (<0.1)
Seasonal allergy	0	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	2 (<0.1)	4 (<0.1)	6 (<0.1)
Decreased appetite	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abnormal loss of weight	0	1 (<0.1)	1 (<0.1)
Diabetes mellitus	0	1 (<0.1)	1 (<0.1)
Hyperglycaemia	0	1 (<0.1)	1 (<0.1)
Psychiatric disorders	0	11 (<0.1)	11 (<0.1)
Insomnia	0	4 (<0.1)	4 (<0.1)
Abnormal dreams	0	3 (<0.1)	3 (<0.1)
Sleep disorder	0	2 (<0.1)	2 (<0.1)
Affect lability	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Nightmare	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Nervous system disorders	148 (1.0)	249 (1.7)	397 (1.4)
Headache	111 (0.8)	185 (1.3)	296 (1.0)
Dizziness	12 (<0.1)	22 (0.2)	34 (0.1)
Dysgeusia	6 (<0.1)	10 (<0.1)	16 (<0.1)
Paraesthesia	5 (<0.1)	9 (<0.1)	14 (<0.1)
Hyperaesthesia	0	5 (<0.1)	5 (<0.1)
Hypoaesthesia	0	4 (<0.1)	4 (<0.1)
Somnolence	0	2 (<0.1)	2 (<0.1)
Syncope	0	2 (<0.1)	2 (<0.1)
Ageusia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Balance disorder	0	1 (<0.1)	1 (<0.1)
Burning sensation	0	1 (<0.1)	1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	1 (<0.1)
Disturbance in attention	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Mental impairment	0	1 (<0.1)	1 (<0.1)
Migraine	6 (<0.1)	1 (<0.1)	7 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Neuralgia	0	1 (<0.1)	1 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Presyncope	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Nervous system disorders (Cont.)			
Sinus headache	0	1 (<0.1)	1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anosmia	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	1 (<0.1)	0	1 (<0.1)
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Hyposmia	1 (<0.1)	0	1 (<0.1)
Sciatica	1 (<0.1)	0	1 (<0.1)
Eye disorders	3 (<0.1)	5 (<0.1)	8 (<0.1)
Visual impairment	0	2 (<0.1)	2 (<0.1)
Blepharospasm	0	1 (<0.1)	1 (<0.1)
Eye irritation	0	1 (<0.1)	1 (<0.1)
Vitreous floaters	0	1 (<0.1)	1 (<0.1)
Eye swelling	1 (<0.1)	0	1 (<0.1)
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	3 (<0.1)	8 (<0.1)	11 (<0.1)
Tinnitus	1 (<0.1)	5 (<0.1)	6 (<0.1)
Ear discomfort	0	1 (<0.1)	1 (<0.1)
Vertigo	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vertigo positional	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Ear and labyrinth disorders (Cont.)			
Ear pain	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	5 (<0.1)	6 (<0.1)	11 (<0.1)
Tachycardia	0	4 (<0.1)	4 (<0.1)
Sinus tachycardia	0	2 (<0.1)	2 (<0.1)
Arrhythmia	2 (<0.1)	0	2 (<0.1)
Bradycardia	1 (<0.1)	0	1 (<0.1)
Palpitations	2 (<0.1)	0	2 (<0.1)
Vascular disorders	15 (0.1)	21 (0.1)	36 (0.1)
Hypertension	12 (<0.1)	8 (<0.1)	20 (<0.1)
Flushing	1 (<0.1)	6 (<0.1)	7 (<0.1)
Hot flush	2 (<0.1)	5 (<0.1)	7 (<0.1)
Deep vein thrombosis	0	1 (<0.1)	1 (<0.1)
Peripheral coldness	0	1 (<0.1)	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	36 (0.3)	45 (0.3)	81 (0.3)
Nasal congestion	6 (<0.1)	18 (0.1)	24 (<0.1)
Cough	4 (<0.1)	12 (<0.1)	16 (<0.1)
Rhinorrhoea	9 (<0.1)	11 (<0.1)	20 (<0.1)
Oropharyngeal pain	13 (<0.1)	8 (<0.1)	21 (<0.1)
Dyspnoea	2 (<0.1)	5 (<0.1)	7 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Throat irritation	3 (<0.1)	4 (<0.1)	7 (<0.1)
Asthma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus congestion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus pain	0	1 (<0.1)	1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0	1 (<0.1)
Dysphonia	1 (<0.1)	0	1 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	0	1 (<0.1)
Pleurisy	1 (<0.1)	0	1 (<0.1)
Productive cough	2 (<0.1)	0	2 (<0.1)
Pulmonary embolism	1 (<0.1)	0	1 (<0.1)
Tachypnoea	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	64 (0.4)	72 (0.5)	136 (0.5)
Diarrhoea	23 (0.2)	35 (0.2)	58 (0.2)
Nausea	32 (0.2)	25 (0.2)	57 (0.2)
Abdominal pain	0	6 (<0.1)	6 (<0.1)
Vomiting	3 (<0.1)	4 (<0.1)	7 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Lip swelling	0	2 (<0.1)	2 (<0.1)
Swollen tongue	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Gastrointestinal disorders (Cont.)			
Toothache	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abdominal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abdominal pain upper	1 (<0.1)	1 (<0.1)	2 (<0.1)
Aphthous ulcer	0	1 (<0.1)	1 (<0.1)
Dry mouth	0	1 (<0.1)	1 (<0.1)
Dyspepsia	0	1 (<0.1)	1 (<0.1)
Gastroesophageal reflux disease	0	1 (<0.1)	1 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Dysphagia	1 (<0.1)	0	1 (<0.1)
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Gingival pain	1 (<0.1)	0	1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	0	1 (<0.1)
Paraesthesia oral	3 (<0.1)	0	3 (<0.1)
Salivary hypersecretion	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	27 (0.2)	65 (0.5)	92 (0.3)
Rash	5 (<0.1)	13 (<0.1)	18 (<0.1)
Urticaria	1 (<0.1)	10 (<0.1)	11 (<0.1)
Pruritus	9 (<0.1)	8 (<0.1)	17 (<0.1)
Hyperhidrosis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Night sweats	4 (<0.1)	6 (<0.1)	10 (<0.1)

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Erythema	0	5 (<0.1)	5 (<0.1)
Skin burning sensation	0	3 (<0.1)	3 (<0.1)
Alopecia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dermatitis	0	2 (<0.1)	2 (<0.1)
Psoriasis	0	2 (<0.1)	2 (<0.1)
Rash pruritic	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acne	0	1 (<0.1)	1 (<0.1)
Angioedema	0	1 (<0.1)	1 (<0.1)
Macule	0	1 (<0.1)	1 (<0.1)
Pityriasis rosea	0	1 (<0.1)	1 (<0.1)
Rash erythematous	0	1 (<0.1)	1 (<0.1)
Skin warm	0	1 (<0.1)	1 (<0.1)
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)
Dermatitis contact	1 (<0.1)	0	1 (<0.1)
Ecchymosis	1 (<0.1)	0	1 (<0.1)
Skin discolouration	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	122 (0.8)	187 (1.3)	309 (1.1)
Myalgia	56 (0.4)	91 (0.6)	147 (0.5)
Arthralgia	73 (0.5)	79 (0.6)	152 (0.5)
Pain in extremity	8 (<0.1)	15 (0.1)	23 (<0.1)
Neck pain	1 (<0.1)	9 (<0.1)	10 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Back pain	1 (<0.1)	8 (<0.1)	9 (<0.1)
Musculoskeletal pain	5 (<0.1)	6 (<0.1)	11 (<0.1)
Muscle spasms	3 (<0.1)	4 (<0.1)	7 (<0.1)
Joint range of motion decreased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Bone pain	0	2 (<0.1)	2 (<0.1)
Limb discomfort	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tendonitis	0	2 (<0.1)	2 (<0.1)
Arthropathy	0	1 (<0.1)	1 (<0.1)
Axillary mass	0	1 (<0.1)	1 (<0.1)
Bone lesion	0	1 (<0.1)	1 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Costochondritis	0	1 (<0.1)	1 (<0.1)
Flank pain	0	1 (<0.1)	1 (<0.1)
Joint stiffness	0	1 (<0.1)	1 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Musculoskeletal stiffness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neck mass	0	1 (<0.1)	1 (<0.1)
Osteoarthritis	0	1 (<0.1)	1 (<0.1)
Polyarthritis	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Temporomandibular joint syndrome	0	1 (<0.1)	1 (<0.1)
Muscle tightness	1 (<0.1)	0	1 (<0.1)
Muscle twitching	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	3 (<0.1)	2 (<0.1)	5 (<0.1)
Menorrhagia	0	2 (<0.1)	2 (<0.1)
Breast pain	1 (<0.1)	0	1 (<0.1)
Dysmenorrhoea	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	267 (1.9)	562 (3.9)	829 (2.9)
Fatigue	153 (1.1)	192 (1.3)	345 (1.2)
Injection site pain	34 (0.2)	107 (0.7)	141 (0.5)
Injection site erythema	11 (<0.1)	87 (0.6)	98 (0.3)
Injection site swelling	11 (<0.1)	60 (0.4)	71 (0.2)
Injection site pruritus	11 (<0.1)	52 (0.4)	63 (0.2)
Chills	12 (<0.1)	37 (0.3)	49 (0.2)
Injection site induration	7 (<0.1)	28 (0.2)	35 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Pyrexia	7 (<0.1)	27 (0.2)	34 (0.1)
Injection site rash	1 (<0.1)	25 (0.2)	26 (<0.1)
Axillary pain	3 (<0.1)	19 (0.1)	22 (<0.1)
Pain	6 (<0.1)	17 (0.1)	23 (<0.1)
Swelling	4 (<0.1)	8 (<0.1)	12 (<0.1)
Malaise	4 (<0.1)	7 (<0.1)	11 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	6 (<0.1)	7 (<0.1)
Injection site urticaria	0	5 (<0.1)	5 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)	6 (<0.1)
Injection site haemorrhage	1 (<0.1)	4 (<0.1)	5 (<0.1)
Reactogenicity event	3 (<0.1)	4 (<0.1)	7 (<0.1)
Chest discomfort	1 (<0.1)	3 (<0.1)	4 (<0.1)
Injection site bruising	9 (<0.1)	3 (<0.1)	12 (<0.1)
Injection site reaction	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tenderness	0	3 (<0.1)	3 (<0.1)
Vaccination site erythema	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vaccination site lymphadenopathy	0	3 (<0.1)	3 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site irritation	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	2 (<0.1)
Injection site nodule	1 (<0.1)	2 (<0.1)	3 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011103.sas 20NOV2020 06:55

Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Peripheral swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vaccination site swelling	0	2 (<0.1)	2 (<0.1)
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)	2 (<0.1)
Influenza like illness	0	1 (<0.1)	1 (<0.1)
Injection site haematoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site scab	0	1 (<0.1)	1 (<0.1)
Non-cardiac chest pain	0	1 (<0.1)	1 (<0.1)
Oedema peripheral	0	1 (<0.1)	1 (<0.1)
Vaccination site induration	0	1 (<0.1)	1 (<0.1)
Vaccination site pain	0	1 (<0.1)	1 (<0.1)
Vaccination site pruritus	0	1 (<0.1)	1 (<0.1)
Vaccination site rash	0	1 (<0.1)	1 (<0.1)
Asthenia	4 (<0.1)	0	4 (<0.1)
Chest pain	1 (<0.1)	0	1 (<0.1)
Discomfort	1 (<0.1)	0	1 (<0.1)
Feeling abnormal	1 (<0.1)	0	1 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Injection site mass	1 (<0.1)	0	1 (<0.1)
Injection site paraesthesia	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Investigations	5 (<0.1)	14 (<0.1)	19 (<0.1)
Blood pressure increased	3 (<0.1)	5 (<0.1)	8 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)	2 (<0.1)
Blood pressure systolic increased	0	2 (<0.1)	2 (<0.1)
Body temperature increased	0	2 (<0.1)	2 (<0.1)
Heart rate increased	0	2 (<0.1)	2 (<0.1)
Heart rate irregular	0	1 (<0.1)	1 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Blood glucose increased	1 (<0.1)	0	1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	6 (<0.1)	5 (<0.1)	11 (<0.1)
Contusion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injection related reaction	0	1 (<0.1)	1 (<0.1)
Procedural headache	0	1 (<0.1)	1 (<0.1)
Tooth fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vaccination complication	0	1 (<0.1)	1 (<0.1)
Fall	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14366) n (%)	mRNA-1273 (N=14316) n (%)	Total (N=28682) n (%)
Injury, poisoning and procedural complications (Cont.)			
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	0	2 (<0.1)	2 (<0.1)
Axillary lymphadenectomy	0	2 (<0.1)	2 (<0.1)
Uncoded	31 (0.2)	121 (0.8)	152 (0.5)
Uncoded	31 (0.2)	121 (0.8)	152 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011103.sas 20NOV2020 06:55

Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	14 (4.2)	16 (4.7)	30 (4.4)
Number of Unsolicited Adverse Events	28	19	47
Infections and infestations	0	1 (0.3)	1 (0.1)
Viral infection	0	1 (0.3)	1 (0.1)
Blood and lymphatic system disorders	2 (0.6)	0	2 (0.3)
Lymphadenopathy	2 (0.6)	0	2 (0.3)
Nervous system disorders	7 (2.1)	4 (1.2)	11 (1.6)
Headache	6 (1.8)	2 (0.6)	8 (1.2)
Ageusia	0	1 (0.3)	1 (0.1)
Dizziness	0	1 (0.3)	1 (0.1)
Migraine	1 (0.3)	0	1 (0.1)
Gastrointestinal disorders	2 (0.6)	1 (0.3)	3 (0.4)
Diarrhoea	0	1 (0.3)	1 (0.1)
Abdominal pain	1 (0.3)	0	1 (0.1)
Dyspepsia	1 (0.3)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Skin and subcutaneous tissue disorders	2 (0.6)	0	2 (0.3)
Rash	2 (0.6)	0	2 (0.3)
Musculoskeletal and connective tissue disorders	6 (1.8)	4 (1.2)	10 (1.5)
Myalgia	1 (0.3)	2 (0.6)	3 (0.4)
Limb discomfort	0	1 (0.3)	1 (0.1)
Pain in extremity	0	1 (0.3)	1 (0.1)
Arthralgia	1 (0.3)	0	1 (0.1)
Axillary mass	1 (0.3)	0	1 (0.1)
Back pain	1 (0.3)	0	1 (0.1)
Musculoskeletal pain	1 (0.3)	0	1 (0.1)
Musculoskeletal stiffness	1 (0.3)	0	1 (0.1)
Neck pain	1 (0.3)	0	1 (0.1)
General disorders and administration site conditions	5 (1.5)	7 (2.1)	12 (1.8)
Injection site induration	0	2 (0.6)	2 (0.3)
Injection site pain	0	2 (0.6)	2 (0.3)
Chest pain	0	1 (0.3)	1 (0.1)
Fatigue	4 (1.2)	1 (0.3)	5 (0.7)
Injection site erythema	0	1 (0.3)	1 (0.1)
Pyrexia	0	1 (0.3)	1 (0.1)
Chills	1 (0.3)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011103.sas 20NOV2020 06:55

Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=334) n (%)	mRNA-1273 (N=341) n (%)	Total (N=675) n (%)
Uncoded	2 (0.6)	1 (0.3)	3 (0.4)
Uncoded	2 (0.6)	1 (0.3)	3 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011103.sas 20NOV2020 06:55

Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	10 (2.2)	16 (3.0)	26 (2.6)
Number of Unsolicited Adverse Events	14	35	49
Blood and lymphatic system disorders	1 (0.2)	0	1 (0.1)
Lymphadenopathy	1 (0.2)	0	1 (0.1)
Nervous system disorders	5 (1.1)	5 (0.9)	10 (1.0)
Headache	5 (1.1)	4 (0.8)	9 (0.9)
Essential tremor	0	1 (0.2)	1 (0.1)
Respiratory, thoracic and mediastinal disorders	0	2 (0.4)	2 (0.2)
Oropharyngeal pain	0	2 (0.4)	2 (0.2)
Gastrointestinal disorders	1 (0.2)	1 (0.2)	2 (0.2)
Nausea	0	1 (0.2)	1 (0.1)
Diarrhoea	1 (0.2)	0	1 (0.1)
Skin and subcutaneous tissue disorders	0	1 (0.2)	1 (0.1)
Urticaria	0	1 (0.2)	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011103.sas 20NOV2020 06:55

Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Musculoskeletal and connective tissue disorders	1 (0.2)	2 (0.4)	3 (0.3)
Myalgia	0	2 (0.4)	2 (0.2)
Arthralgia	1 (0.2)	1 (0.2)	2 (0.2)
Muscular weakness	0	1 (0.2)	1 (0.1)
Reproductive system and breast disorders	0	1 (0.2)	1 (0.1)
Erectile dysfunction	0	1 (0.2)	1 (0.1)
General disorders and administration site conditions	5 (1.1)	10 (1.9)	15 (1.5)
Fatigue	2 (0.4)	5 (0.9)	7 (0.7)
Chills	0	2 (0.4)	2 (0.2)
Injection site pain	0	2 (0.4)	2 (0.2)
Adverse drug reaction	0	1 (0.2)	1 (0.1)
Injection site erythema	1 (0.2)	1 (0.2)	2 (0.2)
Injection site paraesthesia	0	1 (0.2)	1 (0.1)
Injection site pruritus	0	1 (0.2)	1 (0.1)
Pain	0	1 (0.2)	1 (0.1)
Pyrexia	1 (0.2)	1 (0.2)	2 (0.2)
Vaccination site lymphadenopathy	0	1 (0.2)	1 (0.1)
Injection site swelling	1 (0.2)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=465) n (%)	mRNA-1273 (N=527) n (%)	Total (N=993) n (%)
Uncoded	1 (0.2)	3 (0.6)	4 (0.4)
Uncoded	1 (0.2)	3 (0.6)	4 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	86 (0.6)	82 (0.5)	168 (0.6)
Number of Unsolicited Adverse Events	111	109	220
Infections and infestations	16 (0.1)	10 (<0.1)	26 (<0.1)
Pneumonia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cellulitis	0	1 (<0.1)	1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)	1 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Sepsis	0	1 (<0.1)	1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
COVID-19	3 (<0.1)	0	3 (<0.1)
Diverticulitis	1 (<0.1)	0	1 (<0.1)
Osteomyelitis	1 (<0.1)	0	1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0	1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0	1 (<0.1)
Septic shock	1 (<0.1)	0	1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Urinary tract infection	2 (<0.1)	0	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011301.sas 20NOV2020 06:55

Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (<0.1)	6 (<0.1)	10 (<0.1)
Prostate cancer	2 (<0.1)	2 (<0.1)	4 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Lung cancer metastatic	0	1 (<0.1)	1 (<0.1)
Malignant melanoma	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	0	1 (<0.1)	1 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dehydration	1 (<0.1)	2 (<0.1)	3 (<0.1)
Psychiatric disorders	6 (<0.1)	3 (<0.1)	9 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Alcohol abuse	1 (<0.1)	0	1 (<0.1)
Anxiety	1 (<0.1)	0	1 (<0.1)
Confusional state	1 (<0.1)	0	1 (<0.1)
Depression	2 (<0.1)	0	2 (<0.1)
Major depression	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Psychiatric disorders (Cont.)			
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	6 (<0.1)	7 (<0.1)	13 (<0.1)
Syncope	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cerebrovascular accident	0	1 (<0.1)	1 (<0.1)
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Seizure	0	1 (<0.1)	1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Migraine	1 (<0.1)	0	1 (<0.1)
Paraesthesia	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Eye disorders	1 (<0.1)	0	1 (<0.1)
Retinal detachment	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	11 (<0.1)	12 (<0.1)	23 (<0.1)
Atrial fibrillation	2 (<0.1)	3 (<0.1)	5 (<0.1)
Myocardial infarction	0	3 (<0.1)	3 (<0.1)
Cardiac failure congestive	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute myocardial infarction	1 (<0.1)	1 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Cardiac disorders (Cont.)			
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic left ventricular failure	0	1 (<0.1)	1 (<0.1)
Coronary artery disease	2 (<0.1)	1 (<0.1)	3 (<0.1)
Acute left ventricular failure	1 (<0.1)	0	1 (<0.1)
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Cardiac failure	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Tachycardia	1 (<0.1)	0	1 (<0.1)
Vascular disorders	8 (<0.1)	4 (<0.1)	12 (<0.1)
Hypertension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypotension	0	1 (<0.1)	1 (<0.1)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic aneurysm	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	2 (<0.1)	0	2 (<0.1)
Respiratory, thoracic and mediastinal disorders	11 (<0.1)	5 (<0.1)	16 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)	5 (<0.1)
Acute respiratory failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Dyspnoea	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011301.sas 20NOV2020 06:55

Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Chronic obstructive pulmonary disease	2 (<0.1)	0	2 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Pleural effusion	1 (<0.1)	0	1 (<0.1)
Pleuritic pain	1 (<0.1)	0	1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	6 (<0.1)	11 (<0.1)	17 (<0.1)
Colitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Nausea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abdominal pain upper	0	1 (<0.1)	1 (<0.1)
Diarrhoea	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Vomiting	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abdominal pain	2 (<0.1)	0	2 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Food poisoning	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)	3 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011301.sas 20NOV2020 06:55

Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Hepatobiliary disorders (Cont.)			
Cholecystitis	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	0	2 (<0.1)
Angioedema	1 (<0.1)	0	1 (<0.1)
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	4 (<0.1)	8 (<0.1)	12 (<0.1)
Arthritis	0	1 (<0.1)	1 (<0.1)
Back pain	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	0	1 (<0.1)	1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle spasms	0	1 (<0.1)	1 (<0.1)
Musculoskeletal chest pain	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spinal stenosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteoarthritis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	1 (<0.1)	4 (<0.1)	5 (<0.1)
Nephrolithiasis	0	4 (<0.1)	4 (<0.1)
Acute kidney injury	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011301.sas 20NOV2020 06:55

Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Reproductive system and breast disorders	0	2 (<0.1)	2 (<0.1)
Ovarian cyst	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
General disorders and administration site conditions	6 (<0.1)	5 (<0.1)	11 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chest pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oedema peripheral	0	1 (<0.1)	1 (<0.1)
Feeling hot	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Precancerous condition	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	8 (<0.1)	8 (<0.1)	16 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Road traffic accident	0	2 (<0.1)	2 (<0.1)
Back injury	0	1 (<0.1)	1 (<0.1)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Facial bones fracture	0	1 (<0.1)	1 (<0.1)
Fall	0	1 (<0.1)	1 (<0.1)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Skin laceration	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Tendon rupture	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Abdominal injury	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Joint injury	1 (<0.1)	0	1 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Rib fracture	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	2 (<0.1)	3 (<0.1)	5 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Transurethral prostatectomy	0	1 (<0.1)	1 (<0.1)
Hip arthroplasty	1 (<0.1)	0	1 (<0.1)
Umbilical hernia repair	1 (<0.1)	0	1 (<0.1)
Social circumstances	1 (<0.1)	0	1 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	1 (<0.1)	0	1 (<0.1)
Lead dislodgement	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.13.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Uncoded	6 (<0.1)	4 (<0.1)	10 (<0.1)
Uncoded	6 (<0.1)	4 (<0.1)	10 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.18.1
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	29 (0.2)	70 (0.5)	99 (0.3)
Number of Unsolicited Adverse Events	32	84	116
Blood and lymphatic system disorders	0	2 (<0.1)	2 (<0.1)
Lymphadenopathy	0	2 (<0.1)	2 (<0.1)
Immune system disorders	0	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Nervous system disorders	10 (<0.1)	12 (<0.1)	22 (<0.1)
Headache	8 (<0.1)	9 (<0.1)	17 (<0.1)
Dizziness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Syncope	0	1 (<0.1)	1 (<0.1)
Migraine	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	0	1 (<0.1)	1 (<0.1)
Vertigo	0	1 (<0.1)	1 (<0.1)
Vascular disorders	9 (<0.1)	3 (<0.1)	12 (<0.1)
Hypertension	9 (<0.1)	3 (<0.1)	12 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011801.sas 20NOV2020 06:56

Table 14.3.1.18.1
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders	0	1 (<0.1)	1 (<0.1)
Nausea	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)	2 (<0.1)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Rash	0	1 (<0.1)	1 (<0.1)
Musculoskeletal and connective tissue disorders	4 (<0.1)	11 (<0.1)	15 (<0.1)
Myalgia	0	7 (<0.1)	7 (<0.1)
Arthralgia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Muscle spasms	0	1 (<0.1)	1 (<0.1)
Neck pain	0	1 (<0.1)	1 (<0.1)
Pain in extremity	0	1 (<0.1)	1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)	1 (<0.1)
Back pain	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	6 (<0.1)	31 (0.2)	37 (0.1)
Injection site erythema	0	11 (<0.1)	11 (<0.1)
Fatigue	3 (<0.1)	9 (<0.1)	12 (<0.1)
Injection site swelling	0	4 (<0.1)	4 (<0.1)
Chills	0	2 (<0.1)	2 (<0.1)
Injection site pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011801.sas 20NOV2020 06:56

Table 14.3.1.18.1
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
General disorders and administration site conditions (Cont.)			
Chest discomfort	0	1 (<0.1)	1 (<0.1)
Injection site induration	0	1 (<0.1)	1 (<0.1)
Malaise	0	1 (<0.1)	1 (<0.1)
Pyrexia	0	1 (<0.1)	1 (<0.1)
Swelling face	0	1 (<0.1)	1 (<0.1)
Asthenia	1 (<0.1)	0	1 (<0.1)
Swelling	1 (<0.1)	0	1 (<0.1)
Investigations	2 (<0.1)	6 (<0.1)	8 (<0.1)
Blood pressure increased	2 (<0.1)	5 (<0.1)	7 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)	1 (<0.1)
Uncoded	0	7 (<0.1)	7 (<0.1)
Uncoded	0	7 (<0.1)	7 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1529 (10.1)	1414 (9.3)	2943 (9.7)
Number of Unsolicited Adverse Events	2330	2268	4598
Infections and infestations	588 (3.9)	435 (2.9)	1023 (3.4)
Urinary tract infection	89 (0.6)	68 (0.4)	157 (0.5)
Sinusitis	33 (0.2)	43 (0.3)	76 (0.3)
Upper respiratory tract infection	44 (0.3)	36 (0.2)	80 (0.3)
COVID-19	147 (1.0)	22 (0.1)	169 (0.6)
Herpes zoster	12 (<0.1)	16 (0.1)	28 (<0.1)
Pharyngitis streptococcal	18 (0.1)	14 (<0.1)	32 (0.1)
Tooth infection	11 (<0.1)	14 (<0.1)	25 (<0.1)
Tooth abscess	17 (0.1)	13 (<0.1)	30 (<0.1)
Viral infection	22 (0.1)	12 (<0.1)	34 (0.1)
Ear infection	9 (<0.1)	11 (<0.1)	20 (<0.1)
Cellulitis	9 (<0.1)	9 (<0.1)	18 (<0.1)
Pharyngitis	12 (<0.1)	8 (<0.1)	20 (<0.1)
Rhinovirus infection	4 (<0.1)	8 (<0.1)	12 (<0.1)
Conjunctivitis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Diverticulitis	8 (<0.1)	7 (<0.1)	15 (<0.1)
Gastroenteritis	6 (<0.1)	7 (<0.1)	13 (<0.1)
Bronchitis	9 (<0.1)	6 (<0.1)	15 (<0.1)
Hordeolum	7 (<0.1)	6 (<0.1)	13 (<0.1)
Localised infection	7 (<0.1)	6 (<0.1)	13 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011903.sas 20NOV2020 06:56

Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Paronychia	2 (<0.1)	6 (<0.1)	8 (<0.1)
Pneumonia	10 (<0.1)	6 (<0.1)	16 (<0.1)
Acute sinusitis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Otitis media	6 (<0.1)	5 (<0.1)	11 (<0.1)
Gingivitis	5 (<0.1)	4 (<0.1)	9 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Bacterial vaginosis	4 (<0.1)	3 (<0.1)	7 (<0.1)
Enterovirus infection	0	3 (<0.1)	3 (<0.1)
Folliculitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Fungal infection	6 (<0.1)	3 (<0.1)	9 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Herpes simplex	0	3 (<0.1)	3 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Lyme disease	0	3 (<0.1)	3 (<0.1)
Rhinitis	4 (<0.1)	3 (<0.1)	7 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Subcutaneous abscess	0	3 (<0.1)	3 (<0.1)
Vulvovaginal candidiasis	0	3 (<0.1)	3 (<0.1)
Appendicitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	0	2 (<0.1)	2 (<0.1)
Clostridium difficile colitis	0	2 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011903.sas 20NOV2020 06:56

Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Cystitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Impetigo	0	2 (<0.1)	2 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Onychomycosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Otitis externa	8 (<0.1)	2 (<0.1)	10 (<0.1)
Otitis media acute	3 (<0.1)	2 (<0.1)	5 (<0.1)
Postoperative wound infection	0	2 (<0.1)	2 (<0.1)
Respiratory tract infection	5 (<0.1)	2 (<0.1)	7 (<0.1)
Sinusitis bacterial	2 (<0.1)	2 (<0.1)	4 (<0.1)
Skin infection	3 (<0.1)	2 (<0.1)	5 (<0.1)
Staphylococcal skin infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tonsillitis	5 (<0.1)	2 (<0.1)	7 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)	2 (<0.1)
Viral upper respiratory tract infection	6 (<0.1)	2 (<0.1)	8 (<0.1)
Body tinea	0	1 (<0.1)	1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Candida infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cat scratch disease	0	1 (<0.1)	1 (<0.1)
Catheter site infection	0	1 (<0.1)	1 (<0.1)
Colonic abscess	0	1 (<0.1)	1 (<0.1)
Coronavirus infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011903.sas 20NOV2020 06:56

Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Furuncle	0	1 (<0.1)	1 (<0.1)
Gastroenteritis viral	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastrointestinal infection	0	1 (<0.1)	1 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected bite	0	1 (<0.1)	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Joint abscess	0	1 (<0.1)	1 (<0.1)
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Laryngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasopharyngitis	5 (<0.1)	1 (<0.1)	6 (<0.1)
Oral candidiasis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Oral herpes	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Papilloma viral infection	0	1 (<0.1)	1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)
Parotitis	0	1 (<0.1)	1 (<0.1)
Periodontitis	0	1 (<0.1)	1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Postoperative abscess	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Pyelonephritis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Respiratory tract infection viral	5 (<0.1)	1 (<0.1)	6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Streptococcal infection	0	1 (<0.1)	1 (<0.1)
Tinea infection	0	1 (<0.1)	1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Viral rhinitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	0	1 (<0.1)	1 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Denture stomatitis	1 (<0.1)	0	1 (<0.1)
Epididymitis	1 (<0.1)	0	1 (<0.1)
Eye infection	3 (<0.1)	0	3 (<0.1)
Eye infection bacterial	1 (<0.1)	0	1 (<0.1)
Fungal skin infection	1 (<0.1)	0	1 (<0.1)
Gardnerella infection	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Infections and infestations (Cont.)			
Genital herpes	1 (<0.1)	0	1 (<0.1)
Influenza	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Perirectal abscess	1 (<0.1)	0	1 (<0.1)
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Suspected COVID-19	2 (<0.1)	0	2 (<0.1)
Syphilis	1 (<0.1)	0	1 (<0.1)
Tinea pedis	2 (<0.1)	0	2 (<0.1)
Tinea versicolour	1 (<0.1)	0	1 (<0.1)
Viral sinusitis	1 (<0.1)	0	1 (<0.1)
Vulvovaginal mycotic infection	7 (<0.1)	0	7 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	34 (0.2)	35 (0.2)	69 (0.2)
Basal cell carcinoma	11 (<0.1)	5 (<0.1)	16 (<0.1)
Malignant melanoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Squamous cell carcinoma	6 (<0.1)	3 (<0.1)	9 (<0.1)
Melanocytic naevus	0	2 (<0.1)	2 (<0.1)
Prostate cancer	4 (<0.1)	2 (<0.1)	6 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Benign neoplasm of thyroid gland	0	1 (<0.1)	1 (<0.1)
Breast neoplasm	0	1 (<0.1)	1 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Gastric cancer	0	1 (<0.1)	1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lung cancer metastatic	0	1 (<0.1)	1 (<0.1)
Meningioma	0	1 (<0.1)	1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Neoplasm malignant	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	1 (<0.1)	3 (<0.1)
Thyroid cancer	0	1 (<0.1)	1 (<0.1)
Uterine leiomyoma	0	1 (<0.1)	1 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Chondromatosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Colon cancer stage III	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Skin cancer	2 (<0.1)	0	2 (<0.1)
Blood and lymphatic system disorders	14 (<0.1)	25 (0.2)	39 (0.1)
Lymphadenopathy	8 (<0.1)	15 (<0.1)	23 (<0.1)
Anaemia	1 (<0.1)	4 (<0.1)	5 (<0.1)
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Lymphadenitis	1 (<0.1)	0	1 (<0.1)
Immune system disorders	10 (<0.1)	6 (<0.1)	16 (<0.1)
Seasonal allergy	5 (<0.1)	4 (<0.1)	9 (<0.1)
Drug hypersensitivity	0	1 (<0.1)	1 (<0.1)
Hypersensitivity	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Food allergy	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Endocrine disorders	4 (<0.1)	6 (<0.1)	10 (<0.1)
Hypothyroidism	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Thyroid mass	0	1 (<0.1)	1 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Hypogonadism	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	57 (0.4)	47 (0.3)	104 (0.3)
Type 2 diabetes mellitus	1 (<0.1)	9 (<0.1)	10 (<0.1)
Hyperlipidaemia	9 (<0.1)	8 (<0.1)	17 (<0.1)
Hypercholesterolaemia	12 (<0.1)	6 (<0.1)	18 (<0.1)
Vitamin D deficiency	1 (<0.1)	5 (<0.1)	6 (<0.1)
Dehydration	8 (<0.1)	3 (<0.1)	11 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Decreased appetite	3 (<0.1)	2 (<0.1)	5 (<0.1)
Gout	7 (<0.1)	2 (<0.1)	9 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hypertriglyceridaemia	0	2 (<0.1)	2 (<0.1)
Insulin resistance	0	2 (<0.1)	2 (<0.1)
Abnormal loss of weight	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetes mellitus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)	1 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Metabolism and nutrition disorders (Cont.)			
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypophosphataemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Dyslipidaemia	2 (<0.1)	0	2 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Glucose tolerance impaired	3 (<0.1)	0	3 (<0.1)
Hypocalcaemia	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	1 (<0.1)	0	1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	53 (0.3)	52 (0.3)	105 (0.3)
Anxiety	17 (0.1)	20 (0.1)	37 (0.1)
Depression	13 (<0.1)	20 (0.1)	33 (0.1)
Attention deficit hyperactivity disorder	6 (<0.1)	5 (<0.1)	11 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bipolar disorder	3 (<0.1)	1 (<0.1)	4 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Insomnia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Intentional self-injury	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Psychiatric disorders (Cont.)			
Major depression	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post-traumatic stress disorder	0	1 (<0.1)	1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)	1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	0	1 (<0.1)
Confusional state	2 (<0.1)	0	2 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Generalised anxiety disorder	2 (<0.1)	0	2 (<0.1)
Mental status changes	2 (<0.1)	0	2 (<0.1)
Nicotine dependence	1 (<0.1)	0	1 (<0.1)
Panic attack	2 (<0.1)	0	2 (<0.1)
Persistent depressive disorder	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Stress	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	124 (0.8)	123 (0.8)	247 (0.8)
Headache	69 (0.5)	67 (0.4)	136 (0.4)
Anosmia	4 (<0.1)	6 (<0.1)	10 (<0.1)
Sciatica	3 (<0.1)	6 (<0.1)	9 (<0.1)
Dizziness	8 (<0.1)	5 (<0.1)	13 (<0.1)
Migraine	5 (<0.1)	5 (<0.1)	10 (<0.1)
Paraesthesia	5 (<0.1)	4 (<0.1)	9 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	3 (<0.1)	5 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Nervous system disorders (Cont.)			
Cervical radiculopathy	0	3 (<0.1)	3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Syncope	10 (<0.1)	3 (<0.1)	13 (<0.1)
Ageusia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Cerebrovascular accident	1 (<0.1)	2 (<0.1)	3 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Presyncope	4 (<0.1)	2 (<0.1)	6 (<0.1)
Transient ischaemic attack	0	2 (<0.1)	2 (<0.1)
Amnesia	0	1 (<0.1)	1 (<0.1)
Balance disorder	0	1 (<0.1)	1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Hyperaesthesia	0	1 (<0.1)	1 (<0.1)
Hyposmia	0	1 (<0.1)	1 (<0.1)
Lethargy	0	1 (<0.1)	1 (<0.1)
Lumbar radiculopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Memory impairment	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Neuralgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)	1 (<0.1)
Sinus headache	1 (<0.1)	1 (<0.1)	2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Nervous system disorders (Cont.)			
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Head discomfort	1 (<0.1)	0	1 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)
Hypoaesthesia	2 (<0.1)	0	2 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Nerve compression	1 (<0.1)	0	1 (<0.1)
Restless legs syndrome	1 (<0.1)	0	1 (<0.1)
Shift work disorder	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Tension headache	1 (<0.1)	0	1 (<0.1)
Eye disorders	21 (0.1)	20 (0.1)	41 (0.1)
Dry eye	2 (<0.1)	2 (<0.1)	4 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Blepharitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cataract	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Eye discharge	0	1 (<0.1)	1 (<0.1)
Eye irritation	0	1 (<0.1)	1 (<0.1)
Eye pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye pruritus	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Eye disorders (Cont.)			
Eyelid cyst	0	1 (<0.1)	1 (<0.1)
Glaucoma	0	1 (<0.1)	1 (<0.1)
Keratitis	0	1 (<0.1)	1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Ocular hyperaemia	0	1 (<0.1)	1 (<0.1)
Vision blurred	0	1 (<0.1)	1 (<0.1)
Vitreous disorder	0	1 (<0.1)	1 (<0.1)
Vitreous floaters	2 (<0.1)	1 (<0.1)	3 (<0.1)
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Eye swelling	1 (<0.1)	0	1 (<0.1)
Eye ulcer	1 (<0.1)	0	1 (<0.1)
Eyelid ptosis	1 (<0.1)	0	1 (<0.1)
Lacrimation increased	1 (<0.1)	0	1 (<0.1)
Macular degeneration	1 (<0.1)	0	1 (<0.1)
Macular hole	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Retinal tear	1 (<0.1)	0	1 (<0.1)
Swelling of eyelid	1 (<0.1)	0	1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Ear and labyrinth disorders	21 (0.1)	17 (0.1)	38 (0.1)
Vertigo positional	0	5 (<0.1)	5 (<0.1)
Vertigo	3 (<0.1)	4 (<0.1)	7 (<0.1)
Ear pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cerumen impaction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Deafness neurosensory	0	1 (<0.1)	1 (<0.1)
Ear canal erythema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Middle ear effusion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Motion sickness	0	1 (<0.1)	1 (<0.1)
Tinnitus	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ear congestion	2 (<0.1)	0	2 (<0.1)
Ear discomfort	1 (<0.1)	0	1 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	0	1 (<0.1)
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Otorrhoea	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	3 (<0.1)	0	3 (<0.1)
Cardiac disorders	37 (0.2)	40 (0.3)	77 (0.3)
Atrial fibrillation	7 (<0.1)	9 (<0.1)	16 (<0.1)
Coronary artery disease	4 (<0.1)	6 (<0.1)	10 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Palpitations	2 (<0.1)	4 (<0.1)	6 (<0.1)
Tachycardia	5 (<0.1)	4 (<0.1)	9 (<0.1)
Angina pectoris	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cardiac failure congestive	2 (<0.1)	3 (<0.1)	5 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Cardiac disorders (Cont.)			
Sinus tachycardia	0	3 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute myocardial infarction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cardiac failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic left ventricular failure	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	0	1 (<0.1)	1 (<0.1)
Tachyarrhythmia	0	1 (<0.1)	1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0	1 (<0.1)
Arrhythmia	4 (<0.1)	0	4 (<0.1)
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Atrial tachycardia	1 (<0.1)	0	1 (<0.1)
Bradycardia	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Pericarditis	1 (<0.1)	0	1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	81 (0.5)	77 (0.5)	158 (0.5)
Hypertension	63 (0.4)	64 (0.4)	127 (0.4)
Hypertensive urgency	2 (<0.1)	2 (<0.1)	4 (<0.1)
Orthostatic hypotension	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Vascular disorders (Cont.)			
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Deep vein thrombosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Flushing	0	1 (<0.1)	1 (<0.1)
Haematoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hot flush	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypotension	0	1 (<0.1)	1 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)	1 (<0.1)
Systolic hypertension	0	1 (<0.1)	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	2 (<0.1)	0	2 (<0.1)
Ischaemia	1 (<0.1)	0	1 (<0.1)
Lymphoedema	1 (<0.1)	0	1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0	1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	176 (1.2)	149 (1.0)	325 (1.1)
Cough	69 (0.5)	61 (0.4)	130 (0.4)
Nasal congestion	43 (0.3)	57 (0.4)	100 (0.3)
Rhinorrhoea	41 (0.3)	51 (0.3)	92 (0.3)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Oropharyngeal pain	54 (0.4)	42 (0.3)	96 (0.3)
Dyspnoea	22 (0.1)	21 (0.1)	43 (0.1)
Asthma	6 (<0.1)	5 (<0.1)	11 (<0.1)
Chronic obstructive pulmonary disease	5 (<0.1)	5 (<0.1)	10 (<0.1)
Respiratory tract congestion	4 (<0.1)	4 (<0.1)	8 (<0.1)
Sinus congestion	9 (<0.1)	4 (<0.1)	13 (<0.1)
Upper-airway cough syndrome	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pulmonary embolism	4 (<0.1)	3 (<0.1)	7 (<0.1)
Dyspnoea exertional	0	2 (<0.1)	2 (<0.1)
Rhinitis allergic	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sinus pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sneezing	2 (<0.1)	2 (<0.1)	4 (<0.1)
Throat irritation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wheezing	2 (<0.1)	2 (<0.1)	4 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Dysphonia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Emphysema	0	1 (<0.1)	1 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)	1 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Productive cough	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Respiratory disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tonsillolith	1 (<0.1)	1 (<0.1)	2 (<0.1)
Acute respiratory failure	2 (<0.1)	0	2 (<0.1)
Dry throat	1 (<0.1)	0	1 (<0.1)
Epistaxis	2 (<0.1)	0	2 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0	1 (<0.1)
Pharyngeal erythema	1 (<0.1)	0	1 (<0.1)
Pleural effusion	1 (<0.1)	0	1 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Respiratory failure	1 (<0.1)	0	1 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	130 (0.9)	143 (0.9)	273 (0.9)
Nausea	28 (0.2)	36 (0.2)	64 (0.2)
Diarrhoea	31 (0.2)	35 (0.2)	66 (0.2)
Gastrooesophageal reflux disease	5 (<0.1)	16 (0.1)	21 (<0.1)
Vomiting	7 (<0.1)	12 (<0.1)	19 (<0.1)
Toothache	9 (<0.1)	11 (<0.1)	20 (<0.1)
Abdominal pain upper	2 (<0.1)	7 (<0.1)	9 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders (Cont.)			
Abdominal pain	9 (<0.1)	5 (<0.1)	14 (<0.1)
Colitis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Constipation	3 (<0.1)	5 (<0.1)	8 (<0.1)
Dental caries	6 (<0.1)	4 (<0.1)	10 (<0.1)
Abdominal pain lower	2 (<0.1)	3 (<0.1)	5 (<0.1)
Haematochezia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Food poisoning	3 (<0.1)	2 (<0.1)	5 (<0.1)
Gastric ulcer	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hiatus hernia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Abdominal discomfort	3 (<0.1)	1 (<0.1)	4 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)
Diverticular perforation	0	1 (<0.1)	1 (<0.1)
Diverticulum	1 (<0.1)	1 (<0.1)	2 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Faeces soft	0	1 (<0.1)	1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	1 (<0.1)
Hyperchlorhydria	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders (Cont.)			
Irritable bowel syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Mouth ulceration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Oesophageal ulcer	0	1 (<0.1)	1 (<0.1)
Oesophagitis	0	1 (<0.1)	1 (<0.1)
Oral mucosal blistering	0	1 (<0.1)	1 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Paraesthesia oral	0	1 (<0.1)	1 (<0.1)
Proctalgia	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Salivary hypersecretion	0	1 (<0.1)	1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tooth impacted	1 (<0.1)	1 (<0.1)	2 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Aphthous ulcer	1 (<0.1)	0	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Dyspepsia	2 (<0.1)	0	2 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Gastrointestinal disorders (Cont.)			
Flatulence	1 (<0.1)	0	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	1 (<0.1)	0	1 (<0.1)
Large intestine polyp	3 (<0.1)	0	3 (<0.1)
Lip swelling	1 (<0.1)	0	1 (<0.1)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Oral pain	1 (<0.1)	0	1 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	11 (<0.1)	11 (<0.1)
Cholelithiasis	0	6 (<0.1)	6 (<0.1)
Cholecystitis	0	2 (<0.1)	2 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	66 (0.4)	65 (0.4)	131 (0.4)
Dermatitis contact	11 (<0.1)	10 (<0.1)	21 (<0.1)
Rash	11 (<0.1)	10 (<0.1)	21 (<0.1)
Acne	2 (<0.1)	5 (<0.1)	7 (<0.1)
Pruritus	4 (<0.1)	5 (<0.1)	9 (<0.1)
Dermatitis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Urticaria	1 (<0.1)	4 (<0.1)	5 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Skin lesion	3 (<0.1)	3 (<0.1)	6 (<0.1)
Actinic keratosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Blister	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dermatitis atopic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Pityriasis rosea	0	2 (<0.1)	2 (<0.1)
Rosacea	2 (<0.1)	2 (<0.1)	4 (<0.1)
Alopecia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dermal cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dermatitis allergic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Erythema	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hand dermatitis	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	1 (<0.1)	1 (<0.1)
Hyperhidrosis	0	1 (<0.1)	1 (<0.1)
Ingrowing nail	0	1 (<0.1)	1 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Nail disorder	0	1 (<0.1)	1 (<0.1)
Rash erythematous	0	1 (<0.1)	1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urticaria papular	2 (<0.1)	1 (<0.1)	3 (<0.1)
Angioedema	3 (<0.1)	0	3 (<0.1)
Cold sweat	1 (<0.1)	0	1 (<0.1)
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)
Dry skin	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Ecchymosis	3 (<0.1)	0	3 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Ingrown hair	1 (<0.1)	0	1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Livedo reticularis	1 (<0.1)	0	1 (<0.1)
Night sweats	1 (<0.1)	0	1 (<0.1)
Onychoclasia	1 (<0.1)	0	1 (<0.1)
Psoriasis	1 (<0.1)	0	1 (<0.1)
Scab	1 (<0.1)	0	1 (<0.1)
Seborrheic dermatitis	1 (<0.1)	0	1 (<0.1)
Skin mass	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	147 (1.0)	176 (1.2)	323 (1.1)
Arthralgia	25 (0.2)	29 (0.2)	54 (0.2)
Myalgia	29 (0.2)	24 (0.2)	53 (0.2)
Back pain	23 (0.2)	22 (0.1)	45 (0.1)
Musculoskeletal pain	4 (<0.1)	13 (<0.1)	17 (<0.1)
Neck pain	2 (<0.1)	13 (<0.1)	15 (<0.1)
Muscle spasms	7 (<0.1)	10 (<0.1)	17 (<0.1)
Pain in extremity	12 (<0.1)	10 (<0.1)	22 (<0.1)
Tendonitis	7 (<0.1)	9 (<0.1)	16 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	5 (<0.1)	8 (<0.1)
Osteoarthritis	10 (<0.1)	5 (<0.1)	15 (<0.1)
Arthritis	1 (<0.1)	4 (<0.1)	5 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Bursitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Musculoskeletal chest pain	5 (<0.1)	4 (<0.1)	9 (<0.1)
Rotator cuff syndrome	4 (<0.1)	4 (<0.1)	8 (<0.1)
Joint swelling	0	3 (<0.1)	3 (<0.1)
Musculoskeletal stiffness	0	3 (<0.1)	3 (<0.1)
Exostosis	0	2 (<0.1)	2 (<0.1)
Flank pain	0	2 (<0.1)	2 (<0.1)
Muscular weakness	0	2 (<0.1)	2 (<0.1)
Neck mass	0	2 (<0.1)	2 (<0.1)
Osteoporosis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Trigger finger	0	2 (<0.1)	2 (<0.1)
Bone pain	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	0	1 (<0.1)	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	1 (<0.1)
Fibromyalgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Floating patella	0	1 (<0.1)	1 (<0.1)
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Groin pain	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint range of motion decreased	0	1 (<0.1)	1 (<0.1)
Joint stiffness	0	1 (<0.1)	1 (<0.1)
Limb discomfort	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Muscle tightness	0	1 (<0.1)	1 (<0.1)
Muscle twitching	0	1 (<0.1)	1 (<0.1)
Osteopenia	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Plantar fasciitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spinal osteoarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Axillary mass	1 (<0.1)	0	1 (<0.1)
Costochondritis	3 (<0.1)	0	3 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Intervertebral disc disorder	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteitis	1 (<0.1)	0	1 (<0.1)
Pain in jaw	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Synovial cyst	1 (<0.1)	0	1 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	33 (0.2)	30 (0.2)	63 (0.2)
Nephrolithiasis	19 (0.1)	15 (<0.1)	34 (0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Renal and urinary disorders (Cont.)			
Chronic kidney disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dysuria	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute kidney injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
Haematuria	5 (<0.1)	1 (<0.1)	6 (<0.1)
Hydronephrosis	0	1 (<0.1)	1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)
Renal mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal pain	0	1 (<0.1)	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Micturition urgency	1 (<0.1)	0	1 (<0.1)
Pollakiuria	1 (<0.1)	0	1 (<0.1)
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Urinary incontinence	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)	1 (<0.1)
Abortion spontaneous	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	19 (0.1)	23 (0.2)	42 (0.1)
Pelvic pain	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Reproductive system and breast disorders (Cont.)			
Dysmenorrhoea	0	2 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Benign prostatic hyperplasia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Breast cyst	0	1 (<0.1)	1 (<0.1)
Breast disorder	0	1 (<0.1)	1 (<0.1)
Breast mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast pain	0	1 (<0.1)	1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Erectile dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopausal symptoms	0	1 (<0.1)	1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)	1 (<0.1)
Ovarian cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Prostatitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
Uterine polyp	0	1 (<0.1)	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Amenorrhoea	1 (<0.1)	0	1 (<0.1)
Bartholin's cyst	1 (<0.1)	0	1 (<0.1)
Cystocele	1 (<0.1)	0	1 (<0.1)
Endometriosis	1 (<0.1)	0	1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Reproductive system and breast disorders (Cont.)			
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	1 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	121 (0.8)	114 (0.8)	235 (0.8)
Fatigue	63 (0.4)	46 (0.3)	109 (0.4)
Pain	19 (0.1)	22 (0.1)	41 (0.1)
Chills	17 (0.1)	18 (0.1)	35 (0.1)
Pyrexia	20 (0.1)	15 (<0.1)	35 (0.1)
Injection site erythema	0	9 (<0.1)	9 (<0.1)
Injection site pain	3 (<0.1)	8 (<0.1)	11 (<0.1)
Injection site induration	0	6 (<0.1)	6 (<0.1)
Chest discomfort	6 (<0.1)	5 (<0.1)	11 (<0.1)
Injection site rash	0	4 (<0.1)	4 (<0.1)
Chest pain	5 (<0.1)	3 (<0.1)	8 (<0.1)
Injection site swelling	0	3 (<0.1)	3 (<0.1)
Non-cardiac chest pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Swelling face	1 (<0.1)	3 (<0.1)	4 (<0.1)
Oedema peripheral	4 (<0.1)	2 (<0.1)	6 (<0.1)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
General disorders and administration site conditions (Cont.)			
Axillary pain	0	1 (<0.1)	1 (<0.1)
Crying	0	1 (<0.1)	1 (<0.1)
Cyst	3 (<0.1)	1 (<0.1)	4 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)	2 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Induration	0	1 (<0.1)	1 (<0.1)
Inflammation	0	1 (<0.1)	1 (<0.1)
Injection site pruritus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site warmth	0	1 (<0.1)	1 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Malaise	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Peripheral swelling	4 (<0.1)	1 (<0.1)	5 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Asthenia	2 (<0.1)	0	2 (<0.1)
Facial pain	1 (<0.1)	0	1 (<0.1)
Gait disturbance	1 (<0.1)	0	1 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site bruising	1 (<0.1)	0	1 (<0.1)
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Precancerous condition	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Investigations	27 (0.2)	30 (0.2)	57 (0.2)
Blood pressure increased	5 (<0.1)	4 (<0.1)	9 (<0.1)
Hepatic enzyme increased	0	3 (<0.1)	3 (<0.1)
Blood pressure systolic increased	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)	2 (<0.1)
Transaminases increased	0	2 (<0.1)	2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Blood cholesterol increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood glucose decreased	0	1 (<0.1)	1 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood triglycerides increased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)	2 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Hepatitis B antibody positive	0	1 (<0.1)	1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	0	1 (<0.1)	1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Vitamin K	0	1 (<0.1)	1 (<0.1)
White blood cell count increased	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Investigations (Cont.)			
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)
Biopsy skin	1 (<0.1)	0	1 (<0.1)
Blood glucose increased	1 (<0.1)	0	1 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood potassium decreased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
Colonoscopy	1 (<0.1)	0	1 (<0.1)
Heart rate increased	1 (<0.1)	0	1 (<0.1)
Lipase increased	1 (<0.1)	0	1 (<0.1)
Mammogram abnormal	1 (<0.1)	0	1 (<0.1)
SARS-CoV-2 test positive	5 (<0.1)	0	5 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0	1 (<0.1)
Vitamin D decreased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	162 (1.1)	157 (1.0)	319 (1.1)
Skin laceration	26 (0.2)	17 (0.1)	43 (0.1)
Ligament sprain	7 (<0.1)	15 (<0.1)	22 (<0.1)
Muscle strain	10 (<0.1)	13 (<0.1)	23 (<0.1)
Arthropod bite	6 (<0.1)	9 (<0.1)	15 (<0.1)
Foot fracture	7 (<0.1)	8 (<0.1)	15 (<0.1)
Limb injury	4 (<0.1)	8 (<0.1)	12 (<0.1)
Procedural pain	8 (<0.1)	7 (<0.1)	15 (<0.1)
Tooth fracture	8 (<0.1)	7 (<0.1)	15 (<0.1)
Concussion	3 (<0.1)	6 (<0.1)	9 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Fall	6 (<0.1)	6 (<0.1)	12 (<0.1)
Meniscus injury	3 (<0.1)	6 (<0.1)	9 (<0.1)
Hand fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Animal bite	6 (<0.1)	3 (<0.1)	9 (<0.1)
Arthropod sting	4 (<0.1)	3 (<0.1)	7 (<0.1)
Contusion	8 (<0.1)	3 (<0.1)	11 (<0.1)
Head injury	1 (<0.1)	3 (<0.1)	4 (<0.1)
Joint injury	2 (<0.1)	3 (<0.1)	5 (<0.1)
Rib fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Cartilage injury	0	2 (<0.1)	2 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Clavicle fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Epicondylitis	0	2 (<0.1)	2 (<0.1)
Facial bones fracture	0	2 (<0.1)	2 (<0.1)
Humerus fracture	0	2 (<0.1)	2 (<0.1)
Ligament rupture	0	2 (<0.1)	2 (<0.1)
Muscle rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<0.1)
Ankle fracture	4 (<0.1)	1 (<0.1)	5 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Back injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bone fragmentation	0	1 (<0.1)	1 (<0.1)
Burns first degree	0	1 (<0.1)	1 (<0.1)
Burns second degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)	1 (<0.1)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)	1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	0	1 (<0.1)	1 (<0.1)
Ligament injury	0	1 (<0.1)	1 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Nasal injury	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Procedural nausea	0	1 (<0.1)	1 (<0.1)
Road traffic accident	2 (<0.1)	1 (<0.1)	3 (<0.1)
Scar	0	1 (<0.1)	1 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Tendon injury	0	1 (<0.1)	1 (<0.1)
Thermal burn	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thoracic vertebral fracture	0	1 (<0.1)	1 (<0.1)
Tooth injury	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Abdominal injury	1 (<0.1)	0	1 (<0.1)
Bone contusion	1 (<0.1)	0	1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0	1 (<0.1)
Eye injury	1 (<0.1)	0	1 (<0.1)
Foreign body	3 (<0.1)	0	3 (<0.1)
Foreign body in ear	1 (<0.1)	0	1 (<0.1)
Fracture	1 (<0.1)	0	1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Injection related reaction	1 (<0.1)	0	1 (<0.1)
Lip injury	1 (<0.1)	0	1 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post-traumatic pain	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0	1 (<0.1)
Scratch	1 (<0.1)	0	1 (<0.1)
Skin abrasion	5 (<0.1)	0	5 (<0.1)
Stress fracture	3 (<0.1)	0	3 (<0.1)
Superficial injury of eye	2 (<0.1)	0	2 (<0.1)
Tibia fracture	1 (<0.1)	0	1 (<0.1)
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Wound	2 (<0.1)	0	2 (<0.1)
Surgical and medical procedures	12 (<0.1)	16 (0.1)	28 (<0.1)
Endodontic procedure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Thyroidectomy	0	2 (<0.1)	2 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curetting of chalazion	0	1 (<0.1)	1 (<0.1)
Cyst removal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dental operation	0	1 (<0.1)	1 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lipoma excision	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Surgical and medical procedures (Cont.)			
Phlebectomy	0	1 (<0.1)	1 (<0.1)
Skin cyst excision	0	1 (<0.1)	1 (<0.1)
Skin neoplasm excision	0	1 (<0.1)	1 (<0.1)
Spinal fusion surgery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Transurethral prostatectomy	0	1 (<0.1)	1 (<0.1)
Artificial crown procedure	1 (<0.1)	0	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Cataract operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Knee arthroplasty	1 (<0.1)	0	1 (<0.1)
Tooth extraction	1 (<0.1)	0	1 (<0.1)
Tooth repair	2 (<0.1)	0	2 (<0.1)
Umbilical hernia repair	1 (<0.1)	0	1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menopause	0	1 (<0.1)	1 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	2 (<0.1)	4 (<0.1)	6 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Device dislocation	0	1 (<0.1)	1 (<0.1)
Embedded device	0	1 (<0.1)	1 (<0.1)
Lead dislodgement	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.19.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Uncoded	74 (0.5)	72 (0.5)	146 (0.5)
Uncoded	74 (0.5)	72 (0.5)	146 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011903.sas 20NOV2020 06:56

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	95 (0.6)	96 (0.6)	9 (<0.1)	4 (<0.1)	3 (<0.1)	0	207 (1.4)
Grade 0	24 (0.2)	12640 (83.3)	551 (3.6)	191 (1.3)	31 (0.2)	0	13437 (88.6)
Grade 1	1 (<0.1)	601 (4.0)	183 (1.2)	102 (0.7)	26 (0.2)	0	913 (6.0)
Grade 2	2 (<0.1)	186 (1.2)	87 (0.6)	96 (0.6)	27 (0.2)	0	398 (2.6)
Grade 3	0	50 (0.3)	39 (0.3)	58 (0.4)	61 (0.4)	0	208 (1.4)
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	122 (0.8)	13575 (89.5)	869 (5.7)	451 (3.0)	148 (1.0)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	52 (0.3)	1138 (7.5)	79 (0.5)	41 (0.3)	21 (0.1)	0	1331 (8.8)
Grade 0	60 (0.4)	11370 (75.0)	492 (3.2)	197 (1.3)	38 (0.3)	0	12157 (80.2)
Grade 1	5 (<0.1)	721 (4.8)	172 (1.1)	96 (0.6)	28 (0.2)	0	1022 (6.7)
Grade 2	4 (<0.1)	282 (1.9)	91 (0.6)	72 (0.5)	21 (0.1)	0	470 (3.1)
Grade 3	1 (<0.1)	64 (0.4)	35 (0.2)	45 (0.3)	40 (0.3)	0	185 (1.2)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	13575 (89.5)	869 (5.7)	451 (3.0)	148 (1.0)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	82 (0.5)	5493 (36.2)	358 (2.4)	206 (1.4)	77 (0.5)	0	6216 (41.0)
Grade 0	40 (0.3)	7720 (50.9)	372 (2.5)	137 (0.9)	35 (0.2)	0	8304 (54.8)
Grade 1	0	239 (1.6)	80 (0.5)	62 (0.4)	17 (0.1)	0	398 (2.6)
Grade 2	0	100 (0.7)	44 (0.3)	34 (0.2)	9 (<0.1)	0	187 (1.2)
Grade 3	0	23 (0.2)	15 (<0.1)	12 (<0.1)	10 (<0.1)	0	60 (0.4)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	13575 (89.5)	869 (5.7)	451 (3.0)	148 (1.0)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	18 (2.2)	2 (0.2)	1 (0.1)	0	0	21 (2.6)
Grade 0	3 (0.4)	673 (83.0)	30 (3.7)	7 (0.9)	1 (0.1)	0	714 (88.0)
Grade 1	0	30 (3.7)	10 (1.2)	1 (0.1)	0	0	41 (5.1)
Grade 2	0	13 (1.6)	2 (0.2)	3 (0.4)	1 (0.1)	0	19 (2.3)
Grade 3	0	10 (1.2)	3 (0.4)	2 (0.2)	1 (0.1)	0	16 (2.0)
Grade 4	0	0	0	0	0	0	0
Total	3 (0.4)	744 (91.7)	47 (5.8)	14 (1.7)	3 (0.4)	0	811 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	35 (87.5)	2 (5.0)	0	0	0	37 (92.5)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	2 (5.0)	0	0	0	0	2 (5.0)
Grade 3	0	1 (2.5)	0	0	0	0	1 (2.5)
Grade 4	0	0	0	0	0	0	0
Total	0	38 (95.0)	2 (5.0)	0	0	0	40 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	7 (100)	0	0	0	0	7 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	7 (100)	0	0	0	0	7 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	2 (2.5)	0	0	0	0	2 (2.5)
Grade 0	1 (1.3)	63 (79.7)	6 (7.6)	0	0	0	70 (88.6)
Grade 1	0	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)	0	5 (6.3)
Grade 2	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 3	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 4	0	0	0	0	0	0	0
Total	1 (1.3)	68 (86.1)	7 (8.9)	2 (2.5)	1 (1.3)	0	79 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	47 (0.3)	19 (0.1)	0	0	1 (<0.1)	0	67 (0.4)
Grade 0	63 (0.4)	11689 (77.1)	379 (2.5)	107 (0.7)	20 (0.1)	0	12258 (80.8)
Grade 1	6 (<0.1)	1226 (8.1)	251 (1.7)	121 (0.8)	24 (0.2)	0	1628 (10.7)
Grade 2	5 (<0.1)	503 (3.3)	157 (1.0)	128 (0.8)	28 (0.2)	0	821 (5.4)
Grade 3	1 (<0.1)	136 (0.9)	82 (0.5)	95 (0.6)	75 (0.5)	0	389 (2.6)
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	122 (0.8)	13575 (89.5)	869 (5.7)	451 (3.0)	148 (1.0)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	95 (0.6)	118 (0.8)	2 (<0.1)	1 (<0.1)	0	0	216 (1.4)
Grade 0	24 (0.2)	13299 (87.7)	238 (1.6)	28 (0.2)	5 (<0.1)	0	13594 (89.6)
Grade 1	3 (<0.1)	653 (4.3)	261 (1.7)	42 (0.3)	4 (<0.1)	0	963 (6.4)
Grade 2	0	127 (0.8)	111 (0.7)	59 (0.4)	11 (<0.1)	0	308 (2.0)
Grade 3	0	20 (0.1)	12 (<0.1)	27 (0.2)	25 (0.2)	0	84 (0.6)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14217 (93.7)	624 (4.1)	157 (1.0)	45 (0.3)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t14030202.sas 20NOV2020 08:25

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	52 (0.3)	1219 (8.0)	44 (0.3)	10 (<0.1)	5 (<0.1)	0	1330 (8.8)
Grade 0	67 (0.4)	12163 (80.2)	267 (1.8)	42 (0.3)	5 (<0.1)	0	12544 (82.7)
Grade 1	3 (<0.1)	655 (4.3)	222 (1.5)	49 (0.3)	6 (<0.1)	0	935 (6.2)
Grade 2	0	148 (1.0)	79 (0.5)	40 (0.3)	13 (<0.1)	0	280 (1.8)
Grade 3	0	32 (0.2)	12 (<0.1)	16 (0.1)	16 (0.1)	0	76 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14217 (93.7)	624 (4.1)	157 (1.0)	45 (0.3)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	82 (0.5)	5816 (38.4)	238 (1.6)	68 (0.4)	11 (<0.1)	0	6215 (41.0)
Grade 0	37 (0.2)	8182 (54.0)	299 (2.0)	47 (0.3)	14 (<0.1)	0	8579 (56.6)
Grade 1	3 (<0.1)	171 (1.1)	68 (0.4)	25 (0.2)	6 (<0.1)	0	273 (1.8)
Grade 2	0	39 (0.3)	18 (0.1)	11 (<0.1)	6 (<0.1)	0	74 (0.5)
Grade 3	0	9 (<0.1)	1 (<0.1)	6 (<0.1)	8 (<0.1)	0	24 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14217 (93.7)	624 (4.1)	157 (1.0)	45 (0.3)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	15 (1.8)	1 (0.1)	0	0	0	16 (2.0)
Grade 0	2 (0.2)	748 (92.2)	21 (2.6)	7 (0.9)	1 (0.1)	0	779 (96.1)
Grade 1	0	6 (0.7)	2 (0.2)	1 (0.1)	0	0	9 (1.1)
Grade 2	0	1 (0.1)	2 (0.2)	3 (0.4)	1 (0.1)	0	7 (0.9)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	2 (0.2)	770 (94.9)	26 (3.2)	11 (1.4)	2 (0.2)	0	811 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	38 (95.0)	1 (2.5)	1 (2.5)	0	0	40 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	38 (95.0)	1 (2.5)	1 (2.5)	0	0	40 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	7 (100)	0	0	0	0	7 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	7 (100)	0	0	0	0	7 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	2 (2.5)	0	0	0	0	2 (2.5)
Grade 0	1 (1.3)	74 (93.7)	1 (1.3)	1 (1.3)	0	0	77 (97.5)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (1.3)	76 (96.2)	1 (1.3)	1 (1.3)	0	0	79 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	47 (0.3)	21 (0.1)	0	0	0	0	68 (0.4)
Grade 0	68 (0.4)	12749 (84.1)	142 (0.9)	15 (<0.1)	2 (<0.1)	0	12976 (85.6)
Grade 1	7 (<0.1)	1133 (7.5)	297 (2.0)	33 (0.2)	4 (<0.1)	0	1474 (9.7)
Grade 2	0	255 (1.7)	160 (1.1)	66 (0.4)	9 (<0.1)	0	490 (3.2)
Grade 3	0	59 (0.4)	25 (0.2)	43 (0.3)	30 (0.2)	0	157 (1.0)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14217 (93.7)	624 (4.1)	157 (1.0)	45 (0.3)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	95 (0.6)	119 (0.8)	2 (<0.1)	0	0	0	216 (1.4)
Grade 0	26 (0.2)	14671 (96.7)	144 (0.9)	3 (<0.1)	0	0	14844 (97.9)
Grade 1	0	45 (0.3)	48 (0.3)	2 (<0.1)	0	0	95 (0.6)
Grade 2	1 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)	0	10 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14837 (97.8)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	52 (0.3)	1256 (8.3)	22 (0.1)	0	0	0	1330 (8.8)
Grade 0	69 (0.5)	13381 (88.2)	127 (0.8)	1 (<0.1)	1 (<0.1)	0	13579 (89.5)
Grade 1	1 (<0.1)	183 (1.2)	44 (0.3)	4 (<0.1)	1 (<0.1)	0	233 (1.5)
Grade 2	0	15 (<0.1)	4 (<0.1)	1 (<0.1)	0	0	20 (0.1)
Grade 3	0	2 (<0.1)	0	1 (<0.1)	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14837 (97.8)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	82 (0.5)	6052 (39.9)	76 (0.5)	5 (<0.1)	0	0	6215 (41.0)
Grade 0	39 (0.3)	8678 (57.2)	89 (0.6)	1 (<0.1)	1 (<0.1)	0	8808 (58.1)
Grade 1	1 (<0.1)	97 (0.6)	31 (0.2)	1 (<0.1)	1 (<0.1)	0	131 (0.9)
Grade 2	0	10 (<0.1)	1 (<0.1)	0	0	0	11 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14837 (97.8)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	16 (2.0)	0	0	0	0	16 (2.0)
Grade 0	2 (0.2)	757 (93.3)	5 (0.6)	0	0	0	764 (94.2)
Grade 1	0	23 (2.8)	4 (0.5)	0	0	0	27 (3.3)
Grade 2	0	2 (0.2)	0	0	0	0	2 (0.2)
Grade 3	0	2 (0.2)	0	0	0	0	2 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	2 (0.2)	800 (98.6)	9 (1.1)	0	0	0	811 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	35 (87.5)	1 (2.5)	0	0	0	36 (90.0)
Grade 1	0	4 (10.0)	0	0	0	0	4 (10.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	39 (97.5)	1 (2.5)	0	0	0	40 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	6 (85.7)	0	0	0	0	6 (85.7)
Grade 1	0	1 (14.3)	0	0	0	0	1 (14.3)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	7 (100)	0	0	0	0	7 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	2 (2.5)	0	0	0	0	2 (2.5)
Grade 0	1 (1.3)	76 (96.2)	0	0	0	0	77 (97.5)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (1.3)	78 (98.7)	0	0	0	0	79 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	47 (0.3)	21 (0.1)	0	0	0	0	68 (0.4)
Grade 0	72 (0.5)	14478 (95.5)	102 (0.7)	1 (<0.1)	0	0	14653 (96.6)
Grade 1	2 (<0.1)	307 (2.0)	87 (0.6)	3 (<0.1)	0	0	399 (2.6)
Grade 2	1 (<0.1)	27 (0.2)	8 (<0.1)	2 (<0.1)	2 (<0.1)	0	40 (0.3)
Grade 3	0	4 (<0.1)	0	1 (<0.1)	0	0	5 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	122 (0.8)	14837 (97.8)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	95 (0.6)	103 (0.7)	34 (0.2)	1 (<0.1)	0	0	233 (1.5)
Grade 0	46 (0.3)	10136 (66.8)	1344 (8.9)	43 (0.3)	3 (<0.1)	0	11572 (76.3)
Grade 1	8 (<0.1)	1309 (8.6)	1868 (12.3)	59 (0.4)	1 (<0.1)	0	3245 (21.4)
Grade 2	1 (<0.1)	47 (0.3)	37 (0.2)	21 (0.1)	0	0	106 (0.7)
Grade 3	0	5 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	0	9 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	150 (1.0)	11600 (76.5)	3284 (21.7)	126 (0.8)	5 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	53 (0.3)	1006 (6.6)	267 (1.8)	6 (<0.1)	0	0	1332 (8.8)
Grade 0	52 (0.3)	8385 (55.3)	1371 (9.0)	46 (0.3)	3 (<0.1)	0	9857 (65.0)
Grade 1	45 (0.3)	2159 (14.2)	1598 (10.5)	66 (0.4)	2 (<0.1)	0	3870 (25.5)
Grade 2	0	46 (0.3)	46 (0.3)	8 (<0.1)	0	0	100 (0.7)
Grade 3	0	4 (<0.1)	2 (<0.1)	0	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	150 (1.0)	11600 (76.5)	3284 (21.7)	126 (0.8)	5 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	88 (0.6)	4713 (31.1)	1369 (9.0)	44 (0.3)	2 (<0.1)	0	6216 (41.0)
Grade 0	54 (0.4)	5962 (39.3)	1113 (7.3)	46 (0.3)	2 (<0.1)	0	7177 (47.3)
Grade 1	8 (<0.1)	913 (6.0)	781 (5.2)	34 (0.2)	1 (<0.1)	0	1737 (11.5)
Grade 2	0	9 (<0.1)	20 (0.1)	1 (<0.1)	0	0	30 (0.2)
Grade 3	0	3 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	5 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	150 (1.0)	11600 (76.5)	3284 (21.7)	126 (0.8)	5 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	18 (2.2)	3 (0.4)	0	0	0	21 (2.6)
Grade 0	3 (0.4)	474 (58.4)	89 (11.0)	2 (0.2)	0	0	568 (70.0)
Grade 1	0	136 (16.8)	72 (8.9)	4 (0.5)	0	0	212 (26.1)
Grade 2	0	3 (0.4)	7 (0.9)	0	0	0	10 (1.2)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	3 (0.4)	631 (77.8)	171 (21.1)	6 (0.7)	0	0	811 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)

Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	21 (52.5)	4 (10.0)	0	0	0	25 (62.5)
Grade 1	0	10 (25.0)	3 (7.5)	0	0	0	13 (32.5)
Grade 2	0	2 (5.0)	0	0	0	0	2 (5.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	33 (82.5)	7 (17.5)	0	0	0	40 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (57.1)	3 (42.9)	0	0	0	7 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	4 (57.1)	3 (42.9)	0	0	0	7 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	2 (2.5)	0	0	0	0	2 (2.5)
Grade 0	1 (1.3)	58 (73.4)	10 (12.7)	0	0	0	69 (87.3)
Grade 1	0	6 (7.6)	2 (2.5)	0	0	0	8 (10.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (1.3)	66 (83.5)	12 (15.2)	0	0	0	79 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	47 (0.3)	16 (0.1)	6 (<0.1)	0	0	0	69 (0.5)
Grade 0	50 (0.3)	8141 (53.7)	751 (5.0)	20 (0.1)	1 (<0.1)	0	8963 (59.1)
Grade 1	52 (0.3)	3327 (21.9)	2424 (16.0)	74 (0.5)	3 (<0.1)	0	5880 (38.8)
Grade 2	1 (<0.1)	104 (0.7)	99 (0.7)	29 (0.2)	0	0	233 (1.5)
Grade 3	0	12 (<0.1)	4 (<0.1)	3 (<0.1)	1 (<0.1)	0	20 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	150 (1.0)	11600 (76.5)	3284 (21.7)	126 (0.8)	5 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	95 (0.6)	112 (0.7)	0	0	0	0	207 (1.4)
Grade 0	28 (0.2)	14870 (98.1)	27 (0.2)	6 (<0.1)	2 (<0.1)	0	14933 (98.5)
Grade 1	0	20 (0.1)	0	0	0	0	20 (0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)	0	0	0	2 (<0.1)
Grade 3	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	123 (0.8)	15006 (99.0)	28 (0.2)	6 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	52 (0.3)	1275 (8.4)	3 (<0.1)	0	1 (<0.1)	0	1331 (8.8)
Grade 0	71 (0.5)	13676 (90.2)	22 (0.1)	6 (<0.1)	0	0	13775 (90.8)
Grade 1	0	36 (0.2)	2 (<0.1)	0	0	0	38 (0.3)
Grade 2	0	14 (<0.1)	0	0	1 (<0.1)	0	15 (<0.1)
Grade 3	0	5 (<0.1)	1 (<0.1)	0	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	123 (0.8)	15006 (99.0)	28 (0.2)	6 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	82 (0.5)	6121 (40.4)	10 (<0.1)	2 (<0.1)	1 (<0.1)	0	6216 (41.0)
Grade 0	41 (0.3)	8865 (58.5)	16 (0.1)	4 (<0.1)	1 (<0.1)	0	8927 (58.9)
Grade 1	0	14 (<0.1)	1 (<0.1)	0	0	0	15 (<0.1)
Grade 2	0	6 (<0.1)	1 (<0.1)	0	0	0	7 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	123 (0.8)	15006 (99.0)	28 (0.2)	6 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	21 (2.6)	0	0	0	0	21 (2.6)
Grade 0	3 (0.4)	782 (96.4)	1 (0.1)	1 (0.1)	0	0	787 (97.0)
Grade 1	0	2 (0.2)	0	0	0	0	2 (0.2)
Grade 2	0	1 (0.1)	0	0	0	0	1 (0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	3 (0.4)	806 (99.4)	1 (0.1)	1 (0.1)	0	0	811 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	40 (100)	0	0	0	0	40 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	40 (100)	0	0	0	0	40 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	7 (100)	0	0	0	0	7 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	7 (100)	0	0	0	0	7 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	2 (2.5)	0	0	0	0	2 (2.5)
Grade 0	1 (1.3)	76 (96.2)	0	0	0	0	77 (97.5)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (1.3)	78 (98.7)	0	0	0	0	79 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	47 (0.3)	20 (0.1)	0	0	0	0	67 (0.4)
Grade 0	76 (0.5)	14897 (98.2)	23 (0.2)	6 (<0.1)	1 (<0.1)	0	15003 (98.9)
Grade 1	0	60 (0.4)	3 (<0.1)	0	0	0	63 (0.4)
Grade 2	0	21 (0.1)	1 (<0.1)	0	1 (<0.1)	0	23 (0.2)
Grade 3	0	8 (<0.1)	1 (<0.1)	0	0	0	9 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	123 (0.8)	15006 (99.0)	28 (0.2)	6 (<0.1)	2 (<0.1)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	95 (0.6)	86 (0.6)	17 (0.1)	3 (<0.1)	6 (<0.1)	0	207 (1.4)
Grade 0	23 (0.2)	11287 (74.4)	835 (5.5)	129 (0.9)	97 (0.6)	0	12371 (81.6)
Grade 1	3 (<0.1)	799 (5.3)	524 (3.5)	108 (0.7)	125 (0.8)	0	1559 (10.3)
Grade 2	2 (<0.1)	130 (0.9)	129 (0.9)	49 (0.3)	50 (0.3)	0	360 (2.4)
Grade 3	0	137 (0.9)	173 (1.1)	84 (0.6)	271 (1.8)	0	665 (4.4)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	3 (<0.1)
Total	123 (0.8)	12440 (82.0)	1679 (11.1)	374 (2.5)	549 (3.6)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	52 (0.3)	1048 (6.9)	137 (0.9)	34 (0.2)	60 (0.4)	0	1331 (8.8)
Grade 0	54 (0.4)	10021 (66.1)	821 (5.4)	123 (0.8)	134 (0.9)	0	11153 (73.5)
Grade 1	12 (<0.1)	1024 (6.8)	452 (3.0)	103 (0.7)	105 (0.7)	0	1696 (11.2)
Grade 2	1 (<0.1)	188 (1.2)	115 (0.8)	48 (0.3)	59 (0.4)	0	411 (2.7)
Grade 3	4 (<0.1)	159 (1.0)	154 (1.0)	66 (0.4)	191 (1.3)	0	574 (3.8)
Grade 4	0	0	0	0	0	0	0
Total	123 (0.8)	12440 (82.0)	1679 (11.1)	374 (2.5)	549 (3.6)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	82 (0.5)	5020 (33.1)	719 (4.7)	151 (1.0)	244 (1.6)	0	6216 (41.0)
Grade 0	37 (0.2)	6850 (45.2)	637 (4.2)	129 (0.9)	142 (0.9)	0	7795 (51.4)
Grade 1	3 (<0.1)	427 (2.8)	214 (1.4)	48 (0.3)	70 (0.5)	0	762 (5.0)
Grade 2	0	62 (0.4)	52 (0.3)	18 (0.1)	27 (0.2)	0	159 (1.0)
Grade 3	1 (<0.1)	81 (0.5)	57 (0.4)	28 (0.2)	66 (0.4)	0	233 (1.5)
Grade 4	0	0	0	0	0	0	0
Total	123 (0.8)	12440 (82.0)	1679 (11.1)	374 (2.5)	549 (3.6)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	16 (2.0)	3 (0.4)	0	2 (0.2)	0	21 (2.6)
Grade 0	3 (0.4)	636 (78.4)	28 (3.5)	4 (0.5)	5 (0.6)	0	676 (83.4)
Grade 1	0	54 (6.7)	12 (1.5)	2 (0.2)	4 (0.5)	0	72 (8.9)
Grade 2	0	9 (1.1)	6 (0.7)	2 (0.2)	0	0	17 (2.1)
Grade 3	0	16 (2.0)	5 (0.6)	1 (0.1)	3 (0.4)	0	25 (3.1)
Grade 4	0	0	0	0	0	0	0
Total	3 (0.4)	731 (90.1)	54 (6.7)	9 (1.1)	14 (1.7)	0	811 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	31 (77.5)	3 (7.5)	0	0	0	34 (85.0)
Grade 1	0	3 (7.5)	2 (5.0)	1 (2.5)	0	0	6 (15.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	34 (85.0)	5 (12.5)	1 (2.5)	0	0	40 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	6 (85.7)	1 (14.3)	0	0	0	7 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	6 (85.7)	1 (14.3)	0	0	0	7 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	2 (2.5)	0	0	0	0	2 (2.5)
Grade 0	1 (1.3)	65 (82.3)	3 (3.8)	0	1 (1.3)	0	70 (88.6)
Grade 1	0	2 (2.5)	2 (2.5)	0	0	0	4 (5.1)
Grade 2	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 3	0	1 (1.3)	1 (1.3)	0	0	0	2 (2.5)
Grade 4	0	0	0	0	0	0	0
Total	1 (1.3)	71 (89.9)	6 (7.6)	0	1 (1.3)	0	79 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	47 (0.3)	15 (<0.1)	3 (<0.1)	0	2 (<0.1)	0	67 (0.4)
Grade 0	55 (0.4)	10058 (66.3)	495 (3.3)	59 (0.4)	51 (0.3)	0	10718 (70.7)
Grade 1	15 (<0.1)	1702 (11.2)	642 (4.2)	113 (0.7)	92 (0.6)	0	2564 (16.9)
Grade 2	2 (<0.1)	312 (2.1)	216 (1.4)	64 (0.4)	57 (0.4)	0	651 (4.3)
Grade 3	4 (<0.1)	352 (2.3)	322 (2.1)	137 (0.9)	347 (2.3)	0	1162 (7.7)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	3 (<0.1)
Total	123 (0.8)	12440 (82.0)	1679 (11.1)	374 (2.5)	549 (3.6)	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	91 (0.6)	121 (0.8)	0	0	0	0	212 (1.4)
Grade 0	31 (0.2)	14918 (98.4)	1 (<0.1)	0	0	0	14950 (98.6)
Grade 1	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	122 (0.8)	15042 (99.2)	1 (<0.1)	0	0	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	52 (0.3)	1276 (8.4)	0	0	0	0	1328 (8.8)
Grade 0	70 (0.5)	13759 (90.7)	1 (<0.1)	0	0	0	13830 (91.2)
Grade 1	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	122 (0.8)	15042 (99.2)	1 (<0.1)	0	0	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	82 (0.5)	6138 (40.5)	0	0	0	0	6220 (41.0)
Grade 0	40 (0.3)	8899 (58.7)	1 (<0.1)	0	0	0	8940 (59.0)
Grade 1	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Total	122 (0.8)	15042 (99.2)	1 (<0.1)	0	0	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	1 (0.1)	0	0	0	0	1 (0.1)
Grade 0	2 (0.2)	799 (98.5)	0	0	0	0	801 (98.8)
Grade 1	0	7 (0.9)	0	0	0	0	7 (0.9)
Grade 2	0	2 (0.2)	0	0	0	0	2 (0.2)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	2 (0.2)	809 (99.8)	0	0	0	0	811 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	38 (95.0)	0	0	0	0	38 (95.0)
Grade 1	0	1 (2.5)	0	0	0	0	1 (2.5)
Grade 2	0	1 (2.5)	0	0	0	0	1 (2.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	40 (100)	0	0	0	0	40 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	7 (100)	0	0	0	0	7 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	7 (100)	0	0	0	0	7 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	1 (1.3)	78 (98.7)	0	0	0	0	79 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (1.3)	78 (98.7)	0	0	0	0	79 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15165)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	47 (0.3)	24 (0.2)	0	0	0	0	71 (0.5)
Grade 0	75 (0.5)	15000 (98.9)	1 (<0.1)	0	0	0	15076 (99.4)
Grade 1	0	7 (<0.1)	0	0	0	0	7 (<0.1)
Grade 2	0	6 (<0.1)	0	0	0	0	6 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	5 (<0.1)	0	0	0	0	5 (<0.1)
Total	122 (0.8)	15042 (99.2)	1 (<0.1)	0	0	0	15165 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	97 (0.6)	78 (0.5)	6 (<0.1)	4 (<0.1)	3 (<0.1)	0	188 (1.2)
Grade 0	31 (0.2)	12622 (83.1)	572 (3.8)	169 (1.1)	40 (0.3)	0	13434 (88.5)
Grade 1	3 (<0.1)	578 (3.8)	202 (1.3)	101 (0.7)	26 (0.2)	0	910 (6.0)
Grade 2	3 (<0.1)	196 (1.3)	123 (0.8)	106 (0.7)	31 (0.2)	0	459 (3.0)
Grade 3	1 (<0.1)	61 (0.4)	30 (0.2)	45 (0.3)	56 (0.4)	0	193 (1.3)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	13535 (89.1)	933 (6.1)	425 (2.8)	156 (1.0)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	64 (0.4)	1134 (7.5)	68 (0.4)	39 (0.3)	24 (0.2)	0	1329 (8.8)
Grade 0	54 (0.4)	11336 (74.7)	555 (3.7)	180 (1.2)	50 (0.3)	0	12175 (80.2)
Grade 1	9 (<0.1)	700 (4.6)	173 (1.1)	95 (0.6)	19 (0.1)	0	996 (6.6)
Grade 2	5 (<0.1)	286 (1.9)	101 (0.7)	74 (0.5)	28 (0.2)	0	494 (3.3)
Grade 3	3 (<0.1)	79 (0.5)	36 (0.2)	37 (0.2)	35 (0.2)	0	190 (1.3)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	13535 (89.1)	933 (6.1)	425 (2.8)	156 (1.0)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	102 (0.7)	5341 (35.2)	389 (2.6)	173 (1.1)	78 (0.5)	0	6083 (40.1)
Grade 0	27 (0.2)	7778 (51.2)	397 (2.6)	155 (1.0)	42 (0.3)	0	8399 (55.3)
Grade 1	5 (<0.1)	264 (1.7)	100 (0.7)	52 (0.3)	16 (0.1)	0	437 (2.9)
Grade 2	1 (<0.1)	118 (0.8)	33 (0.2)	35 (0.2)	11 (<0.1)	0	198 (1.3)
Grade 3	0	34 (0.2)	14 (<0.1)	10 (<0.1)	9 (<0.1)	0	67 (0.4)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	13535 (89.1)	933 (6.1)	425 (2.8)	156 (1.0)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	19 (3.2)	0	0	0	0	19 (3.2)
Grade 0	0	504 (84.7)	19 (3.2)	3 (0.5)	3 (0.5)	0	529 (88.9)
Grade 1	0	24 (4.0)	1 (0.2)	0	0	0	25 (4.2)
Grade 2	0	12 (2.0)	1 (0.2)	2 (0.3)	0	0	15 (2.5)
Grade 3	0	5 (0.8)	0	2 (0.3)	0	0	7 (1.2)
Grade 4	0	0	0	0	0	0	0
Total	0	564 (94.8)	21 (3.5)	7 (1.2)	3 (0.5)	0	595 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	35 (89.7)	2 (5.1)	0	1 (2.6)	0	38 (97.4)
Grade 1	0	1 (2.6)	0	0	0	0	1 (2.6)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	36 (92.3)	2 (5.1)	0	1 (2.6)	0	39 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	21 (95.5)	0	1 (4.5)	0	0	22 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	21 (95.5)	0	1 (4.5)	0	0	22 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	55 (0.4)	16 (0.1)	1 (<0.1)	2 (<0.1)	0	0	74 (0.5)
Grade 0	55 (0.4)	11612 (76.5)	405 (2.7)	95 (0.6)	22 (0.1)	0	12189 (80.3)
Grade 1	14 (<0.1)	1212 (8.0)	268 (1.8)	103 (0.7)	25 (0.2)	0	1622 (10.7)
Grade 2	7 (<0.1)	527 (3.5)	187 (1.2)	145 (1.0)	36 (0.2)	0	902 (5.9)
Grade 3	4 (<0.1)	168 (1.1)	72 (0.5)	80 (0.5)	73 (0.5)	0	397 (2.6)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	13535 (89.1)	933 (6.1)	425 (2.8)	156 (1.0)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	97 (0.6)	89 (0.6)	3 (<0.1)	2 (<0.1)	0	0	191 (1.3)
Grade 0	37 (0.2)	13401 (88.3)	253 (1.7)	25 (0.2)	6 (<0.1)	0	13722 (90.4)
Grade 1	1 (<0.1)	645 (4.2)	241 (1.6)	45 (0.3)	3 (<0.1)	0	935 (6.2)
Grade 2	0	103 (0.7)	94 (0.6)	61 (0.4)	7 (<0.1)	0	265 (1.7)
Grade 3	0	23 (0.2)	15 (<0.1)	18 (0.1)	15 (<0.1)	0	71 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14261 (93.9)	606 (4.0)	151 (1.0)	31 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	65 (0.4)	1214 (8.0)	38 (0.3)	11 (<0.1)	1 (<0.1)	0	1329 (8.8)
Grade 0	64 (0.4)	12201 (80.4)	290 (1.9)	45 (0.3)	7 (<0.1)	0	12607 (83.0)
Grade 1	3 (<0.1)	682 (4.5)	171 (1.1)	37 (0.2)	4 (<0.1)	0	897 (5.9)
Grade 2	0	139 (0.9)	89 (0.6)	41 (0.3)	9 (<0.1)	0	278 (1.8)
Grade 3	3 (<0.1)	25 (0.2)	18 (0.1)	17 (0.1)	10 (<0.1)	0	73 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14261 (93.9)	606 (4.0)	151 (1.0)	31 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	102 (0.7)	5672 (37.4)	235 (1.5)	63 (0.4)	13 (<0.1)	0	6085 (40.1)
Grade 0	32 (0.2)	8384 (55.2)	286 (1.9)	50 (0.3)	8 (<0.1)	0	8760 (57.7)
Grade 1	0	180 (1.2)	70 (0.5)	18 (0.1)	4 (<0.1)	0	272 (1.8)
Grade 2	0	22 (0.1)	14 (<0.1)	16 (0.1)	5 (<0.1)	0	57 (0.4)
Grade 3	1 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)	0	10 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14261 (93.9)	606 (4.0)	151 (1.0)	31 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	8 (1.3)	0	0	0	0	8 (1.3)
Grade 0	0	536 (90.1)	31 (5.2)	4 (0.7)	1 (0.2)	0	572 (96.1)
Grade 1	0	6 (1.0)	4 (0.7)	1 (0.2)	0	0	11 (1.8)
Grade 2	0	1 (0.2)	1 (0.2)	1 (0.2)	0	0	3 (0.5)
Grade 3	0	1 (0.2)	0	0	0	0	1 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	0	552 (92.8)	36 (6.1)	6 (1.0)	1 (0.2)	0	595 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	37 (94.9)	1 (2.6)	1 (2.6)	0	0	39 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	37 (94.9)	1 (2.6)	1 (2.6)	0	0	39 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	22 (100)	0	0	0	0	22 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	22 (100)	0	0	0	0	22 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	55 (0.4)	17 (0.1)	1 (<0.1)	1 (<0.1)	0	0	74 (0.5)
Grade 0	74 (0.5)	12827 (84.5)	168 (1.1)	15 (<0.1)	2 (<0.1)	0	13086 (86.2)
Grade 1	3 (<0.1)	1148 (7.6)	255 (1.7)	36 (0.2)	5 (<0.1)	0	1447 (9.5)
Grade 2	0	224 (1.5)	150 (1.0)	67 (0.4)	8 (<0.1)	0	449 (3.0)
Grade 3	3 (<0.1)	45 (0.3)	32 (0.2)	32 (0.2)	16 (0.1)	0	128 (0.8)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14261 (93.9)	606 (4.0)	151 (1.0)	31 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	97 (0.6)	91 (0.6)	2 (<0.1)	1 (<0.1)	0	0	191 (1.3)
Grade 0	38 (0.3)	14670 (96.6)	168 (1.1)	11 (<0.1)	0	0	14887 (98.0)
Grade 1	0	40 (0.3)	47 (0.3)	12 (<0.1)	0	0	99 (0.7)
Grade 2	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	0	7 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14803 (97.5)	219 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	65 (0.4)	1238 (8.2)	22 (0.1)	4 (<0.1)	0	0	1329 (8.8)
Grade 0	70 (0.5)	13350 (87.9)	133 (0.9)	14 (<0.1)	0	0	13567 (89.4)
Grade 1	0	204 (1.3)	56 (0.4)	5 (<0.1)	1 (<0.1)	0	266 (1.8)
Grade 2	0	9 (<0.1)	8 (<0.1)	2 (<0.1)	0	0	19 (0.1)
Grade 3	0	2 (<0.1)	0	1 (<0.1)	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14803 (97.5)	219 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	102 (0.7)	5876 (38.7)	94 (0.6)	13 (<0.1)	0	0	6085 (40.1)
Grade 0	33 (0.2)	8821 (58.1)	105 (0.7)	9 (<0.1)	1 (<0.1)	0	8969 (59.1)
Grade 1	0	100 (0.7)	15 (<0.1)	3 (<0.1)	0	0	118 (0.8)
Grade 2	0	5 (<0.1)	5 (<0.1)	1 (<0.1)	0	0	11 (<0.1)
Grade 3	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14803 (97.5)	219 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	8 (1.3)	0	0	0	0	8 (1.3)
Grade 0	0	553 (92.9)	6 (1.0)	0	0	0	559 (93.9)
Grade 1	0	23 (3.9)	2 (0.3)	0	0	0	25 (4.2)
Grade 2	0	2 (0.3)	1 (0.2)	0	0	0	3 (0.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	586 (98.5)	9 (1.5)	0	0	0	595 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	36 (92.3)	0	0	0	0	36 (92.3)
Grade 1	0	1 (2.6)	1 (2.6)	0	0	0	2 (5.1)
Grade 2	0	1 (2.6)	0	0	0	0	1 (2.6)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	38 (97.4)	1 (2.6)	0	0	0	39 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t14030202.sas 20NOV2020 08:25

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	22 (100)	0	0	0	0	22 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	22 (100)	0	0	0	0	22 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	55 (0.4)	18 (0.1)	1 (<0.1)	0	0	0	74 (0.5)
Grade 0	80 (0.5)	14430 (95.0)	124 (0.8)	7 (<0.1)	0	0	14641 (96.4)
Grade 1	0	333 (2.2)	79 (0.5)	13 (<0.1)	0	0	425 (2.8)
Grade 2	0	19 (0.1)	15 (<0.1)	5 (<0.1)	1 (<0.1)	0	40 (0.3)
Grade 3	0	3 (<0.1)	0	1 (<0.1)	0	0	4 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	14803 (97.5)	219 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)

Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	96 (0.6)	77 (0.5)	26 (0.2)	0	0	0	199 (1.3)
Grade 0	48 (0.3)	10132 (66.7)	1383 (9.1)	31 (0.2)	1 (<0.1)	0	11595 (76.4)
Grade 1	7 (<0.1)	1354 (8.9)	1870 (12.3)	41 (0.3)	2 (<0.1)	0	3274 (21.6)
Grade 2	1 (<0.1)	38 (0.3)	41 (0.3)	26 (0.2)	0	0	106 (0.7)
Grade 3	0	4 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	0	10 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	152 (1.0)	11605 (76.4)	3322 (21.9)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	65 (0.4)	958 (6.3)	305 (2.0)	1 (<0.1)	1 (<0.1)	0	1330 (8.8)
Grade 0	54 (0.4)	8399 (55.3)	1420 (9.4)	47 (0.3)	0	0	9920 (65.3)
Grade 1	33 (0.2)	2193 (14.4)	1540 (10.1)	43 (0.3)	3 (<0.1)	0	3812 (25.1)
Grade 2	0	53 (0.3)	54 (0.4)	9 (<0.1)	0	0	116 (0.8)
Grade 3	0	2 (<0.1)	3 (<0.1)	1 (<0.1)	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	152 (1.0)	11605 (76.4)	3322 (21.9)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	108 (0.7)	4597 (30.3)	1360 (9.0)	22 (0.1)	2 (<0.1)	0	6089 (40.1)
Grade 0	39 (0.3)	6044 (39.8)	1159 (7.6)	48 (0.3)	1 (<0.1)	0	7291 (48.0)
Grade 1	5 (<0.1)	950 (6.3)	791 (5.2)	29 (0.2)	1 (<0.1)	0	1776 (11.7)
Grade 2	0	13 (<0.1)	11 (<0.1)	2 (<0.1)	0	0	26 (0.2)
Grade 3	0	1 (<0.1)	1 (<0.1)	0	0	0	2 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	152 (1.0)	11605 (76.4)	3322 (21.9)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	15 (2.5)	7 (1.2)	0	0	0	22 (3.7)
Grade 0	1 (0.2)	371 (62.4)	72 (12.1)	1 (0.2)	0	0	445 (74.8)
Grade 1	0	76 (12.8)	43 (7.2)	2 (0.3)	0	0	121 (20.3)
Grade 2	0	7 (1.2)	0	0	0	0	7 (1.2)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (0.2)	469 (78.8)	122 (20.5)	3 (0.5)	0	0	595 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)

Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	16 (41.0)	4 (10.3)	0	0	0	20 (51.3)
Grade 1	0	11 (28.2)	6 (15.4)	1 (2.6)	0	0	18 (46.2)
Grade 2	0	1 (2.6)	0	0	0	0	1 (2.6)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	28 (71.8)	10 (25.6)	1 (2.6)	0	0	39 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)

Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	0	1 (33.3)	0	0	0	1 (33.3)
Grade 1	0	1 (33.3)	1 (33.3)	0	0	0	2 (66.7)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (33.3)	2 (66.7)	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)

Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	18 (81.8)	0	0	0	0	18 (81.8)
Grade 1	0	3 (13.6)	1 (4.5)	0	0	0	4 (18.2)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	21 (95.5)	1 (4.5)	0	0	0	22 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	0	1 (100)	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	0	1 (100)	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	55 (0.4)	10 (<0.1)	9 (<0.1)	0	0	0	74 (0.5)
Grade 0	56 (0.4)	8116 (53.5)	774 (5.1)	11 (<0.1)	0	0	8957 (59.0)
Grade 1	40 (0.3)	3365 (22.2)	2432 (16.0)	54 (0.4)	3 (<0.1)	0	5894 (38.8)
Grade 2	1 (<0.1)	107 (0.7)	101 (0.7)	33 (0.2)	0	0	242 (1.6)
Grade 3	0	7 (<0.1)	6 (<0.1)	3 (<0.1)	1 (<0.1)	0	17 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	152 (1.0)	11605 (76.4)	3322 (21.9)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	97 (0.6)	91 (0.6)	0	0	0	0	188 (1.2)
Grade 0	38 (0.3)	14913 (98.2)	17 (0.1)	6 (<0.1)	1 (<0.1)	0	14975 (98.6)
Grade 1	0	13 (<0.1)	1 (<0.1)	0	0	0	14 (<0.1)
Grade 2	0	3 (<0.1)	1 (<0.1)	0	0	0	4 (<0.1)
Grade 3	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	15023 (98.9)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	64 (0.4)	1263 (8.3)	1 (<0.1)	1 (<0.1)	0	0	1329 (8.8)
Grade 0	71 (0.5)	13716 (90.3)	14 (<0.1)	5 (<0.1)	0	0	13806 (90.9)
Grade 1	0	30 (0.2)	2 (<0.1)	0	1 (<0.1)	0	33 (0.2)
Grade 2	0	13 (<0.1)	2 (<0.1)	0	0	0	15 (<0.1)
Grade 3	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	15023 (98.9)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	102 (0.7)	5970 (39.3)	6 (<0.1)	4 (<0.1)	1 (<0.1)	0	6083 (40.1)
Grade 0	33 (0.2)	9030 (59.5)	13 (<0.1)	2 (<0.1)	0	0	9078 (59.8)
Grade 1	0	19 (0.1)	0	0	0	0	19 (0.1)
Grade 2	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 3	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	15023 (98.9)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	19 (3.2)	0	0	0	0	19 (3.2)
Grade 0	0	572 (96.1)	1 (0.2)	1 (0.2)	0	0	574 (96.5)
Grade 1	0	1 (0.2)	0	0	0	0	1 (0.2)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	1 (0.2)	0	0	0	0	1 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	0	593 (99.7)	1 (0.2)	1 (0.2)	0	0	595 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	38 (97.4)	0	0	0	0	38 (97.4)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	1 (2.6)	0	0	0	0	1 (2.6)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	39 (100)	0	0	0	0	39 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	22 (100)	0	0	0	0	22 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	22 (100)	0	0	0	0	22 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t14030202.sas 20NOV2020 08:25

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	55 (0.4)	19 (0.1)	0	0	0	0	74 (0.5)
Grade 0	80 (0.5)	14925 (98.3)	14 (<0.1)	6 (<0.1)	0	0	15025 (99.0)
Grade 1	0	55 (0.4)	2 (<0.1)	0	1 (<0.1)	0	58 (0.4)
Grade 2	0	18 (0.1)	3 (<0.1)	0	0	0	21 (0.1)
Grade 3	0	6 (<0.1)	0	0	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	15023 (98.9)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	97 (0.6)	75 (0.5)	8 (<0.1)	3 (<0.1)	5 (<0.1)	0	188 (1.2)
Grade 0	26 (0.2)	11224 (73.9)	825 (5.4)	116 (0.8)	91 (0.6)	0	12282 (80.9)
Grade 1	6 (<0.1)	883 (5.8)	548 (3.6)	122 (0.8)	129 (0.8)	0	1688 (11.1)
Grade 2	3 (<0.1)	133 (0.9)	145 (1.0)	64 (0.4)	66 (0.4)	0	411 (2.7)
Grade 3	3 (<0.1)	132 (0.9)	165 (1.1)	85 (0.6)	230 (1.5)	0	615 (4.1)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	12447 (82.0)	1691 (11.1)	390 (2.6)	521 (3.4)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	64 (0.4)	1073 (7.1)	120 (0.8)	27 (0.2)	45 (0.3)	0	1329 (8.8)
Grade 0	42 (0.3)	9945 (65.5)	821 (5.4)	145 (1.0)	117 (0.8)	0	11070 (72.9)
Grade 1	18 (0.1)	1062 (7.0)	450 (3.0)	109 (0.7)	135 (0.9)	0	1774 (11.7)
Grade 2	2 (<0.1)	178 (1.2)	120 (0.8)	42 (0.3)	62 (0.4)	0	404 (2.7)
Grade 3	9 (<0.1)	189 (1.2)	180 (1.2)	67 (0.4)	162 (1.1)	0	607 (4.0)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	12447 (82.0)	1691 (11.1)	390 (2.6)	521 (3.4)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	102 (0.7)	4893 (32.2)	733 (4.8)	158 (1.0)	197 (1.3)	0	6083 (40.1)
Grade 0	24 (0.2)	6927 (45.6)	640 (4.2)	118 (0.8)	143 (0.9)	0	7852 (51.7)
Grade 1	5 (<0.1)	442 (2.9)	196 (1.3)	62 (0.4)	79 (0.5)	0	784 (5.2)
Grade 2	0	90 (0.6)	59 (0.4)	24 (0.2)	36 (0.2)	0	209 (1.4)
Grade 3	4 (<0.1)	95 (0.6)	63 (0.4)	28 (0.2)	66 (0.4)	0	256 (1.7)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	12447 (82.0)	1691 (11.1)	390 (2.6)	521 (3.4)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	16 (2.7)	2 (0.3)	1 (0.2)	0	0	19 (3.2)
Grade 0	0	466 (78.3)	28 (4.7)	5 (0.8)	3 (0.5)	0	502 (84.4)
Grade 1	0	35 (5.9)	8 (1.3)	2 (0.3)	1 (0.2)	0	46 (7.7)
Grade 2	0	2 (0.3)	2 (0.3)	0	2 (0.3)	0	6 (1.0)
Grade 3	0	11 (1.8)	10 (1.7)	1 (0.2)	0	0	22 (3.7)
Grade 4	0	0	0	0	0	0	0
Total	0	530 (89.1)	50 (8.4)	9 (1.5)	6 (1.0)	0	595 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	33 (84.6)	1 (2.6)	1 (2.6)	0	0	35 (89.7)
Grade 1	0	4 (10.3)	0	0	0	0	4 (10.3)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	37 (94.9)	1 (2.6)	1 (2.6)	0	0	39 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	20 (90.9)	1 (4.5)	0	0	0	21 (95.5)
Grade 1	0	0	0	1 (4.5)	0	0	1 (4.5)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	20 (90.9)	1 (4.5)	1 (4.5)	0	0	22 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	55 (0.4)	17 (0.1)	1 (<0.1)	0	1 (<0.1)	0	74 (0.5)
Grade 0	45 (0.3)	9941 (65.5)	503 (3.3)	52 (0.3)	35 (0.2)	0	10576 (69.7)
Grade 1	19 (0.1)	1766 (11.6)	631 (4.2)	114 (0.8)	103 (0.7)	0	2633 (17.3)
Grade 2	4 (<0.1)	340 (2.2)	223 (1.5)	80 (0.5)	71 (0.5)	0	718 (4.7)
Grade 3	12 (<0.1)	383 (2.5)	333 (2.2)	144 (0.9)	311 (2.0)	0	1183 (7.8)
Grade 4	0	0	0	0	0	0	0
Total	135 (0.9)	12447 (82.0)	1691 (11.1)	390 (2.6)	521 (3.4)	0	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 1 - 30 Minutes Postdose							
UNK	97 (0.6)	95 (0.6)	0	0	0	1 (<0.1)	193 (1.3)
Grade 0	37 (0.2)	14947 (98.4)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	14987 (98.7)
Grade 1	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 2	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	134 (0.9)	15046 (99.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 29							
UNK	59 (0.4)	1269 (8.4)	1 (<0.1)	0	0	0	1329 (8.8)
Grade 0	75 (0.5)	13771 (90.7)	0	1 (<0.1)	0	2 (<0.1)	13849 (91.2)
Grade 1	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	134 (0.9)	15046 (99.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 57							
UNK	99 (0.7)	5991 (39.5)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	6093 (40.1)
Grade 0	35 (0.2)	9050 (59.6)	0	0	0	1 (<0.1)	9086 (59.8)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	5 (<0.1)	0	0	0	0	5 (<0.1)
Total	134 (0.9)	15046 (99.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 1							
UNK	0	2 (0.3)	0	0	0	0	2 (0.3)
Grade 0	0	579 (97.3)	0	0	0	0	579 (97.3)
Grade 1	0	9 (1.5)	0	0	0	0	9 (1.5)
Grade 2	0	4 (0.7)	0	0	0	0	4 (0.7)
Grade 3	0	1 (0.2)	0	0	0	0	1 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	0	595 (100)	0	0	0	0	595 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	37 (94.9)	0	0	0	0	37 (94.9)
Grade 1	0	1 (2.6)	0	0	0	0	1 (2.6)
Grade 2	0	1 (2.6)	0	0	0	0	1 (2.6)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	39 (100)	0	0	0	0	39 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	3 (100)	0	0	0	0	3 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	3 (100)	0	0	0	0	3 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit Day 28							
UNK	0	1 (4.5)	0	0	0	0	1 (4.5)
Grade 0	0	21 (95.5)	0	0	0	0	21 (95.5)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	22 (100)	0	0	0	0	22 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (100)	0	0	0	0	1 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	1 (100)	0	0	0	0	1 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	55 (0.4)	20 (0.1)	0	0	0	0	75 (0.5)
Grade 0	79 (0.5)	14995 (98.8)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	15078 (99.3)
Grade 1	0	15 (<0.1)	0	0	0	0	15 (<0.1)
Grade 2	0	6 (<0.1)	0	0	0	0	6 (<0.1)
Grade 3	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 4	0	7 (<0.1)	0	0	0	0	7 (<0.1)
Total	134 (0.9)	15046 (99.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	15184 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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