Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

	Placebo	mRNA-1273	Total
Randomization Set [1]	15210	15210	30420
Full Analysis Set, n (%) [1]	15170 (99.7)	15181 (99.8)	30351 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	14598 (96.0)	14550 (95.7)	29148 (95.8)
Per-Protocol (PP) Set, n (%) [1]	14073 (92.5)	14134 (92.9)	28207 (92.7)
Safety Set [2]	15166	15185	30351
Solicited Safety Set, n (%) [2]	15163(>99.9)	15179(>99.9)	30342(>99.9)
First Injection Solicited Safety Set, n (%) [2]	15155(>99.9)	15168 (99.9)	30323(>99.9)
Second Injection Solicited Safety Set, n (%) [2]	14566 (96.0)	14677 (96.7)	29243 (96.3)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
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Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

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

	Placebo	mRNA-1273	Total
Randomization Set [1]	8910	8910	17820
Full Analysis Set, n (%) [1]	8886 (99.7)	8888 (99.8)	17774 (99.7)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	8532 (95.8)	8468 (95.0)	17000 (95.4)
Per-Protocol (PP) Set, n (%) [1]	8200 (92.0)	8189 (91.9)	16389 (92.0)
Safety Set [2]	8884	8890	17774
Solicited Safety Set, n (%) [2]	8883(>99.9)	8888(>99.9)	17771(>99.9)
First Injection Solicited Safety Set, n (%) [2]	8878(>99.9)	8882(>99.9)	17760(>99.9)
Second Injection Solicited Safety Set, n (%) [2]	8496 (95.6)	8534 (96.0)	17030 (95.8)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
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Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

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

	Placebo	mRNA-1273	Total
Randomization Set [1]	2541	2534	5075
Full Analysis Set, n (%) [1]	2535 (99.8)	2530 (99.8)	5065 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	2415 (95.0)	2427 (95.8)	4842 (95.4)
Per-Protocol (PP) Set, n (%) [1]	2324 (91.5)	2367 (93.4)	4691 (92.4)
Safety Set [2]	2535	2530	5065
Solicited Safety Set, n (%) [2]	2533(>99.9)	2529(>99.9)	5062(>99.9)
First Injection Solicited Safety Set, n (%) [2]	2532 (99.9)	2529(>99.9)	5061(>99.9)
Second Injection Solicited Safety Set, n (%) [2]	2425 (95.7)	2456 (97.1)	4881 (96.4)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
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Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

	Placebo	mRNA-1273	Total
Randomization Set [1]	3759	3766	7525
Full Analysis Set, n (%) [1]	3749 (99.7)	3763(>99.9)	7512 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	3651 (97.1)	3655 (97.1)	7306 (97.1)
Per-Protocol (PP) Set, n (%) [1]	3549 (94.4)	3578 (95.0)	7127 (94.7)
Safety Set [2]	3747	3765	7512
Solicited Safety Set, n (%) [2]	3747 (100)	3762(>99.9)	7509(>99.9)
First Injection Solicited Safety Set, n (%) [2]	3745(>99.9)	3757 (99.8)	7502 (99.9)
Second Injection Solicited Safety Set, n (%) [2]	3645 (97.3)	3687 (97.9)	7332 (97.6)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
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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=15181)	Total (N=30351)
Age at Screening (Years)			
n	15170	15181	30351
Mean	51.3 (15.60)	51.4 (15.50)	51.4 (15.55)
(SD)			
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)	11413 (75.2)	22831 (75.2)
Mean	45.0 (12.30)	45.1 (12.35)	45.0 (12.32)
(SD)			
Median	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3752 (24.7)	3768 (24.8)	7520 (24.8)
Mean	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
(SD)			
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11418 (75.3)	11413 (75.2)	22831 (75.2)
>=65 and <70 Years	1817 (12.0)	1905 (12.5)	3722 (12.3)
>=70 and <75 Years	1194 (7.9)	1205 (7.9)	2399 (7.9)
>=75 and <80 Years	507 (3.3)	467 (3.1)	974 (3.2)
>=80 Years	234 (1.5)	191 (1.3)	425 (1.4)

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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=15181)	Total (N=30351)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11418 (75.3)	11413 (75.2)	22831 (75.2)
>=65 and <75 Years	3011 (19.8)	3110 (20.5)	6121 (20.2)
>=75 and <85 Years	692 (4.6)	617 (4.1)	1309 (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)	8888 (58.5)	17774 (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	744 (4.9)	710 (4.7)	1454 (4.8)
Significant Cardiac Disease	744 (4.9)	752 (5.0)	1496 (4.9)
Severe Obesity	1021 (6.7)	1025 (6.8)	2046 (6.7)
Diabetes	1440 (9.5)	1435 (9.5)	2875 (9.5)
Liver Disease	96 (0.6)	100 (0.7)	196 (0.6)
Human Immunodeficiency Virus Infection	87 (0.6)	92 (0.6)	179 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	3418 (22.5)	3399 (22.4)	6817 (22.5)
One Risk Factor for Severe COVID-19	2798 (18.4)	2775 (18.3)	5573 (18.4)
Two or More Risk Factors for Severe COVID-19	620 (4.1)	624 (4.1)	1244 (4.1)
No	11752 (77.5)	11782 (77.6)	23534 (77.5)

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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=15181)	Total (N=30351)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	9116 (60.1)	9118 (60.1)	18234 (60.1)
>=18 and <65 Years and at Risk	2302 (15.2)	2295 (15.1)	4597 (15.1)
>=65 Years and Not at Risk	2636 (17.4)	2664 (17.5)	5300 (17.5)
>=65 Years and at Risk	1116 (7.4)	1104 (7.3)	2220 (7.3)
Baseline RT-PCR Results, n (%)			
Negative	14923 (98.4)	14917 (98.3)	29840 (98.3)
Positive	95 (0.6)	87 (0.6)	182 (0.6)
Missing	152 (1.0)	177 (1.2)	329 (1.1)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	14726 (97.1)	14690 (96.8)	29416 (96.9)
Positive	303 (2.0)	305 (2.0)	608 (2.0)
Missing	141 (0.9)	186 (1.2)	327 (1.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	14598 (96.2)	14550 (95.8)	29148 (96.0)
Positive	337 (2.2)	343 (2.3)	680 (2.2)
Missing	235 (1.5)	288 (1.9)	523 (1.7)
Sex, n (%)			
Male	8062 (53.1)	7923 (52.2)	15985 (52.7)
Female	7108 (46.9)	7258 (47.8)	14366 (47.3)

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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=15181)	Total (N=30351)
Race, n (%)			
White	11995 (79.1)	12029 (79.2)	24024 (79.2)
Black or African American	1527 (10.1)	1563 (10.3)	3090 (10.2)
Asian	731 (4.8)	651 (4.3)	1382 (4.6)
American Indian or Alaska Native	121 (0.8)	112 (0.7)	233 (0.8)
Native Hawaiian or Other Pacific Islander	32 (0.2)	35 (0.2)	67 (0.2)
Multiracial	321 (2.1)	315 (2.1)	636 (2.1)
Other	316 (2.1)	321 (2.1)	637 (2.1)
Not Reported	73 (0.5)	96 (0.6)	169 (0.6)
Unknown	54 (0.4)	59 (0.4)	113 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	3114 (20.5)	3121 (20.6)	6235 (20.5)
Not Hispanic or Latino	11917 (78.6)	11918 (78.5)	23835 (78.5)
Not Reported	85 (0.6)	104 (0.7)	189 (0.6)
Unknown	54 (0.4)	38 (0.3)	92 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	4632 (30.5)	4650 (30.6)	9282 (30.6)
Non-minority	10512 (69.3)	10505 (69.2)	21017 (69.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	9461 (62.4)	9529 (62.8)	18990 (62.6)
Communities of Color	5683 (37.5)	5626 (37.1)	11309 (37.3)
Missing	26 (0.2)	26 (0.2)	52 (0.2)

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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=15181)	Total (N=30351)
Weight (kg)			
n	15009	14989	29998
Mean (SD)	85.87 (21.651)	85.71 (21.978)	85.79 (21.814)
Median	83.00	83.00	83.00
Min, Max	27.1, 223.0	30.3, 236.4	27.1, 236.4
Height (cm)			
n	15008	14989	29997
Mean (SD)	170.90 (10.049)	170.73 (9.935)	170.81 (9.992)
Median	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)			
n	15007	14985	29992
Mean (SD)	29.32 (6.688)	29.32 (6.858)	29.32 (6.773)
Median	28.13	28.12	28.13
Min, Max	10.3, 72.7	11.2, 86.1	10.3, 86.1

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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=15181)	Total (N=30351)
Occupational Risk, n (%) [2]	12505 (82.4)	12429 (81.9)	24934 (82.2)
Healthcare Workers	3831 (25.3)	3790 (25.0)	7621 (25.1)
Emergency Response	297 (2.0)	302 (2.0)	599 (2.0)
Retail or Restaurant Operations	974 (6.4)	954 (6.3)	1928 (6.4)
Manufacturing and Production Operations	421 (2.8)	425 (2.8)	846 (2.8)
Warehouse Shipping and Fulfillment Centers	175 (1.2)	191 (1.3)	366 (1.2)
Transportation and Delivery Services	473 (3.1)	482 (3.2)	955 (3.1)
Border Protection and Military Personnel	68 (0.4)	69 (0.5)	137 (0.5)
Personal Care and In-Home Services	469 (3.1)	469 (3.1)	938 (3.1)
Hospitality and Tourism Workers	232 (1.5)	237 (1.6)	469 (1.5)
Pastoral, Social or Public Health Workers	503 (3.3)	533 (3.5)	1036 (3.4)
Educators and Students	1552 (10.2)	1543 (10.2)	3095 (10.2)
Other	4803 (31.7)	4818 (31.7)	9621 (31.7)
Location and Living Circumstances Risk, n (%) [2]	12613 (83.1)	12646 (83.3)	25259 (83.2)
Resides in Nursing Home or Assisted Living Facility	29 (0.2)	33 (0.2)	62 (0.2)
Resides in Multi-Family Dwelling	409 (2.7)	462 (3.0)	871 (2.9)
Resides in High Density Housing	1307 (8.6)	1285 (8.5)	2592 (8.5)
Resides in Low Density, Multi-Family Setting	1482 (9.8)	1479 (9.7)	2961 (9.8)
Resides in a Single Family Home	8350 (55.0)	8329 (54.9)	16679 (55.0)
Other	2165 (14.3)	2189 (14.4)	4354 (14.3)

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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=8888)	Total (N=17774)
Age at Screening (Years)			
n	8886	8888	17774
Mean	43.8 (12.33)	44.0 (12.40)	43.9 (12.36)
(SD)			
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)	8888 (100)	17773(>99.9)
Mean	43.8 (12.33)	44.0 (12.40)	43.9 (12.36)
(SD)			
Median	44.0	44.0	44.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	1 (<0.1)	0	1 (<0.1)
Mean	72.0 (NA)		72.0 (NA)
(SD)			
Median	72.0		72.0
Min, Max	72, 72		72, 72
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8885(>99.9)	8888 (100)	17773(>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

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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=8888)	Total (N=17774)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8885 (>99.9)	8888 (100)	17773 (>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)	8888 (100)	17774 (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)	19 (0.2)	36 (0.2)
Significant Cardiac Disease	11 (0.1)	12 (0.1)	23 (0.1)
Severe Obesity	69 (0.8)	59 (0.7)	128 (0.7)
Diabetes	33 (0.4)	32 (0.4)	65 (0.4)
Liver Disease	8 (<0.1)	6 (<0.1)	14 (<0.1)
Human Immunodeficiency Virus Infection	13 (0.1)	14 (0.2)	27 (0.2)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	141 (1.6)	127 (1.4)	268 (1.5)
One Risk Factor for Severe COVID-19	132 (1.5)	115 (1.3)	247 (1.4)
Two or More Risk Factors for Severe COVID-19	9 (0.1)	12 (0.1)	21 (0.1)
No	8745 (98.4)	8761 (98.6)	17506 (98.5)

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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=8888)	Total (N=17774)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	8745 (98.4)	8761 (98.6)	17506 (98.5)
>=18 and <65 Years and at Risk	140 (1.6)	127 (1.4)	267 (1.5)
>=65 Years and Not at Risk	0	0	0
>=65 Years and at Risk	1 (<0.1)	0	1 (<0.1)
Baseline RT-PCR Results, n (%)			
Negative	8755 (98.5)	8728 (98.2)	17483 (98.4)
Positive	65 (0.7)	64 (0.7)	129 (0.7)
Missing	66 (0.7)	96 (1.1)	162 (0.9)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	8595 (96.7)	8555 (96.3)	17150 (96.5)
Positive	216 (2.4)	230 (2.6)	446 (2.5)
Missing	75 (0.8)	103 (1.2)	178 (1.0)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	8532 (96.0)	8468 (95.3)	17000 (95.6)
Positive	239 (2.7)	260 (2.9)	499 (2.8)
Missing	115 (1.3)	160 (1.8)	275 (1.5)
Sex, n (%)			
Male	4632 (52.1)	4544 (51.1)	9176 (51.6)
Female	4254 (47.9)	4344 (48.9)	8598 (48.4)

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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=8888)	Total (N=17774)
Race, n (%)			
White	6789 (76.4)	6756 (76.0)	13545 (76.2)
Black or African American	899 (10.1)	968 (10.9)	1867 (10.5)
Asian	570 (6.4)	501 (5.6)	1071 (6.0)
American Indian or Alaska Native	72 (0.8)	65 (0.7)	137 (0.8)
Native Hawaiian or Other Pacific Islander	20 (0.2)	25 (0.3)	45 (0.3)
Multiracial	232 (2.6)	231 (2.6)	463 (2.6)
Other	229 (2.6)	233 (2.6)	462 (2.6)
Not Reported	42 (0.5)	67 (0.8)	109 (0.6)
Unknown	33 (0.4)	42 (0.5)	75 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	2228 (25.1)	2209 (24.9)	4437 (25.0)
Not Hispanic or Latino	6585 (74.1)	6599 (74.2)	13184 (74.2)
Not Reported	43 (0.5)	58 (0.7)	101 (0.6)
Unknown	30 (0.3)	22 (0.2)	52 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	3104 (34.9)	3145 (35.4)	6249 (35.2)
Non-minority	5774 (65.0)	5729 (64.5)	11503 (64.7)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)
Race and Ethnicity Group, n (%) [6]			
White	4975 (56.0)	5005 (56.3)	9980 (56.1)
Communities of Color	3903 (43.9)	3869 (43.5)	7772 (43.7)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)

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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=8888)	Total (N=17774)
Weight (kg)			
n	8785	8773	17558
Mean (SD)	82.28 (18.036)	81.99 (18.145)	82.14 (18.091)
Median	80.80	80.50	80.70
Min, Max	30.6, 182.4	33.5, 178.7	30.6, 182.4
Height (cm)			
n	8786	8771	17557
Mean (SD)	171.25 (9.910)	171.05 (9.891)	171.15 (9.901)
Median	171.00	170.20	170.70
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0
Body Mass Index (kg/m^2)			
n	8785	8769	17554
Mean (SD)	27.95 (5.146)	27.92 (5.253)	27.93 (5.200)
Median	27.33	27.34	27.34
Min, Max	10.3, 53.1	11.2, 57.9	10.3, 57.9

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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=8888)	Total (N=17774)
Occupational Risk, n (%) [2]	7962 (89.6)	7929 (89.2)	15891 (89.4)
Healthcare Workers	2734 (30.8)	2735 (30.8)	5469 (30.8)
Emergency Response	220 (2.5)	233 (2.6)	453 (2.5)
Retail or Restaurant Operations	689 (7.8)	683 (7.7)	1372 (7.7)
Manufacturing and Production Operations	306 (3.4)	289 (3.3)	595 (3.3)
Warehouse Shipping and Fulfillment Centers	121 (1.4)	138 (1.6)	259 (1.5)
Transportation and Delivery Services	313 (3.5)	335 (3.8)	648 (3.6)
Border Protection and Military Personnel	51 (0.6)	53 (0.6)	104 (0.6)
Personal Care and In-Home Services	330 (3.7)	299 (3.4)	629 (3.5)
Hospitality and Tourism Workers	149 (1.7)	163 (1.8)	312 (1.8)
Pastoral, Social or Public Health Workers	264 (3.0)	296 (3.3)	560 (3.2)
Educators and Students	1113 (12.5)	1083 (12.2)	2196 (12.4)
Other	2591 (29.2)	2582 (29.1)	5173 (29.1)
Location and Living Circumstances Risk, n (%) [2]	7444 (83.8)	7481 (84.2)	14925 (84.0)
Resides in Nursing Home or Assisted Living Facility	6 (<0.1)	11 (0.1)	17 (<0.1)
Resides in Multi-Family Dwelling	266 (3.0)	304 (3.4)	570 (3.2)
Resides in High Density Housing	873 (9.8)	839 (9.4)	1712 (9.6)
Resides in Low Density, Multi-Family Setting	952 (10.7)	934 (10.5)	1886 (10.6)
Resides in a Single Family Home	4739 (53.3)	4771 (53.7)	9510 (53.5)
Other	1306 (14.7)	1329 (15.0)	2635 (14.8)

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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	49.2 (11.28)	48.9 (11.40)	49.0 (11.34)
(SD)			
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)
Mean	49.1 (11.26)	48.9 (11.38)	49.0 (11.32)
(SD)			
Median	51.0	51.0	51.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3 (0.1)	6 (0.2)	9 (0.2)
Mean	72.0 (7.00)	67.7 (4.37)	69.1 (5.37)
(SD)			
Median	72.0	65.5	66.0
Min, Max	65, 79	65, 76	65, 79
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

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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	485 (19.1)	455 (18.0)	940 (18.6)
Significant Cardiac Disease	285 (11.2)	306 (12.1)	591 (11.7)
Severe Obesity	809 (31.9)	807 (31.9)	1616 (31.9)
Diabetes	871 (34.4)	876 (34.6)	1747 (34.5)
Liver Disease	62 (2.4)	76 (3.0)	138 (2.7)
Human Immunodeficiency Virus Infection	59 (2.3)	62 (2.5)	121 (2.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	2163 (85.3)	2171 (85.8)	4334 (85.6)
One Risk Factor for Severe COVID-19	1805 (71.2)	1810 (71.5)	3615 (71.4)
Two or More Risk Factors for Severe COVID-19	358 (14.1)	361 (14.3)	719 (14.2)
No	372 (14.7)	359 (14.2)	731 (14.4)

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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 and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	371 (14.6)	357 (14.1)	728 (14.4)
>=18 and <65 Years and at Risk	2161 (85.2)	2167 (85.7)	4328 (85.4)
>=65 Years and Not at Risk	1 (<0.1)	2 (<0.1)	3 (<0.1)
>=65 Years and at Risk	2 (<0.1)	4 (0.2)	6 (0.1)
Baseline RT-PCR Results, n (%)			
Negative	2474 (97.6)	2478 (97.9)	4952 (97.8)
Positive	20 (0.8)	16 (0.6)	36 (0.7)
Missing	41 (1.6)	36 (1.4)	77 (1.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	2449 (96.6)	2451 (96.9)	4900 (96.7)
Positive	59 (2.3)	42 (1.7)	101 (2.0)
Missing	27 (1.1)	37 (1.5)	64 (1.3)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	2415 (95.3)	2427 (95.9)	4842 (95.6)
Positive	65 (2.6)	47 (1.9)	112 (2.2)
Missing	55 (2.2)	56 (2.2)	111 (2.2)
Sex, n (%)			
Male	1329 (52.4)	1305 (51.6)	2634 (52.0)
Female	1206 (47.6)	1225 (48.4)	2431 (48.0)

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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)
Race, n (%)			
White	1870 (73.8)	1900 (75.1)	3770 (74.4)
Black or African American	413 (16.3)	374 (14.8)	787 (15.5)
Asian	84 (3.3)	85 (3.4)	169 (3.3)
American Indian or Alaska Native	23 (0.9)	26 (1.0)	49 (1.0)
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)	16 (0.6)	34 (0.7)
Unknown	13 (0.5)	11 (0.4)	24 (0.5)
Ethnicity, n (%)			
Hispanic or Latino	552 (21.8)	558 (22.1)	1110 (21.9)
Not Hispanic or Latino	1960 (77.3)	1953 (77.2)	3913 (77.3)
Not Reported	15 (0.6)	14 (0.6)	29 (0.6)
Unknown	8 (0.3)	5 (0.2)	13 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	968 (38.2)	927 (36.6)	1895 (37.4)
Non-minority	1562 (61.6)	1597 (63.1)	3159 (62.4)
Missing	5 (0.2)	6 (0.2)	11 (0.2)
Race and Ethnicity Group, n (%) [6]			
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)

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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	2509	2500	5009
Mean (SD)	102.37 (28.335)	102.65 (28.960)	102.51 (28.646)
Median	99.00	99.69	99.27
Min, Max	27.1, 223.0	30.3, 236.4	27.1, 236.4
Height (cm)			
n	2508	2501	5009
Mean (SD)	170.93 (10.192)	170.75 (9.952)	170.84 (10.072)
Median	170.43	170.18	170.18
Min, Max	123.5, 203.2	111.0, 202.8	111.0, 203.2
Body Mass Index (kg/m^2)			
n	2508	2500	5008
Mean (SD)	35.01 (9.176)	35.21 (9.570)	35.11 (9.374)
Median	33.77	33.69	33.73
Min, Max	10.7, 72.7	11.7, 86.1	10.7, 86.1

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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]	2165 (85.4)	2144 (84.7)	4309 (85.1)
Healthcare Workers	593 (23.4)	595 (23.5)	1188 (23.5)
Emergency Response	58 (2.3)	49 (1.9)	107 (2.1)
Retail or Restaurant Operations	186 (7.3)	171 (6.8)	357 (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	98 (3.9)	97 (3.8)	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	270 (10.7)	276 (10.9)	546 (10.8)
Other	789 (31.1)	810 (32.0)	1599 (31.6)
Location and Living Circumstances Risk, n (%) [2]	2080 (82.1)	2046 (80.9)	4126 (81.5)
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	195 (7.7)	195 (7.7)	390 (7.7)
Resides in Low Density, Multi-Family Setting	275 (10.8)	301 (11.9)	576 (11.4)
Resides in a Single Family Home	1366 (53.9)	1288 (50.9)	2654 (52.4)
Other	331 (13.1)	315 (12.5)	646 (12.8)

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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	70.7 (4.90)	70.4 (4.66)	70.6 (4.79)
(SD)			
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)
Mean	40.0 (NA)	64.0 (NA)	52.0 (16.97)
(SD)			
Median	40.0	64.0	52.0
Min, Max	40, 40	64, 64	40, 64
>=65 Years	3748(>99.9)	3762(>99.9)	7510(>99.9)
Mean	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
(SD)			
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
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)	1205 (32.0)	2397 (31.9)
>=75 and <80 Years	506 (13.5)	466 (12.4)	972 (12.9)
>=80 Years	234 (6.2)	191 (5.1)	425 (5.7)

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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)	3105 (82.5)	6113 (81.4)
>=75 and <85 Years	691 (18.4)	616 (16.4)	1307 (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	242 (6.5)	236 (6.3)	478 (6.4)
Significant Cardiac Disease	448 (11.9)	434 (11.5)	882 (11.7)
Severe Obesity	143 (3.8)	159 (4.2)	302 (4.0)
Diabetes	536 (14.3)	527 (14.0)	1063 (14.2)
Liver Disease	26 (0.7)	18 (0.5)	44 (0.6)
Human Immunodeficiency Virus Infection	15 (0.4)	16 (0.4)	31 (0.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1114 (29.7)	1101 (29.3)	2215 (29.5)
One Risk Factor for Severe COVID-19	861 (23.0)	850 (22.6)	1711 (22.8)
Two or More Risk Factors for Severe COVID-19	253 (6.7)	251 (6.7)	504 (6.7)
No	2635 (70.3)	2662 (70.7)	5297 (70.5)

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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 and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 Years and Not at Risk	2635 (70.3)	2662 (70.7)	5297 (70.5)
>=65 Years and at Risk	1113 (29.7)	1100 (29.2)	2213 (29.5)
Baseline RT-PCR Results, n (%)			
Negative	3694 (98.5)	3711 (98.6)	7405 (98.6)
Positive	10 (0.3)	7 (0.2)	17 (0.2)
Missing	45 (1.2)	45 (1.2)	90 (1.2)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	3682 (98.2)	3684 (97.9)	7366 (98.1)
Positive	28 (0.7)	33 (0.9)	61 (0.8)
Missing	39 (1.0)	46 (1.2)	85 (1.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	3651 (97.4)	3655 (97.1)	7306 (97.3)
Positive	33 (0.9)	36 (1.0)	69 (0.9)
Missing	65 (1.7)	72 (1.9)	137 (1.8)
Sex, n (%)			
Male	2101 (56.0)	2074 (55.1)	4175 (55.6)
Female	1648 (44.0)	1689 (44.9)	3337 (44.4)

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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)
Race, n (%)			
White	3336 (89.0)	3373 (89.6)	6709 (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	33 (0.9)	27 (0.7)	60 (0.8)
Not Reported	13 (0.3)	13 (0.3)	26 (0.3)
Unknown	8 (0.2)	6 (0.2)	14 (0.2)
Ethnicity, n (%)			
Hispanic or Latino	334 (8.9)	354 (9.4)	688 (9.2)
Not Hispanic or Latino	3372 (89.9)	3366 (89.4)	6738 (89.7)
Not Reported	27 (0.7)	32 (0.9)	59 (0.8)
Unknown	16 (0.4)	11 (0.3)	27 (0.4)
Race and Ethnicity Group, n (%) [5]			
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 (%) [6]			
White	3060 (81.6)	3068 (81.5)	6128 (81.6)
Communities of Color	676 (18.0)	689 (18.3)	1365 (18.2)
Missing	13 (0.3)	6 (0.2)	19 (0.3)

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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	3715	3716	7431
Mean (SD)	83.22 (19.001)	83.08 (19.351)	83.15 (19.176)
Median	81.60	81.20	81.36
Min, Max	34.8, 184.5	31.5, 165.0	31.5, 184.5
Height (cm)			
n	3714	3717	7431
Mean (SD)	170.05 (10.228)	169.96 (9.990)	170.01 (10.109)
Median	170.18	170.18	170.18
Min, Max	124.5, 223.5	123.0, 208.3	123.0, 223.5
Body Mass Index (kg/m^2)			
n	3714	3716	7430
Mean (SD)	28.71 (5.877)	28.66 (5.879)	28.68 (5.877)
Median	27.73	27.85	27.78
Min, Max	12.1, 71.1	11.2, 62.9	11.2, 71.1

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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)
Occupational Risk, n (%) [2]	2378 (63.4)	2356 (62.6)	4734 (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	43 (1.1)	36 (1.0)	79 (1.1)
Pastoral, Social or Public Health Workers	138 (3.7)	147 (3.9)	285 (3.8)
Educators and Students	169 (4.5)	184 (4.9)	353 (4.7)
Other	1423 (38.0)	1426 (37.9)	2849 (37.9)
Location and Living Circumstances Risk, n (%) [2]	3089 (82.4)	3119 (82.9)	6208 (82.6)
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	239 (6.4)	251 (6.7)	490 (6.5)
Resides in Low Density, Multi-Family Setting	255 (6.8)	244 (6.5)	499 (6.6)
Resides in a Single Family Home	2245 (59.9)	2270 (60.3)	4515 (60.1)
Other	528 (14.1)	545 (14.5)	1073 (14.3)

Note: Footnotes are listed on the last page.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

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] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] 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.
[5] 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.
[6] 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.

Table 14.2.1.2.1
Summary of RT-PCR Test and Elecsys Anti-SARS-CoV-2 Assay Results at Baseline
Full Analysis Set

Baseline SARS-CoV-2 Status	Baseline RT-PCR Result [1]	Baseline Elecsys Result [1]	Placebo (N=15170) n (%)	mRNA-1273 (N=15181) n (%)	Total (N=30351) n (%)
Positive			337 (2.2)	343 (2.3)	680 (2.2)
	Positive	Positive	61 (0.4)	49 (0.3)	110 (0.4)
	Positive	Negative/Missing	34 (0.2)	38 (0.3)	72 (0.2)
	Negative/Missing	Positive	242 (1.6)	256 (1.7)	498 (1.6)
Negative	Negative	Negative	14598 (96.2)	14550 (95.8)	29148 (96.0)
Missing			235 (1.5)	288 (1.9)	523 (1.7)
	Negative	Missing	86 (0.6)	114 (0.8)	200 (0.7)
	Missing	Negative	94 (0.6)	102 (0.7)	196 (0.6)
	Missing	Missing	55 (0.4)	72 (0.5)	127 (0.4)

RT-PCR = reverse transcription polymerase chain reaction.
[1] Subjects with no RT-PCR result or no Elecsys result include those who were tested but had no result and those who were not tested.
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Table 14.2.1.3.3
Summary of RT-PCR Test Results for SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
	Placebo (N=14598)	mRNA-1273 (N=14550)	Placebo (N=337)	mRNA-1273 (N=343)	Placebo (N=15170)	mRNA-1273 (N=15181)
Baseline [1]						
Negative	14598 (100)	14550 (100)	239 (70.9)	253 (73.8)	14923 (98.4)	14917 (98.3)
Positive	0	0	95 (28.2)	87 (25.4)	95 (0.6)	87 (0.6)
Missing [2]	0	0	3 (0.9)	3 (0.9)	152 (1.0)	177 (1.2)
Day 29 [1]						
Negative	13694 (93.8)	13771 (94.6)	267 (79.2)	257 (74.9)	14152 (93.3)	14257 (93.9)
Positive	49 (0.3)	16 (0.1)	28 (8.3)	29 (8.5)	79 (0.5)	45 (0.3)
Missing [2]	855 (5.9)	763 (5.2)	42 (12.5)	57 (16.6)	939 (6.2)	879 (5.8)

RT-PCR = reverse transcription polymerase chain reaction.
[1] RT-PCR tests are scheduled at Day 1 (baseline) and Day 29 for all subjects in the study.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
[3] A subject may have multiple RT-PCR results, and will be counted under Positive if the subject had at least one positive result. A subject is counted in the time windows with the 1st occurrence of positive RT-PCR results excluding baseline and Day 29.
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Table 14.2.1.3.3
Summary of RT-PCR Test Results for SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
	Placebo (N=14598)	mRNA-1273 (N=14550)	Placebo (N=337)	mRNA-1273 (N=343)	Placebo (N=15170)	mRNA-1273 (N=15181)
RT-PCR Test Excluding Baseline and Day 29 [3]						
Negative	1050 (7.2)	990 (6.8)	16 (4.7)	20 (5.8)	1112 (7.3)	1066 (7.0)
Positive	300 (2.1)	25 (0.2)	6 (1.8)	8 (2.3)	308 (2.0)	34 (0.2)
Prior to 14 Days After First Injection	11 (3.7)	5 (20.0)	5 (83.3)	8 (100)	16 (5.2)	14 (41.2)
14 Days After First Injection and Prior to Second Injection	39 (13.0)	3 (12.0)	0	0	39 (12.7)	3 (8.8)
Second Injection and Prior to 14 Days After Second Injection	22 (7.3)	0	0	0	22 (7.1)	0
14 Days After Second Injection and Beyond	228 (76.0)	17 (68.0)	1 (16.7)	0	231 (75.0)	17 (50.0)

RT-PCR = reverse transcription polymerase chain reaction.
[1] RT-PCR tests are scheduled at Day 1 (baseline) and Day 29 for all subjects in the study.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
[3] A subject may have multiple RT-PCR results, and will be counted under Positive if the subject had at least one positive result. A subject is counted in the time windows with the 1st occurrence of positive RT-PCR results excluding baseline and Day 29.
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Table 14.2.1.5.1.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=185) n (%)	mRNA-1273 (N=11) n (%)
Number of Subjects with Any Symptom [1]	185 (100)	11 (100)
Respiratory Symptom		
Clinical Evidence of Pneumonia	4 (2.2)	0
Cough	155 (83.8)	6 (54.5)
Difficulty Breathing	55 (29.7)	1 (9.1)
Radiographical Evidence of Pneumonia	3 (1.6)	0
Shortness of Breath	78 (42.2)	2 (18.2)
Systemic Symptom		
Body Aches	111 (60.0)	7 (63.6)
Chills	95 (51.4)	4 (36.4)
Diarrhea	70 (37.8)	2 (18.2)
Fatigue	156 (84.3)	9 (81.8)
Fever [2]	54 (29.2)	2 (18.2)
Headache	145 (78.4)	10 (90.9)
Muscle Aches (Myalgia)	114 (61.6)	5 (45.5)
Nasal Congestion	138 (74.6)	8 (72.7)
Nausea	65 (35.1)	3 (27.3)
New Loss of Smell	115 (62.2)	3 (27.3)
New Loss of Taste	106 (57.3)	3 (27.3)
Runny Nose (Rhinorrhea)	121 (65.4)	6 (54.5)
Sore Throat	85 (45.9)	7 (63.6)
Vomiting	18 (9.7)	1 (9.1)

All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
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Table 14.2.1.5.1.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=185) n (%)	mRNA-1273 (N=11) n (%)
Number of Subjects with Any Severe Symptom [1]	32 (17.3)	0
Acute Renal Dysfunction	2 (1.1)	0
Acute Respiratory Distress Syndrome	1 (0.5)	0
ECMO	0	0
High-Flow Oxygen	1 (0.5)	0
Mechanical Ventilation	0	0
Non-Invasive Ventilation	1 (0.5)	0
Admission to An Intensive Care Unit due to SARS-CoV-2	1 (0.5)	0
Heart Rate >= 125 beats per minute	0	0
Hepatic Dysfunction	0	0
Neurologic Dysfunction	1 (0.5)	0
Oxygen Saturation <= 93% [3]	28 (15.1)	0
Oxygen Saturation of SpO2 <= 93% on Room Air at Sea Level	29 (15.7)	0
PaO2/FIO2 Ratio < 300 mmHg	0	0
Respiratory Failure	1 (0.5)	0
Respiratory Rate >= 30 per Minute	0	0
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	5 (2.7)	0
Vasopressors Required	0	0

All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
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Table 14.2.1.5.3.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set - Subjects with Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=30) n (%)	mRNA-1273 (N=0) n (%)
Number of Subjects with Any Symptom [1]	30 (100)	0
Respiratory Symptom		
Clinical Evidence of Pneumonia	4 (13.3)	0
Cough	28 (93.3)	0
Difficulty Breathing	16 (53.3)	0
Radiographical Evidence of Pneumonia	3 (10.0)	0
Shortness of Breath	23 (76.7)	0
Systemic Symptom		
Body Aches	26 (86.7)	0
Chills	19 (63.3)	0
Diarrhea	14 (46.7)	0
Fatigue	27 (90.0)	0
Fever [2]	13 (43.3)	0
Headache	25 (83.3)	0
Muscle Aches (Myalgia)	24 (80.0)	0
Nasal Congestion	21 (70.0)	0
Nausea	13 (43.3)	0
New Loss of Smell	16 (53.3)	0
New Loss of Taste	15 (50.0)	0
Runny Nose (Rhinorrhea)	18 (60.0)	0
Sore Throat	15 (50.0)	0
Vomiting	7 (23.3)	0

All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of severe COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
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Table 14.2.1.5.3.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set - Subjects with Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=30) n (%)	mRNA-1273 (N=0) n (%)
Number of Subjects with Any Severe Symptom [1]	30 (100)	0
Acute Renal Dysfunction	2 (6.7)	0
Acute Respiratory Distress Syndrome	1 (3.3)	0
ECMO	0	0
High-Flow Oxygen	1 (3.3)	0
Mechanical Ventilation	0	0
Non-Invasive Ventilation	1 (3.3)	0
Admission to An Intensive Care Unit due to SARS-CoV-2	1 (3.3)	0
Heart Rate >= 125 beats per minute	0	0
Hepatic Dysfunction	0	0
Neurologic Dysfunction	1 (3.3)	0
Oxygen Saturation <= 93% [3]	27 (90.0)	0
Oxygen Saturation of SpO2 <= 93% on Room Air at Sea Level	28 (93.3)	0
PaO2/FIO2 Ratio < 300 mmHg	0	0
Respiratory Failure	1 (3.3)	0
Respiratory Rate >= 30 per Minute	0	0
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	4 (13.3)	0
Vasopressors Required	0	0

All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of severe COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
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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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Solicited Adverse Reactions - N1	15163	15179	30342
Any Solicited Adverse Reactions	9108 (60.1)	14400 (94.9)	23508 (77.5)
95% CI	59.3, 60.8	94.5, 95.2	77.0, 77.9
Grade 1	5824 (38.4)	4822 (31.8)	10646 (35.1)
Grade 2	2613 (17.2)	6165 (40.6)	8778 (28.9)
Grade 3	662 (4.4)	3394 (22.4)	4056 (13.4)
Grade 4	9 (<0.1)	19 (0.1)	28 (<0.1)
Solicited Local Adverse Reactions - N1	15162	15179	30341
Any Solicited Local Adverse Reactions	4450 (29.3)	14027 (92.4)	18477 (60.9)
95% CI	28.6, 30.1	92.0, 92.8	60.3, 61.4
Grade 1	4152 (27.4)	9007 (59.3)	13159 (43.4)
Grade 2	153 (1.0)	3602 (23.7)	3755 (12.4)
Grade 3	145 (1.0)	1418 (9.3)	1563 (5.2)
Grade 4	0	0	0
Pain - N1	15162	15179	30341
Any	4037 (26.6)	13965 (92.0)	18002 (59.3)
Grade 1	3839 (25.3)	9827 (64.7)	13666 (45.0)
Grade 2	106 (0.7)	3216 (21.2)	3322 (10.9)
Grade 3	92 (0.6)	922 (6.1)	1014 (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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Erythema (Redness) - N1	15162	15179	30341
Any	117 (0.8)	1522 (10.0)	1639 (5.4)
Grade 1	80 (0.5)	607 (4.0)	687 (2.3)
Grade 2	10 (<0.1)	591 (3.9)	601 (2.0)
Grade 3	27 (0.2)	324 (2.1)	351 (1.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	15162	15179	30341
Any	95 (0.6)	2232 (14.7)	2327 (7.7)
Grade 1	64 (0.4)	1142 (7.5)	1206 (4.0)
Grade 2	15 (<0.1)	764 (5.0)	779 (2.6)
Grade 3	16 (0.1)	326 (2.1)	342 (1.1)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	15162	15179	30341
Any	1098 (7.2)	3011 (19.8)	4109 (13.5)
Grade 1	1002 (6.6)	2534 (16.7)	3536 (11.7)
Grade 2	51 (0.3)	367 (2.4)	418 (1.4)
Grade 3	45 (0.3)	110 (0.7)	155 (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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Solicited Systemic Adverse Reactions - N1	15163	15179	30342
Any Solicited Systemic Adverse Reactions	8112 (53.5)	12770 (84.1)	20882 (68.8)
95% CI	52.7, 54.3	83.5, 84.7	68.3, 69.3
Grade 1	4964 (32.7)	4059 (26.7)	9023 (29.7)
Grade 2	2583 (17.0)	6082 (40.1)	8665 (28.6)
Grade 3	556 (3.7)	2610 (17.2)	3166 (10.4)
Grade 4	9 (<0.1)	19 (0.1)	28 (<0.1)
Fever - N1	15162	15178	30340
Any	86 (0.6)	2353 (15.5)	2439 (8.0)
Grade 1	61 (0.4)	1409 (9.3)	1470 (4.8)
Grade 2	12 (<0.1)	715 (4.7)	727 (2.4)
Grade 3	4 (<0.1)	212 (1.4)	216 (0.7)
Grade 4	9 (<0.1)	17 (0.1)	26 (<0.1)
Headache - N1	15162	15179	30341
Any	5603 (37.0)	9825 (64.7)	15428 (50.8)
Grade 1	4363 (28.8)	5580 (36.8)	9943 (32.8)
Grade 2	899 (5.9)	3376 (22.2)	4275 (14.1)
Grade 3	341 (2.2)	869 (5.7)	1210 (4.0)
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 14.3.1.1.3
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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Fatigue - N1	15162	15179	30341
Any	5544 (36.6)	10627 (70.0)	16171 (53.3)
Grade 1	3348 (22.1)	3819 (25.2)	7167 (23.6)
Grade 2	1996 (13.2)	5279 (34.8)	7275 (24.0)
Grade 3	200 (1.3)	1528 (10.1)	1728 (5.7)
Grade 4	0	1 (<0.1)	1 (<0.1)
Myalgia - N1	15162	15179	30341
Any	3113 (20.5)	9334 (61.5)	12447 (41.0)
Grade 1	2201 (14.5)	3689 (24.3)	5890 (19.4)
Grade 2	814 (5.4)	4263 (28.1)	5077 (16.7)
Grade 3	98 (0.6)	1382 (9.1)	1480 (4.9)
Grade 4	0	0	0
Arthralgia - N1	15162	15179	30341
Any	2666 (17.6)	7044 (46.4)	9710 (32.0)
Grade 1	1884 (12.4)	3250 (21.4)	5134 (16.9)
Grade 2	702 (4.6)	2981 (19.6)	3683 (12.1)
Grade 3	80 (0.5)	812 (5.3)	892 (2.9)
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 14.3.1.1.3
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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Nausea/Vomiting - N1	15162	15179	30341
Any	1716 (11.3)	3484 (23.0)	5200 (17.1)
Grade 1	1378 (9.1)	2619 (17.3)	3997 (13.2)
Grade 2	315 (2.1)	835 (5.5)	1150 (3.8)
Grade 3	23 (0.2)	29 (0.2)	52 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Chills - N1	15162	15179	30341
Any	1470 (9.7)	6891 (45.4)	8361 (27.6)
Grade 1	1130 (7.5)	3137 (20.7)	4267 (14.1)
Grade 2	309 (2.0)	3543 (23.3)	3852 (12.7)
Grade 3	31 (0.2)	211 (1.4)	242 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Solicited Adverse Reactions - N1	11413	11412	22825
Any Solicited Adverse Reactions	7085 (62.1)	10887 (95.4)	17972 (78.7)
95% CI	61.2, 63.0	95.0, 95.8	78.2, 79.3
Grade 1	4465 (39.1)	3268 (28.6)	7733 (33.9)
Grade 2	2121 (18.6)	4841 (42.4)	6962 (30.5)
Grade 3	493 (4.3)	2761 (24.2)	3254 (14.3)
Grade 4	6 (<0.1)	17 (0.1)	23 (0.1)
Solicited Local Adverse Reactions - N1	11412	11412	22824
Any Solicited Local Adverse Reactions	3578 (31.4)	10676 (93.6)	14254 (62.5)
95% CI	30.5, 32.2	93.1, 94.0	61.8, 63.1
Grade 1	3384 (29.7)	6490 (56.9)	9874 (43.3)
Grade 2	116 (1.0)	3053 (26.8)	3169 (13.9)
Grade 3	78 (0.7)	1133 (9.9)	1211 (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.
[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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Pain - N1	11412	11412	22824
Any	3275 (28.7)	10639 (93.2)	13914 (61.0)
Grade 1	3152 (27.6)	7083 (62.1)	10235 (44.8)
Grade 2	80 (0.7)	2777 (24.3)	2857 (12.5)
Grade 3	43 (0.4)	779 (6.8)	822 (3.6)
Grade 4	0	0	0
Erythema (Redness) - N1	11412	11412	22824
Any	84 (0.7)	1188 (10.4)	1272 (5.6)
Grade 1	55 (0.5)	477 (4.2)	532 (2.3)
Grade 2	7 (<0.1)	472 (4.1)	479 (2.1)
Grade 3	22 (0.2)	239 (2.1)	261 (1.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	11412	11412	22824
Any	67 (0.6)	1755 (15.4)	1822 (8.0)
Grade 1	50 (0.4)	908 (8.0)	958 (4.2)
Grade 2	11 (<0.1)	610 (5.3)	621 (2.7)
Grade 3	6 (<0.1)	237 (2.1)	243 (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 14.3.1.1.6
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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Lymphadenopathy - N1 [1]	11412	11412	22824
Any	875 (7.7)	2534 (22.2)	3409 (14.9)
Grade 1	808 (7.1)	2118 (18.6)	2926 (12.8)
Grade 2	43 (0.4)	336 (2.9)	379 (1.7)
Grade 3	24 (0.2)	80 (0.7)	104 (0.5)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	11413	11412	22825
Any Solicited Systemic Adverse Reactions	6348 (55.6)	9817 (86.0)	16165 (70.8)
95% CI	54.7, 56.5	85.4, 86.7	70.2, 71.4
Grade 1	3803 (33.3)	2852 (25.0)	6655 (29.2)
Grade 2	2099 (18.4)	4790 (42.0)	6889 (30.2)
Grade 3	440 (3.9)	2158 (18.9)	2598 (11.4)
Grade 4	6 (<0.1)	17 (0.1)	23 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Fever - N1	11412	11411	22823
Any	75 (0.7)	1977 (17.3)	2052 (9.0)
Grade 1	56 (0.5)	1152 (10.1)	1208 (5.3)
Grade 2	10 (<0.1)	615 (5.4)	625 (2.7)
Grade 3	3 (<0.1)	194 (1.7)	197 (0.9)
Grade 4	6 (<0.1)	16 (0.1)	22 (<0.1)
Headache - N1	11412	11412	22824
Any	4526 (39.7)	7819 (68.5)	12345 (54.1)
Grade 1	3453 (30.3)	4216 (36.9)	7669 (33.6)
Grade 2	797 (7.0)	2881 (25.2)	3678 (16.1)
Grade 3	276 (2.4)	722 (6.3)	998 (4.4)
Grade 4	0	0	0
Fatigue - N1	11412	11412	22824
Any	4342 (38.0)	8188 (71.7)	12530 (54.9)
Grade 1	2558 (22.4)	2788 (24.4)	5346 (23.4)
Grade 2	1625 (14.2)	4147 (36.3)	5772 (25.3)
Grade 3	159 (1.4)	1252 (11.0)	1411 (6.2)
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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Myalgia - N1	11412	11412	22824
Any	2430 (21.3)	7384 (64.7)	9814 (43.0)
Grade 1	1677 (14.7)	2730 (23.9)	4407 (19.3)
Grade 2	674 (5.9)	3491 (30.6)	4165 (18.2)
Grade 3	79 (0.7)	1163 (10.2)	1242 (5.4)
Grade 4	0	0	0
Arthralgia - N1	11412	11412	22824
Any	1997 (17.5)	5532 (48.5)	7529 (33.0)
Grade 1	1379 (12.1)	2416 (21.2)	3795 (16.6)
Grade 2	553 (4.8)	2435 (21.3)	2988 (13.1)
Grade 3	65 (0.6)	680 (6.0)	745 (3.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Nausea/Vomiting - N1	11412	11412	22824
Any	1443 (12.6)	2921 (25.6)	4364 (19.1)
Grade 1	1153 (10.1)	2183 (19.1)	3336 (14.6)
Grade 2	274 (2.4)	722 (6.3)	996 (4.4)
Grade 3	16 (0.1)	16 (0.1)	32 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Chills - N1	11412	11412	22824
Any	1204 (10.6)	5661 (49.6)	6865 (30.1)
Grade 1	915 (8.0)	2485 (21.8)	3400 (14.9)
Grade 2	266 (2.3)	2997 (26.3)	3263 (14.3)
Grade 3	23 (0.2)	179 (1.6)	202 (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 14.3.1.1.6
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=3767) n (%)	Total (N=7517) n (%)
Solicited Adverse Reactions - N1	3750	3767	7517
Any Solicited Adverse Reactions	2023 (53.9)	3513 (93.3)	5536 (73.6)
95% CI	52.3, 55.6	92.4, 94.0	72.6, 74.6
Grade 1	1359 (36.2)	1554 (41.3)	2913 (38.8)
Grade 2	492 (13.1)	1324 (35.1)	1816 (24.2)
Grade 3	169 (4.5)	633 (16.8)	802 (10.7)
Grade 4	3 (<0.1)	2 (<0.1)	5 (<0.1)
Solicited Local Adverse Reactions - N1	3750	3767	7517
Any Solicited Local Adverse Reactions	872 (23.3)	3351 (89.0)	4223 (56.2)
95% CI	21.9, 24.6	87.9, 89.9	55.0, 57.3
Grade 1	768 (20.5)	2517 (66.8)	3285 (43.7)
Grade 2	37 (1.0)	549 (14.6)	586 (7.8)
Grade 3	67 (1.8)	285 (7.6)	352 (4.7)
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 14.3.1.1.6
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=3767) n (%)	Total (N=7517) n (%)
Pain - N1	3750	3767	7517
Any	762 (20.3)	3326 (88.3)	4088 (54.4)
Grade 1	687 (18.3)	2744 (72.8)	3431 (45.6)
Grade 2	26 (0.7)	439 (11.7)	465 (6.2)
Grade 3	49 (1.3)	143 (3.8)	192 (2.6)
Grade 4	0	0	0
Erythema (Redness) - N1	3750	3767	7517
Any	33 (0.9)	334 (8.9)	367 (4.9)
Grade 1	25 (0.7)	130 (3.5)	155 (2.1)
Grade 2	3 (<0.1)	119 (3.2)	122 (1.6)
Grade 3	5 (0.1)	85 (2.3)	90 (1.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	3750	3767	7517
Any	28 (0.7)	477 (12.7)	505 (6.7)
Grade 1	14 (0.4)	234 (6.2)	248 (3.3)
Grade 2	4 (0.1)	154 (4.1)	158 (2.1)
Grade 3	10 (0.3)	89 (2.4)	99 (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=3767) n (%)	Total (N=7517) n (%)
Lymphadenopathy - N1 [1]	3750	3767	7517
Any	223 (5.9)	477 (12.7)	700 (9.3)
Grade 1	194 (5.2)	416 (11.0)	610 (8.1)
Grade 2	8 (0.2)	31 (0.8)	39 (0.5)
Grade 3	21 (0.6)	30 (0.8)	51 (0.7)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	3750	3767	7517
Any Solicited Systemic Adverse Reactions	1764 (47.0)	2953 (78.4)	4717 (62.8)
95% CI	45.4, 48.7	77.0, 79.7	61.6, 63.8
Grade 1	1161 (31.0)	1207 (32.0)	2368 (31.5)
Grade 2	484 (12.9)	1292 (34.3)	1776 (23.6)
Grade 3	116 (3.1)	452 (12.0)	568 (7.6)
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=3767) n (%)	Total (N=7517) n (%)
Fever - N1	3750	3767	7517
Any	11 (0.3)	376 (10.0)	387 (5.1)
Grade 1	5 (0.1)	257 (6.8)	262 (3.5)
Grade 2	2 (<0.1)	100 (2.7)	102 (1.4)
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	3767	7517
Any	1077 (28.7)	2006 (53.3)	3083 (41.0)
Grade 1	910 (24.3)	1364 (36.2)	2274 (30.3)
Grade 2	102 (2.7)	495 (13.1)	597 (7.9)
Grade 3	65 (1.7)	147 (3.9)	212 (2.8)
Grade 4	0	0	0
Fatigue - N1	3750	3767	7517
Any	1202 (32.1)	2439 (64.7)	3641 (48.4)
Grade 1	790 (21.1)	1031 (27.4)	1821 (24.2)
Grade 2	371 (9.9)	1132 (30.1)	1503 (20.0)
Grade 3	41 (1.1)	276 (7.3)	317 (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=3767) n (%)	Total (N=7517) n (%)
Myalgia - N1	3750	3767	7517
Any	683 (18.2)	1950 (51.8)	2633 (35.0)
Grade 1	524 (14.0)	959 (25.5)	1483 (19.7)
Grade 2	140 (3.7)	772 (20.5)	912 (12.1)
Grade 3	19 (0.5)	219 (5.8)	238 (3.2)
Grade 4	0	0	0
Arthralgia - N1	3750	3767	7517
Any	669 (17.8)	1512 (40.1)	2181 (29.0)
Grade 1	505 (13.5)	834 (22.1)	1339 (17.8)
Grade 2	149 (4.0)	546 (14.5)	695 (9.2)
Grade 3	15 (0.4)	132 (3.5)	147 (2.0)
Grade 4	0	0	0
Nausea/Vomiting - N1	3750	3767	7517
Any	273 (7.3)	563 (14.9)	836 (11.1)
Grade 1	225 (6.0)	436 (11.6)	661 (8.8)
Grade 2	41 (1.1)	113 (3.0)	154 (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=3767) n (%)	Total (N=7517) n (%)
Chills - N1	3750	3767	7517
Any	266 (7.1)	1230 (32.7)	1496 (19.9)
Grade 1	215 (5.7)	652 (17.3)	867 (11.5)
Grade 2	43 (1.1)	546 (14.5)	589 (7.8)
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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Solicited Adverse Reactions - N1	14583	14538	29121
Any Solicited Adverse Reactions	7023 (48.2)	12800 (88.0)	19823 (68.1)
95% CI	47.3, 49.0	87.5, 88.6	67.5, 68.6
Grade 1	4978 (34.1)	9029 (62.1)	14007 (48.1)
Grade 2	1696 (11.6)	2972 (20.4)	4668 (16.0)
Grade 3	344 (2.4)	795 (5.5)	1139 (3.9)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)
Solicited Local Adverse Reactions - N1	14579	14534	29113
Any Solicited Local Adverse Reactions	2891 (19.8)	12276 (84.5)	15167 (52.1)
95% CI	19.2, 20.5	83.9, 85.0	51.5, 52.7
Grade 1	2738 (18.8)	10352 (71.2)	13090 (45.0)
Grade 2	80 (0.5)	1423 (9.8)	1503 (5.2)
Grade 3	73 (0.5)	501 (3.4)	574 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Pain - N1	14579	14534	29113
Any	2563 (17.6)	12207 (84.0)	14770 (50.7)
Grade 1	2459 (16.9)	10601 (72.9)	13060 (44.9)
Grade 2	52 (0.4)	1211 (8.3)	1263 (4.3)
Grade 3	52 (0.4)	395 (2.7)	447 (1.5)
Grade 4	0	0	0
Erythema (Redness) - N1	14579	14533	29112
Any	63 (0.4)	409 (2.8)	472 (1.6)
Grade 1	45 (0.3)	254 (1.7)	299 (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	14579	14533	29112
Any	49 (0.3)	895 (6.2)	944 (3.2)
Grade 1	36 (0.2)	582 (4.0)	618 (2.1)
Grade 2	7 (<0.1)	235 (1.6)	242 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Lymphadenopathy - N1 [1]	14579	14533	29112
Any	689 (4.7)	1465 (10.1)	2154 (7.4)
Grade 1	637 (4.4)	1327 (9.1)	1964 (6.7)
Grade 2	27 (0.2)	94 (0.6)	121 (0.4)
Grade 3	25 (0.2)	44 (0.3)	69 (0.2)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14583	14537	29120
Any Solicited Systemic Adverse Reactions	6167 (42.3)	7954 (54.7)	14121 (48.5)
95% CI	41.5, 43.1	53.9, 55.5	47.9, 49.1
Grade 1	4203 (28.8)	5171 (35.6)	9374 (32.2)
Grade 2	1665 (11.4)	2367 (16.3)	4032 (13.8)
Grade 3	294 (2.0)	412 (2.8)	706 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Fever - N1	14582	14535	29117
Any	38 (0.3)	79 (0.5)	117 (0.4)
Grade 1	26 (0.2)	51 (0.4)	77 (0.3)
Grade 2	5 (<0.1)	16 (0.1)	21 (<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	14578	14533	29111
Any	3865 (26.5)	4723 (32.5)	8588 (29.5)
Grade 1	3182 (21.8)	3795 (26.1)	6977 (24.0)
Grade 2	496 (3.4)	679 (4.7)	1175 (4.0)
Grade 3	187 (1.3)	249 (1.7)	436 (1.5)
Grade 4	0	0	0
Fatigue - N1	14578	14533	29111
Any	3988 (27.4)	5400 (37.2)	9388 (32.2)
Grade 1	2618 (18.0)	3468 (23.9)	6086 (20.9)
Grade 2	1271 (8.7)	1793 (12.3)	3064 (10.5)
Grade 3	99 (0.7)	138 (0.9)	237 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Myalgia - N1	14578	14533	29111
Any	1987 (13.6)	3244 (22.3)	5231 (18.0)
Grade 1	1510 (10.4)	2318 (15.9)	3828 (13.1)
Grade 2	433 (3.0)	845 (5.8)	1278 (4.4)
Grade 3	44 (0.3)	81 (0.6)	125 (0.4)
Grade 4	0	0	0
Arthralgia - N1	14578	14533	29111
Any	1707 (11.7)	2381 (16.4)	4088 (14.0)
Grade 1	1294 (8.9)	1761 (12.1)	3055 (10.5)
Grade 2	379 (2.6)	565 (3.9)	944 (3.2)
Grade 3	34 (0.2)	54 (0.4)	88 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Nausea/Vomiting - N1	14578	14533	29111
Any	1033 (7.1)	1193 (8.2)	2226 (7.6)
Grade 1	860 (5.9)	998 (6.9)	1858 (6.4)
Grade 2	161 (1.1)	186 (1.3)	347 (1.2)
Grade 3	12 (<0.1)	9 (<0.1)	21 (<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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Chills - N1	14578	14533	29111
Any	836 (5.7)	1144 (7.9)	1980 (6.8)
Grade 1	675 (4.6)	878 (6.0)	1553 (5.3)
Grade 2	148 (1.0)	246 (1.7)	394 (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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Solicited Adverse Reactions - N1	337	342	679
Any Solicited Adverse Reactions	137 (40.7)	261 (76.3)	398 (58.6)
95% CI	35.4, 46.1	71.4, 80.7	54.8, 62.3
Grade 1	82 (24.3)	136 (39.8)	218 (32.1)
Grade 2	41 (12.2)	96 (28.1)	137 (20.2)
Grade 3	13 (3.9)	28 (8.2)	41 (6.0)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Solicited Local Adverse Reactions - N1	337	342	679
Any Solicited Local Adverse Reactions	60 (17.8)	246 (71.9)	306 (45.1)
95% CI	13.9, 22.3	66.8, 76.6	41.3, 48.9
Grade 1	56 (16.6)	178 (52.0)	234 (34.5)
Grade 2	1 (0.3)	55 (16.1)	56 (8.2)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Pain - N1	337	342	679
Any	56 (16.6)	244 (71.3)	300 (44.2)
Grade 1	54 (16.0)	183 (53.5)	237 (34.9)
Grade 2	1 (0.3)	51 (14.9)	52 (7.7)
Grade 3	1 (0.3)	10 (2.9)	11 (1.6)
Grade 4	0	0	0
Erythema (Redness) - N1	337	342	679
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	337	342	679
Any	2 (0.6)	19 (5.6)	21 (3.1)
Grade 1	2 (0.6)	10 (2.9)	12 (1.8)
Grade 2	0	8 (2.3)	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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Lymphadenopathy - N1 [1]	337	342	679
Any	18 (5.3)	53 (15.5)	71 (10.5)
Grade 1	17 (5.0)	38 (11.1)	55 (8.1)
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	337	342	679
Any Solicited Systemic Adverse Reactions	121 (35.9)	210 (61.4)	331 (48.7)
95% CI	30.8, 41.3	56.0, 66.6	44.9, 52.6
Grade 1	69 (20.5)	107 (31.3)	176 (25.9)
Grade 2	40 (11.9)	80 (23.4)	120 (17.7)
Grade 3	11 (3.3)	22 (6.4)	33 (4.9)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Fever - N1	336	342	678
Any	6 (1.8)	32 (9.4)	38 (5.6)
Grade 1	3 (0.9)	20 (5.8)	23 (3.4)
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	337	342	679
Any	82 (24.3)	131 (38.3)	213 (31.4)
Grade 1	59 (17.5)	88 (25.7)	147 (21.6)
Grade 2	16 (4.7)	31 (9.1)	47 (6.9)
Grade 3	7 (2.1)	12 (3.5)	19 (2.8)
Grade 4	0	0	0
Fatigue - N1	337	342	679
Any	72 (21.4)	134 (39.2)	206 (30.3)
Grade 1	40 (11.9)	69 (20.2)	109 (16.1)
Grade 2	28 (8.3)	56 (16.4)	84 (12.4)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Myalgia - N1	337	342	679
Any	47 (13.9)	124 (36.3)	171 (25.2)
Grade 1	27 (8.0)	70 (20.5)	97 (14.3)
Grade 2	18 (5.3)	48 (14.0)	66 (9.7)
Grade 3	2 (0.6)	6 (1.8)	8 (1.2)
Grade 4	0	0	0
Arthralgia - N1	337	342	679
Any	40 (11.9)	85 (24.9)	125 (18.4)
Grade 1	21 (6.2)	53 (15.5)	74 (10.9)
Grade 2	17 (5.0)	27 (7.9)	44 (6.5)
Grade 3	2 (0.6)	5 (1.5)	7 (1.0)
Grade 4	0	0	0
Nausea/Vomiting - N1	337	342	679
Any	26 (7.7)	42 (12.3)	68 (10.0)
Grade 1	18 (5.3)	30 (8.8)	48 (7.1)
Grade 2	8 (2.4)	12 (3.5)	20 (2.9)
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.
[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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Chills - N1	337	342	679
Any	27 (8.0)	80 (23.4)	107 (15.8)
Grade 1	17 (5.0)	43 (12.6)	60 (8.8)
Grade 2	9 (2.7)	34 (9.9)	43 (6.3)
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Adverse Reactions - N1	235	288	523
Any Solicited Adverse Reactions	124 (52.8)	258 (89.6)	382 (73.0)
95% CI	46.2, 59.3	85.5, 92.9	69.0, 76.8
Grade 1	87 (37.0)	177 (61.5)	264 (50.5)
Grade 2	33 (14.0)	56 (19.4)	89 (17.0)
Grade 3	4 (1.7)	25 (8.7)	29 (5.5)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	235	288	523
Any Solicited Local Adverse Reactions	46 (19.6)	243 (84.4)	289 (55.3)
95% CI	14.7, 25.2	79.7, 88.4	50.9, 59.6
Grade 1	43 (18.3)	201 (69.8)	244 (46.7)
Grade 2	1 (0.4)	27 (9.4)	28 (5.4)
Grade 3	2 (0.9)	15 (5.2)	17 (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 14.3.1.1.7
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Pain - N1	235	288	523
Any	39 (16.6)	239 (83.0)	278 (53.2)
Grade 1	36 (15.3)	206 (71.5)	242 (46.3)
Grade 2	1 (0.4)	22 (7.6)	23 (4.4)
Grade 3	2 (0.9)	11 (3.8)	13 (2.5)
Grade 4	0	0	0
Erythema (Redness) - N1	235	288	523
Any	1 (0.4)	12 (4.2)	13 (2.5)
Grade 1	1 (0.4)	8 (2.8)	9 (1.7)
Grade 2	0	4 (1.4)	4 (0.8)
Grade 3	0	0	0
Grade 4	0	0	0
Swelling (Hardness) - N1	235	288	523
Any	1 (0.4)	18 (6.3)	19 (3.6)
Grade 1	1 (0.4)	13 (4.5)	14 (2.7)
Grade 2	0	2 (0.7)	2 (0.4)
Grade 3	0	3 (1.0)	3 (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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Lymphadenopathy - N1 [1]	235	288	523
Any	15 (6.4)	35 (12.2)	50 (9.6)
Grade 1	14 (6.0)	30 (10.4)	44 (8.4)
Grade 2	0	4 (1.4)	4 (0.8)
Grade 3	1 (0.4)	1 (0.3)	2 (0.4)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	235	288	523
Any Solicited Systemic Adverse Reactions	111 (47.2)	156 (54.2)	267 (51.1)
95% CI	40.7, 53.8	48.2, 60.0	46.7, 55.4
Grade 1	74 (31.5)	94 (32.6)	168 (32.1)
Grade 2	34 (14.5)	49 (17.0)	83 (15.9)
Grade 3	3 (1.3)	13 (4.5)	16 (3.1)
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: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Fever - N1	235	287	522
Any	0	4 (1.4)	4 (0.8)
Grade 1	0	3 (1.0)	3 (0.6)
Grade 2	0	1 (0.3)	1 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Headache - N1	235	288	523
Any	80 (34.0)	97 (33.7)	177 (33.8)
Grade 1	65 (27.7)	70 (24.3)	135 (25.8)
Grade 2	13 (5.5)	17 (5.9)	30 (5.7)
Grade 3	2 (0.9)	10 (3.5)	12 (2.3)
Grade 4	0	0	0
Fatigue - N1	235	288	523
Any	73 (31.1)	101 (35.1)	174 (33.3)
Grade 1	51 (21.7)	62 (21.5)	113 (21.6)
Grade 2	20 (8.5)	36 (12.5)	56 (10.7)
Grade 3	2 (0.9)	3 (1.0)	5 (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 14.3.1.1.7
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Myalgia - N1	235	288	523
Any	37 (15.7)	73 (25.3)	110 (21.0)
Grade 1	30 (12.8)	57 (19.8)	87 (16.6)
Grade 2	6 (2.6)	13 (4.5)	19 (3.6)
Grade 3	1 (0.4)	3 (1.0)	4 (0.8)
Grade 4	0	0	0
Arthralgia - N1	235	288	523
Any	36 (15.3)	45 (15.6)	81 (15.5)
Grade 1	26 (11.1)	32 (11.1)	58 (11.1)
Grade 2	9 (3.8)	12 (4.2)	21 (4.0)
Grade 3	1 (0.4)	1 (0.3)	2 (0.4)
Grade 4	0	0	0
Nausea/Vomiting - N1	235	288	523
Any	15 (6.4)	27 (9.4)	42 (8.0)
Grade 1	12 (5.1)	20 (6.9)	32 (6.1)
Grade 2	3 (1.3)	6 (2.1)	9 (1.7)
Grade 3	0	1 (0.3)	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 14.3.1.1.7
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Chills - N1	235	288	523
Any	15 (6.4)	29 (10.1)	44 (8.4)
Grade 1	14 (6.0)	19 (6.6)	33 (6.3)
Grade 2	1 (0.4)	9 (3.1)	10 (1.9)
Grade 3	0	1 (0.3)	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 14.3.1.1.8
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Solicited Adverse Reactions - N1	14119	14183	28302
Any Solicited Adverse Reactions	6056 (42.9)	13101 (92.4)	19157 (67.7)
95% CI	42.1, 43.7	91.9, 92.8	67.1, 68.2
Grade 1	4235 (30.0)	4676 (33.0)	8911 (31.5)
Grade 2	1485 (10.5)	5609 (39.5)	7094 (25.1)
Grade 3	333 (2.4)	2802 (19.8)	3135 (11.1)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Solicited Local Adverse Reactions - N1	14116	14179	28295
Any Solicited Local Adverse Reactions	2650 (18.8)	12594 (88.8)	15244 (53.9)
95% CI	18.1, 19.4	88.3, 89.3	53.3, 54.5
Grade 1	2505 (17.7)	8489 (59.9)	10994 (38.9)
Grade 2	77 (0.5)	3122 (22.0)	3199 (11.3)
Grade 3	68 (0.5)	983 (6.9)	1051 (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.
[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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Pain - N1	14116	14179	28295
Any	2403 (17.0)	12536 (88.4)	14939 (52.8)
Grade 1	2310 (16.4)	9194 (64.8)	11504 (40.7)
Grade 2	56 (0.4)	2758 (19.5)	2814 (9.9)
Grade 3	37 (0.3)	584 (4.1)	621 (2.2)
Grade 4	0	0	0
Erythema (Redness) - N1	14116	14179	28295
Any	52 (0.4)	1227 (8.7)	1279 (4.5)
Grade 1	35 (0.2)	434 (3.1)	469 (1.7)
Grade 2	3 (<0.1)	521 (3.7)	524 (1.9)
Grade 3	14 (<0.1)	272 (1.9)	286 (1.0)
Grade 4	0	0	0
Swelling (Hardness) - N1	14116	14179	28295
Any	47 (0.3)	1746 (12.3)	1793 (6.3)
Grade 1	28 (0.2)	874 (6.2)	902 (3.2)
Grade 2	8 (<0.1)	629 (4.4)	637 (2.3)
Grade 3	11 (<0.1)	243 (1.7)	254 (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 14.3.1.1.8
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Lymphadenopathy - N1 [1]	14116	14179	28295
Any	546 (3.9)	2018 (14.2)	2564 (9.1)
Grade 1	503 (3.6)	1682 (11.9)	2185 (7.7)
Grade 2	24 (0.2)	271 (1.9)	295 (1.0)
Grade 3	19 (0.1)	65 (0.5)	84 (0.3)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14118	14183	28301
Any Solicited Systemic Adverse Reactions	5168 (36.6)	11290 (79.6)	16458 (58.2)
95% CI	35.8, 37.4	78.9, 80.3	57.6, 58.7
Grade 1	3427 (24.3)	3593 (25.3)	7020 (24.8)
Grade 2	1462 (10.4)	5414 (38.2)	6876 (24.3)
Grade 3	276 (2.0)	2269 (16.0)	2545 (9.0)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<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 14.3.1.1.8
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Fever - N1	14113	14176	28289
Any	42 (0.3)	2223 (15.7)	2265 (8.0)
Grade 1	32 (0.2)	1326 (9.4)	1358 (4.8)
Grade 2	5 (<0.1)	685 (4.8)	690 (2.4)
Grade 3	2 (<0.1)	199 (1.4)	201 (0.7)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)
Headache - N1	14116	14179	28295
Any	3311 (23.5)	8348 (58.9)	11659 (41.2)
Grade 1	2655 (18.8)	4648 (32.8)	7303 (25.8)
Grade 2	497 (3.5)	3058 (21.6)	3555 (12.6)
Grade 3	159 (1.1)	642 (4.5)	801 (2.8)
Grade 4	0	0	0
Fatigue - N1	14114	14179	28293
Any	3294 (23.3)	9310 (65.7)	12604 (44.5)
Grade 1	2115 (15.0)	3332 (23.5)	5447 (19.3)
Grade 2	1077 (7.6)	4583 (32.3)	5660 (20.0)
Grade 3	102 (0.7)	1395 (9.8)	1497 (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.
[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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Myalgia - N1	14114	14179	28293
Any	1738 (12.3)	8229 (58.0)	9967 (35.2)
Grade 1	1252 (8.9)	3117 (22.0)	4369 (15.4)
Grade 2	436 (3.1)	3828 (27.0)	4264 (15.1)
Grade 3	50 (0.4)	1284 (9.1)	1334 (4.7)
Grade 4	0	0	0
Arthralgia - N1	14114	14179	28293
Any	1516 (10.7)	6083 (42.9)	7599 (26.9)
Grade 1	1102 (7.8)	2717 (19.2)	3819 (13.5)
Grade 2	371 (2.6)	2613 (18.4)	2984 (10.5)
Grade 3	43 (0.3)	753 (5.3)	796 (2.8)
Grade 4	0	0	0
Nausea/Vomiting - N1	14114	14179	28293
Any	912 (6.5)	2700 (19.0)	3612 (12.8)
Grade 1	740 (5.2)	2022 (14.3)	2762 (9.8)
Grade 2	161 (1.1)	658 (4.6)	819 (2.9)
Grade 3	11 (<0.1)	19 (0.1)	30 (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 14.3.1.1.8
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Chills - N1	14114	14179	28293
Any	778 (5.5)	6292 (44.4)	7070 (25.0)
Grade 1	604 (4.3)	2807 (19.8)	3411 (12.1)
Grade 2	157 (1.1)	3296 (23.2)	3453 (12.2)
Grade 3	17 (0.1)	189 (1.3)	206 (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 14.3.1.1.8
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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Solicited Adverse Reactions - N1	232	230	462
Any Solicited Adverse Reactions	81 (34.9)	186 (80.9)	267 (57.8)
95% CI	28.8, 41.4	75.2, 85.7	53.1, 62.3
Grade 1	51 (22.0)	91 (39.6)	142 (30.7)
Grade 2	27 (11.6)	66 (28.7)	93 (20.1)
Grade 3	3 (1.3)	29 (12.6)	32 (6.9)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	231	230	461
Any Solicited Local Adverse Reactions	42 (18.2)	172 (74.8)	214 (46.4)
95% CI	13.4, 23.8	68.7, 80.3	41.8, 51.1
Grade 1	35 (15.2)	125 (54.3)	160 (34.7)
Grade 2	5 (2.2)	35 (15.2)	40 (8.7)
Grade 3	2 (0.9)	12 (5.2)	14 (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.
[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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Pain - N1	231	230	461
Any	36 (15.6)	169 (73.5)	205 (44.5)
Grade 1	32 (13.9)	125 (54.3)	157 (34.1)
Grade 2	3 (1.3)	36 (15.7)	39 (8.5)
Grade 3	1 (0.4)	8 (3.5)	9 (2.0)
Grade 4	0	0	0
Erythema (Redness) - N1	231	230	461
Any	1 (0.4)	8 (3.5)	9 (2.0)
Grade 1	0	2 (0.9)	2 (0.4)
Grade 2	0	3 (1.3)	3 (0.7)
Grade 3	1 (0.4)	3 (1.3)	4 (0.9)
Grade 4	0	0	0
Swelling (Hardness) - N1	231	230	461
Any	1 (0.4)	11 (4.8)	12 (2.6)
Grade 1	0	4 (1.7)	4 (0.9)
Grade 2	1 (0.4)	5 (2.2)	6 (1.3)
Grade 3	0	2 (0.9)	2 (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 14.3.1.1.8
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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Lymphadenopathy - N1 [1]	231	230	461
Any	11 (4.8)	30 (13.0)	41 (8.9)
Grade 1	8 (3.5)	20 (8.7)	28 (6.1)
Grade 2	3 (1.3)	8 (3.5)	11 (2.4)
Grade 3	0	2 (0.9)	2 (0.4)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	232	230	462
Any Solicited Systemic Adverse Reactions	71 (30.6)	150 (65.2)	221 (47.8)
95% CI	24.7, 37.0	58.7, 71.4	43.2, 52.5
Grade 1	42 (18.1)	61 (26.5)	103 (22.3)
Grade 2	28 (12.1)	68 (29.6)	96 (20.8)
Grade 3	1 (0.4)	21 (9.1)	22 (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.
[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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Fever - N1	231	230	461
Any	1 (0.4)	31 (13.5)	32 (6.9)
Grade 1	1 (0.4)	20 (8.7)	21 (4.6)
Grade 2	0	9 (3.9)	9 (2.0)
Grade 3	0	2 (0.9)	2 (0.4)
Grade 4	0	0	0
Headache - N1	231	230	461
Any	43 (18.6)	97 (42.2)	140 (30.4)
Grade 1	36 (15.6)	60 (26.1)	96 (20.8)
Grade 2	7 (3.0)	31 (13.5)	38 (8.2)
Grade 3	0	6 (2.6)	6 (1.3)
Grade 4	0	0	0
Fatigue - N1	231	230	461
Any	53 (22.9)	104 (45.2)	157 (34.1)
Grade 1	30 (13.0)	42 (18.3)	72 (15.6)
Grade 2	22 (9.5)	50 (21.7)	72 (15.6)
Grade 3	1 (0.4)	12 (5.2)	13 (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.
[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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Myalgia - N1	231	230	461
Any	32 (13.9)	115 (50.0)	147 (31.9)
Grade 1	20 (8.7)	59 (25.7)	79 (17.1)
Grade 2	12 (5.2)	45 (19.6)	57 (12.4)
Grade 3	0	11 (4.8)	11 (2.4)
Grade 4	0	0	0
Arthralgia - N1	231	230	461
Any	24 (10.4)	76 (33.0)	100 (21.7)
Grade 1	17 (7.4)	37 (16.1)	54 (11.7)
Grade 2	7 (3.0)	35 (15.2)	42 (9.1)
Grade 3	0	4 (1.7)	4 (0.9)
Grade 4	0	0	0
Nausea/Vomiting - N1	231	230	461
Any	13 (5.6)	34 (14.8)	47 (10.2)
Grade 1	10 (4.3)	26 (11.3)	36 (7.8)
Grade 2	3 (1.3)	7 (3.0)	10 (2.2)
Grade 3	0	1 (0.4)	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 14.3.1.1.8
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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Chills - N1	231	230	461
Any	17 (7.4)	78 (33.9)	95 (20.6)
Grade 1	14 (6.1)	39 (17.0)	53 (11.5)
Grade 2	3 (1.3)	39 (17.0)	42 (9.1)
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 14.3.1.1.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Solicited Adverse Reactions - N1	215	264	479
Any Solicited Adverse Reactions	95 (44.2)	247 (93.6)	342 (71.4)
95% CI	37.4, 51.1	89.9, 96.2	67.1, 75.4
Grade 1	68 (31.6)	88 (33.3)	156 (32.6)
Grade 2	22 (10.2)	106 (40.2)	128 (26.7)
Grade 3	5 (2.3)	53 (20.1)	58 (12.1)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	215	264	479
Any Solicited Local Adverse Reactions	43 (20.0)	240 (90.9)	283 (59.1)
95% CI	14.9, 26.0	86.8, 94.1	54.5, 63.5
Grade 1	41 (19.1)	164 (62.1)	205 (42.8)
Grade 2	0	51 (19.3)	51 (10.6)
Grade 3	2 (0.9)	25 (9.5)	27 (5.6)
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 14.3.1.1.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Pain - N1	215	264	479
Any	38 (17.7)	238 (90.2)	276 (57.6)
Grade 1	36 (16.7)	179 (67.8)	215 (44.9)
Grade 2	0	47 (17.8)	47 (9.8)
Grade 3	2 (0.9)	12 (4.5)	14 (2.9)
Grade 4	0	0	0
Erythema (Redness) - N1	215	264	479
Any	3 (1.4)	22 (8.3)	25 (5.2)
Grade 1	3 (1.4)	6 (2.3)	9 (1.9)
Grade 2	0	4 (1.5)	4 (0.8)
Grade 3	0	12 (4.5)	12 (2.5)
Grade 4	0	0	0
Swelling (Hardness) - N1	215	264	479
Any	1 (0.5)	32 (12.1)	33 (6.9)
Grade 1	1 (0.5)	12 (4.5)	13 (2.7)
Grade 2	0	11 (4.2)	11 (2.3)
Grade 3	0	9 (3.4)	9 (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 14.3.1.1.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Lymphadenopathy - N1 [1]	215	264	479
Any	10 (4.7)	42 (15.9)	52 (10.9)
Grade 1	10 (4.7)	35 (13.3)	45 (9.4)
Grade 2	0	7 (2.7)	7 (1.5)
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	215	264	479
Any Solicited Systemic Adverse Reactions	84 (39.1)	212 (80.3)	296 (61.8)
95% CI	32.5, 45.9	75.0, 84.9	57.3, 66.2
Grade 1	57 (26.5)	69 (26.1)	126 (26.3)
Grade 2	22 (10.2)	108 (40.9)	130 (27.1)
Grade 3	5 (2.3)	35 (13.3)	40 (8.4)
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 14.3.1.1.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Fever - N1	215	263	478
Any	0	24 (9.1)	24 (5.0)
Grade 1	0	18 (6.8)	18 (3.8)
Grade 2	0	5 (1.9)	5 (1.0)
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Headache - N1	215	264	479
Any	56 (26.0)	157 (59.5)	213 (44.5)
Grade 1	48 (22.3)	96 (36.4)	144 (30.1)
Grade 2	5 (2.3)	50 (18.9)	55 (11.5)
Grade 3	3 (1.4)	11 (4.2)	14 (2.9)
Grade 4	0	0	0
Fatigue - N1	215	264	479
Any	56 (26.0)	168 (63.6)	224 (46.8)
Grade 1	37 (17.2)	58 (22.0)	95 (19.8)
Grade 2	16 (7.4)	89 (33.7)	105 (21.9)
Grade 3	3 (1.4)	21 (8.0)	24 (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.
[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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Myalgia - N1	215	264	479
Any	39 (18.1)	164 (62.1)	203 (42.4)
Grade 1	28 (13.0)	63 (23.9)	91 (19.0)
Grade 2	9 (4.2)	78 (29.5)	87 (18.2)
Grade 3	2 (0.9)	23 (8.7)	25 (5.2)
Grade 4	0	0	0
Arthralgia - N1	215	264	479
Any	29 (13.5)	125 (47.3)	154 (32.2)
Grade 1	23 (10.7)	48 (18.2)	71 (14.8)
Grade 2	5 (2.3)	64 (24.2)	69 (14.4)
Grade 3	1 (0.5)	13 (4.9)	14 (2.9)
Grade 4	0	0	0
Nausea/Vomiting - N1	215	264	479
Any	9 (4.2)	51 (19.3)	60 (12.5)
Grade 1	6 (2.8)	42 (15.9)	48 (10.0)
Grade 2	3 (1.4)	9 (3.4)	12 (2.5)
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 14.3.1.1.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Chills - N1	215	264	479
Any	14 (6.5)	112 (42.4)	126 (26.3)
Grade 1	8 (3.7)	53 (20.1)	61 (12.7)
Grade 2	6 (2.8)	57 (21.6)	63 (13.2)
Grade 3	0	2 (0.8)	2 (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 14.3.1.1.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Solicited Adverse Reactions - N1	14591	14548	29139
Any Solicited Adverse Reactions	8808 (60.4)	13847 (95.2)	22655 (77.7)
95% CI	59.6, 61.2	94.8, 95.5	77.3, 78.2
Grade 1	5648 (38.7)	4609 (31.7)	10257 (35.2)
Grade 2	2514 (17.2)	5947 (40.9)	8461 (29.0)
Grade 3	638 (4.4)	3273 (22.5)	3911 (13.4)
Grade 4	8 (<0.1)	18 (0.1)	26 (<0.1)
Solicited Local Adverse Reactions - N1	14590	14548	29138
Any Solicited Local Adverse Reactions	4304 (29.5)	13490 (92.7)	17794 (61.1)
95% CI	28.8, 30.2	92.3, 93.1	60.5, 61.6
Grade 1	4022 (27.6)	8658 (59.5)	12680 (43.5)
Grade 2	146 (1.0)	3475 (23.9)	3621 (12.4)
Grade 3	136 (0.9)	1357 (9.3)	1493 (5.1)
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 14.3.1.1.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Pain - N1	14590	14548	29138
Any	3907 (26.8)	13433 (92.3)	17340 (59.5)
Grade 1	3720 (25.5)	9458 (65.0)	13178 (45.2)
Grade 2	101 (0.7)	3092 (21.3)	3193 (11.0)
Grade 3	86 (0.6)	883 (6.1)	969 (3.3)
Grade 4	0	0	0
Erythema (Redness) - N1	14590	14548	29138
Any	109 (0.7)	1477 (10.2)	1586 (5.4)
Grade 1	75 (0.5)	590 (4.1)	665 (2.3)
Grade 2	10 (<0.1)	580 (4.0)	590 (2.0)
Grade 3	24 (0.2)	307 (2.1)	331 (1.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	14590	14548	29138
Any	91 (0.6)	2167 (14.9)	2258 (7.7)
Grade 1	61 (0.4)	1110 (7.6)	1171 (4.0)
Grade 2	14 (<0.1)	744 (5.1)	758 (2.6)
Grade 3	16 (0.1)	313 (2.2)	329 (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 14.3.1.1.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Lymphadenopathy - N1 [1]	14590	14548	29138
Any	1054 (7.2)	2880 (19.8)	3934 (13.5)
Grade 1	963 (6.6)	2435 (16.7)	3398 (11.7)
Grade 2	48 (0.3)	342 (2.4)	390 (1.3)
Grade 3	43 (0.3)	103 (0.7)	146 (0.5)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14591	14548	29139
Any Solicited Systemic Adverse Reactions	7841 (53.7)	12293 (84.5)	20134 (69.1)
95% CI	52.9, 54.6	83.9, 85.1	68.6, 69.6
Grade 1	4814 (33.0)	3886 (26.7)	8700 (29.9)
Grade 2	2482 (17.0)	5862 (40.3)	8344 (28.6)
Grade 3	537 (3.7)	2527 (17.4)	3064 (10.5)
Grade 4	8 (<0.1)	18 (0.1)	26 (<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 14.3.1.1.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Fever - N1	14591	14548	29139
Any	79 (0.5)	2273 (15.6)	2352 (8.1)
Grade 1	57 (0.4)	1356 (9.3)	1413 (4.8)
Grade 2	10 (<0.1)	694 (4.8)	704 (2.4)
Grade 3	4 (<0.1)	207 (1.4)	211 (0.7)
Grade 4	8 (<0.1)	16 (0.1)	24 (<0.1)
Headache - N1	14590	14548	29138
Any	5402 (37.0)	9477 (65.1)	14879 (51.1)
Grade 1	4210 (28.9)	5372 (36.9)	9582 (32.9)
Grade 2	863 (5.9)	3273 (22.5)	4136 (14.2)
Grade 3	329 (2.3)	832 (5.7)	1161 (4.0)
Grade 4	0	0	0
Fatigue - N1	14590	14548	29138
Any	5353 (36.7)	10273 (70.6)	15626 (53.6)
Grade 1	3237 (22.2)	3690 (25.4)	6927 (23.8)
Grade 2	1925 (13.2)	5096 (35.0)	7021 (24.1)
Grade 3	191 (1.3)	1486 (10.2)	1677 (5.8)
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 14.3.1.1.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Myalgia - N1	14590	14548	29138
Any	2991 (20.5)	8974 (61.7)	11965 (41.1)
Grade 1	2126 (14.6)	3528 (24.3)	5654 (19.4)
Grade 2	772 (5.3)	4104 (28.2)	4876 (16.7)
Grade 3	93 (0.6)	1342 (9.2)	1435 (4.9)
Grade 4	0	0	0
Arthralgia - N1	14590	14548	29138
Any	2563 (17.6)	6780 (46.6)	9343 (32.1)
Grade 1	1820 (12.5)	3130 (21.5)	4950 (17.0)
Grade 2	667 (4.6)	2858 (19.6)	3525 (12.1)
Grade 3	76 (0.5)	791 (5.4)	867 (3.0)
Grade 4	0	1 (<0.1)	1 (<0.1)
Nausea/Vomiting - N1	14590	14548	29138
Any	1662 (11.4)	3352 (23.0)	5014 (17.2)
Grade 1	1341 (9.2)	2520 (17.3)	3861 (13.3)
Grade 2	298 (2.0)	804 (5.5)	1102 (3.8)
Grade 3	23 (0.2)	27 (0.2)	50 (0.2)
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 14.3.1.1.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Chills - N1	14590	14548	29138
Any	1407 (9.6)	6644 (45.7)	8051 (27.6)
Grade 1	1087 (7.5)	3017 (20.7)	4104 (14.1)
Grade 2	290 (2.0)	3422 (23.5)	3712 (12.7)
Grade 3	30 (0.2)	205 (1.4)	235 (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 14.3.1.1.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Solicited Adverse Reactions - N1	337	343	680
Any Solicited Adverse Reactions	155 (46.0)	282 (82.2)	437 (64.3)
95% CI	40.6, 51.5	77.8, 86.1	60.5, 67.9
Grade 1	84 (24.9)	122 (35.6)	206 (30.3)
Grade 2	54 (16.0)	110 (32.1)	164 (24.1)
Grade 3	16 (4.7)	49 (14.3)	65 (9.6)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Solicited Local Adverse Reactions - N1	337	343	680
Any Solicited Local Adverse Reactions	77 (22.8)	271 (79.0)	348 (51.2)
95% CI	18.5, 27.7	74.3, 83.2	47.3, 55.0
Grade 1	66 (19.6)	180 (52.5)	246 (36.2)
Grade 2	6 (1.8)	68 (19.8)	74 (10.9)
Grade 3	5 (1.5)	23 (6.7)	28 (4.1)
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 14.3.1.1.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Pain - N1	337	343	680
Any	70 (20.8)	268 (78.1)	338 (49.7)
Grade 1	64 (19.0)	183 (53.4)	247 (36.3)
Grade 2	4 (1.2)	69 (20.1)	73 (10.7)
Grade 3	2 (0.6)	16 (4.7)	18 (2.6)
Grade 4	0	0	0
Erythema (Redness) - N1	337	343	680
Any	4 (1.2)	16 (4.7)	20 (2.9)
Grade 1	1 (0.3)	6 (1.7)	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
Swelling (Hardness) - N1	337	343	680
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

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 14.3.1.1.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Lymphadenopathy - N1 [1]	337	343	680
Any	22 (6.5)	70 (20.4)	92 (13.5)
Grade 1	18 (5.3)	49 (14.3)	67 (9.9)
Grade 2	3 (0.9)	15 (4.4)	18 (2.6)
Grade 3	1 (0.3)	6 (1.7)	7 (1.0)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	337	343	680
Any Solicited Systemic Adverse Reactions	140 (41.5)	240 (70.0)	380 (55.9)
95% CI	36.2, 47.0	64.8, 74.8	52.1, 59.7
Grade 1	72 (21.4)	96 (28.0)	168 (24.7)
Grade 2	55 (16.3)	106 (30.9)	161 (23.7)
Grade 3	12 (3.6)	37 (10.8)	49 (7.2)
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 14.3.1.1.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Fever - N1	336	343	679
Any	7 (2.1)	54 (15.7)	61 (9.0)
Grade 1	4 (1.2)	34 (9.9)	38 (5.6)
Grade 2	2 (0.6)	15 (4.4)	17 (2.5)
Grade 3	0	4 (1.2)	4 (0.6)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Headache - N1	337	343	680
Any	98 (29.1)	165 (48.1)	263 (38.7)
Grade 1	70 (20.8)	101 (29.4)	171 (25.1)
Grade 2	21 (6.2)	47 (13.7)	68 (10.0)
Grade 3	7 (2.1)	17 (5.0)	24 (3.5)
Grade 4	0	0	0
Fatigue - N1	337	343	680
Any	96 (28.5)	168 (49.0)	264 (38.8)
Grade 1	50 (14.8)	67 (19.5)	117 (17.2)
Grade 2	41 (12.2)	83 (24.2)	124 (18.2)
Grade 3	5 (1.5)	18 (5.2)	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.
[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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Myalgia - N1	337	343	680
Any	64 (19.0)	176 (51.3)	240 (35.3)
Grade 1	35 (10.4)	87 (25.4)	122 (17.9)
Grade 2	27 (8.0)	74 (21.6)	101 (14.9)
Grade 3	2 (0.6)	15 (4.4)	17 (2.5)
Grade 4	0	0	0
Arthralgia - N1	337	343	680
Any	53 (15.7)	126 (36.7)	179 (26.3)
Grade 1	30 (8.9)	66 (19.2)	96 (14.1)
Grade 2	21 (6.2)	53 (15.5)	74 (10.9)
Grade 3	2 (0.6)	7 (2.0)	9 (1.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	337	343	680
Any	36 (10.7)	64 (18.7)	100 (14.7)
Grade 1	25 (7.4)	47 (13.7)	72 (10.6)
Grade 2	11 (3.3)	16 (4.7)	27 (4.0)
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 14.3.1.1.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Chills - N1	337	343	680
Any	38 (11.3)	124 (36.2)	162 (23.8)
Grade 1	25 (7.4)	62 (18.1)	87 (12.8)
Grade 2	12 (3.6)	59 (17.2)	71 (10.4)
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 14.3.1.1.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Adverse Reactions - N1	235	288	523
Any Solicited Adverse Reactions	145 (61.7)	271 (94.1)	416 (79.5)
95% CI	55.2, 67.9	90.7, 96.5	75.8, 82.9
Grade 1	92 (39.1)	91 (31.6)	183 (35.0)
Grade 2	45 (19.1)	108 (37.5)	153 (29.3)
Grade 3	8 (3.4)	72 (25.0)	80 (15.3)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	235	288	523
Any Solicited Local Adverse Reactions	69 (29.4)	266 (92.4)	335 (64.1)
95% CI	23.6, 35.6	88.7, 95.2	59.8, 68.2
Grade 1	64 (27.2)	169 (58.7)	233 (44.6)
Grade 2	1 (0.4)	59 (20.5)	60 (11.5)
Grade 3	4 (1.7)	38 (13.2)	42 (8.0)
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 14.3.1.1.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Pain - N1	235	288	523
Any	60 (25.5)	264 (91.7)	324 (62.0)
Grade 1	55 (23.4)	186 (64.6)	241 (46.1)
Grade 2	1 (0.4)	55 (19.1)	56 (10.7)
Grade 3	4 (1.7)	23 (8.0)	27 (5.2)
Grade 4	0	0	0
Erythema (Redness) - N1	235	288	523
Any	4 (1.7)	29 (10.1)	33 (6.3)
Grade 1	4 (1.7)	11 (3.8)	15 (2.9)
Grade 2	0	6 (2.1)	6 (1.1)
Grade 3	0	12 (4.2)	12 (2.3)
Grade 4	0	0	0
Swelling (Hardness) - N1	235	288	523
Any	1 (0.4)	39 (13.5)	40 (7.6)
Grade 1	1 (0.4)	19 (6.6)	20 (3.8)
Grade 2	0	10 (3.5)	10 (1.9)
Grade 3	0	10 (3.5)	10 (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 14.3.1.1.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Lymphadenopathy - N1 [1]	235	288	523
Any	22 (9.4)	61 (21.2)	83 (15.9)
Grade 1	21 (8.9)	50 (17.4)	71 (13.6)
Grade 2	0	10 (3.5)	10 (1.9)
Grade 3	1 (0.4)	1 (0.3)	2 (0.4)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	235	288	523
Any Solicited Systemic Adverse Reactions	131 (55.7)	237 (82.3)	368 (70.4)
95% CI	49.1, 62.2	77.4, 86.5	66.2, 74.2
Grade 1	78 (33.2)	77 (26.7)	155 (29.6)
Grade 2	46 (19.6)	114 (39.6)	160 (30.6)
Grade 3	7 (3.0)	46 (16.0)	53 (10.1)
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 14.3.1.1.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Fever - N1	235	287	522
Any	0	26 (9.1)	26 (5.0)
Grade 1	0	19 (6.6)	19 (3.6)
Grade 2	0	6 (2.1)	6 (1.1)
Grade 3	0	1 (0.3)	1 (0.2)
Grade 4	0	0	0
Headache - N1	235	288	523
Any	103 (43.8)	183 (63.5)	286 (54.7)
Grade 1	83 (35.3)	107 (37.2)	190 (36.3)
Grade 2	15 (6.4)	56 (19.4)	71 (13.6)
Grade 3	5 (2.1)	20 (6.9)	25 (4.8)
Grade 4	0	0	0
Fatigue - N1	235	288	523
Any	95 (40.4)	186 (64.6)	281 (53.7)
Grade 1	61 (26.0)	62 (21.5)	123 (23.5)
Grade 2	30 (12.8)	100 (34.7)	130 (24.9)
Grade 3	4 (1.7)	24 (8.3)	28 (5.4)
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 14.3.1.1.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Myalgia - N1	235	288	523
Any	58 (24.7)	184 (63.9)	242 (46.3)
Grade 1	40 (17.0)	74 (25.7)	114 (21.8)
Grade 2	15 (6.4)	85 (29.5)	100 (19.1)
Grade 3	3 (1.3)	25 (8.7)	28 (5.4)
Grade 4	0	0	0
Arthralgia - N1	235	288	523
Any	50 (21.3)	138 (47.9)	188 (35.9)
Grade 1	34 (14.5)	54 (18.8)	88 (16.8)
Grade 2	14 (6.0)	70 (24.3)	84 (16.1)
Grade 3	2 (0.9)	14 (4.9)	16 (3.1)
Grade 4	0	0	0
Nausea/Vomiting - N1	235	288	523
Any	18 (7.7)	68 (23.6)	86 (16.4)
Grade 1	12 (5.1)	52 (18.1)	64 (12.2)
Grade 2	6 (2.6)	15 (5.2)	21 (4.0)
Grade 3	0	1 (0.3)	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 14.3.1.1.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Chills - N1	235	288	523
Any	25 (10.6)	123 (42.7)	148 (28.3)
Grade 1	18 (7.7)	58 (20.1)	76 (14.5)
Grade 2	7 (3.0)	62 (21.5)	69 (13.2)
Grade 3	0	3 (1.0)	3 (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 14.3.1.3.1
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=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Solicited Adverse Reactions - N1	15155	15168	30323
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1596 (10.5)	1572 (10.4)	3168 (10.4)
Day 1, after Vaccination (at Home)	2147 (14.2)	6767 (44.6)	8914 (29.4)
Day 2	1607 (10.6)	4493 (29.6)	6100 (20.1)
Day 3	747 (4.9)	288 (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	244 (1.6)	45 (0.3)	289 (1.0)
Day 7	201 (1.3)	40 (0.3)	241 (0.8)
Solicited Local Adverse Reactions - N1	15151	15164	30315
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1139 (7.5)	1129 (7.4)	2268 (7.5)
Day 1, after Vaccination (at Home)	766 (5.1)	6385 (42.1)	7151 (23.6)
Day 2	580 (3.8)	4911 (32.4)	5491 (18.1)
Day 3	217 (1.4)	255 (1.7)	472 (1.6)
Day 4	117 (0.8)	43 (0.3)	160 (0.5)
Day 5	86 (0.6)	14 (<0.1)	100 (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=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Pain - N1	15151	15164	30315
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1100 (7.3)	1088 (7.2)	2188 (7.2)
Day 1, after Vaccination (at Home)	701 (4.6)	6351 (41.9)	7052 (23.3)
Day 2	491 (3.2)	4930 (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	56 (0.4)	9 (<0.1)	65 (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	15151	15163	30314
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	10 (<0.1)	12 (<0.1)
Day 1, after Vaccination (at Home)	19 (0.1)	52 (0.3)	71 (0.2)
Day 2	19 (0.1)	228 (1.5)	247 (0.8)
Day 3	12 (<0.1)	112 (0.7)	124 (0.4)
Day 4	5 (<0.1)	14 (<0.1)	19 (<0.1)
Day 5	5 (<0.1)	8 (<0.1)	13 (<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=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Swelling (Hardness) - N1	15151	15163	30314
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	11 (<0.1)	190 (1.3)	201 (0.7)
Day 2	19 (0.1)	591 (3.9)	610 (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)	3 (<0.1)	7 (<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]	15151	15163	30314
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)	490 (3.2)	652 (2.2)
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)	57 (0.4)	117 (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=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Solicited Systemic Adverse Reactions - N1	15155	15167	30322
Day 1, 30 Minutes after Vaccination (at Study Clinic)	683 (4.5)	648 (4.3)	1331 (4.4)
Day 1, after Vaccination (at Home)	2004 (13.2)	2908 (19.2)	4912 (16.2)
Day 2	1622 (10.7)	2889 (19.0)	4511 (14.9)
Day 3	783 (5.2)	887 (5.8)	1670 (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	272 (1.8)	222 (1.5)	494 (1.6)
Day 7	229 (1.5)	191 (1.3)	420 (1.4)
Fever - N1	15153	15164	30317
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)	16 (0.1)	21 (<0.1)
Day 2	5 (<0.1)	56 (0.4)	61 (0.2)
Day 3	8 (<0.1)	25 (0.2)	33 (0.1)
Day 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Day 5	9 (<0.1)	7 (<0.1)	16 (<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=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Headache - N1	15150	15163	30313
Day 1, 30 Minutes after Vaccination (at Study Clinic)	364 (2.4)	360 (2.4)	724 (2.4)
Day 1, after Vaccination (at Home)	981 (6.5)	1350 (8.9)	2331 (7.7)
Day 2	961 (6.3)	1548 (10.2)	2509 (8.3)
Day 3	551 (3.6)	710 (4.7)	1261 (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)	231 (1.5)	502 (1.7)
Day 7	228 (1.5)	215 (1.4)	443 (1.5)
Fatigue - N1	15150	15163	30313
Day 1, 30 Minutes after Vaccination (at Study Clinic)	236 (1.6)	248 (1.6)	484 (1.6)
Day 1, after Vaccination (at Home)	1372 (9.1)	1876 (12.4)	3248 (10.7)
Day 2	1093 (7.2)	2132 (14.1)	3225 (10.6)
Day 3	534 (3.5)	688 (4.5)	1222 (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	155 (1.0)	122 (0.8)	277 (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=15155) n	(%)	mRNA-1273 (N=15168) n	(%)	Total (N=30323) n	(%)
Myalgia - N1	15150		15163		30313	
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)	903	(6.0)	1353	(4.5)
Day 2	587	(3.9)	1473	(9.7)	2060	(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	119	(0.8)	95	(0.6)	214	(0.7)
Day 7	114	(0.8)	81	(0.5)	195	(0.6)
Arthralgia - N1	15150		15163		30313	
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)	942	(6.2)	1437	(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=15155) n	(%)	mRNA-1273 (N=15168) n	(%)	Total (N=30323) n	(%)
Nausea/Vomiting - N1	15150		15163		30313	
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	106	(0.7)	81	(0.5)	187	(0.6)
Day 6	119	(0.8)	80	(0.5)	199	(0.7)
Day 7	87	(0.6)	73	(0.5)	160	(0.5)
Chills - N1	15150		15163		30313	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	86	(0.6)	73	(0.5)	159	(0.5)
Day 1, after Vaccination (at Home)	195	(1.3)	272	(1.8)	467	(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	80	(0.5)	60	(0.4)	140	(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=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Solicited Adverse Reactions - N1	14566	14677	29243
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1561 (10.7)	1455 (9.9)	3016 (10.3)
Day 1, after Vaccination (at Home)	1884 (12.9)	8219 (56.0)	10103 (34.5)
Day 2	1223 (8.4)	3652 (24.9)	4875 (16.7)
Day 3	575 (3.9)	141 (1.0)	716 (2.4)
Day 4	348 (2.4)	29 (0.2)	377 (1.3)
Day 5	274 (1.9)	14 (<0.1)	288 (1.0)
Day 6	203 (1.4)	12 (<0.1)	215 (0.7)
Day 7	164 (1.1)	12 (<0.1)	176 (0.6)
Solicited Local Adverse Reactions - N1	14562	14673	29235
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1193 (8.2)	1109 (7.6)	2302 (7.9)
Day 1, after Vaccination (at Home)	757 (5.2)	7992 (54.5)	8749 (29.9)
Day 2	408 (2.8)	3702 (25.2)	4110 (14.1)
Day 3	180 (1.2)	156 (1.1)	336 (1.1)
Day 4	82 (0.6)	26 (0.2)	108 (0.4)
Day 5	55 (0.4)	8 (<0.1)	63 (0.2)
Day 6	31 (0.2)	8 (<0.1)	39 (0.1)
Day 7	29 (0.2)	5 (<0.1)	34 (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=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Pain - N1	14562	14673	29235
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1161 (8.0)	1068 (7.3)	2229 (7.6)
Day 1, after Vaccination (at Home)	703 (4.8)	7969 (54.3)	8672 (29.7)
Day 2	332 (2.3)	3714 (25.3)	4046 (13.8)
Day 3	144 (1.0)	155 (1.1)	299 (1.0)
Day 4	59 (0.4)	23 (0.2)	82 (0.3)
Day 5	38 (0.3)	5 (<0.1)	43 (0.1)
Day 6	24 (0.2)	6 (<0.1)	30 (0.1)
Day 7	16 (0.1)	3 (<0.1)	19 (<0.1)
Erythema (Redness) - N1	14562	14673	29235
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	4 (<0.1)	12 (<0.1)
Day 1, after Vaccination (at Home)	20 (0.1)	114 (0.8)	134 (0.5)
Day 2	9 (<0.1)	511 (3.5)	520 (1.8)
Day 3	10 (<0.1)	495 (3.4)	505 (1.7)
Day 4	2 (<0.1)	113 (0.8)	115 (0.4)
Day 5	3 (<0.1)	14 (<0.1)	17 (<0.1)
Day 6	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 7	1 (<0.1)	3 (<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 14.3.1.3.2
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=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Swelling (Hardness) - N1	14562	14673	29235
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (<0.1)	17 (0.1)	29 (<0.1)
Day 1, after Vaccination (at Home)	11 (<0.1)	473 (3.2)	484 (1.7)
Day 2	12 (<0.1)	922 (6.3)	934 (3.2)
Day 3	6 (<0.1)	296 (2.0)	302 (1.0)
Day 4	3 (<0.1)	67 (0.5)	70 (0.2)
Day 5	1 (<0.1)	9 (<0.1)	10 (<0.1)
Day 6	2 (<0.1)	4 (<0.1)	6 (<0.1)
Day 7	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lymphadenopathy - N1 [1]	14562	14673	29235
Day 1, 30 Minutes after Vaccination (at Study Clinic)	63 (0.4)	76 (0.5)	139 (0.5)
Day 1, after Vaccination (at Home)	144 (1.0)	494 (3.4)	638 (2.2)
Day 2	154 (1.1)	888 (6.1)	1042 (3.6)
Day 3	85 (0.6)	400 (2.7)	485 (1.7)
Day 4	48 (0.3)	154 (1.0)	202 (0.7)
Day 5	39 (0.3)	39 (0.3)	78 (0.3)
Day 6	19 (0.1)	21 (0.1)	40 (0.1)
Day 7	15 (0.1)	18 (0.1)	33 (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=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Solicited Systemic Adverse Reactions - N1	14565	14677	29242
Day 1, 30 Minutes after Vaccination (at Study Clinic)	545 (3.7)	517 (3.5)	1062 (3.6)
Day 1, after Vaccination (at Home)	1746 (12.0)	4156 (28.3)	5902 (20.2)
Day 2	1284 (8.8)	6382 (43.5)	7666 (26.2)
Day 3	624 (4.3)	374 (2.5)	998 (3.4)
Day 4	391 (2.7)	94 (0.6)	485 (1.7)
Day 5	305 (2.1)	46 (0.3)	351 (1.2)
Day 6	238 (1.6)	51 (0.3)	289 (1.0)
Day 7	190 (1.3)	32 (0.2)	222 (0.8)
Fever - N1	14559	14669	29228
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)	206 (1.4)	211 (0.7)
Day 2	8 (<0.1)	1892 (12.9)	1900 (6.5)
Day 3	7 (<0.1)	165 (1.1)	172 (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	6 (<0.1)	3 (<0.1)	9 (<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=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Headache - N1	14562	14673	29235
Day 1, 30 Minutes after Vaccination (at Study Clinic)	264 (1.8)	262 (1.8)	526 (1.8)
Day 1, after Vaccination (at Home)	905 (6.2)	2118 (14.4)	3023 (10.3)
Day 2	783 (5.4)	5342 (36.4)	6125 (21.0)
Day 3	494 (3.4)	440 (3.0)	934 (3.2)
Day 4	329 (2.3)	161 (1.1)	490 (1.7)
Day 5	233 (1.6)	117 (0.8)	350 (1.2)
Day 6	208 (1.4)	97 (0.7)	305 (1.0)
Day 7	194 (1.3)	65 (0.4)	259 (0.9)
Fatigue - N1	14560	14673	29233
Day 1, 30 Minutes after Vaccination (at Study Clinic)	217 (1.5)	231 (1.6)	448 (1.5)
Day 1, after Vaccination (at Home)	1136 (7.8)	2854 (19.5)	3990 (13.6)
Day 2	904 (6.2)	5871 (40.0)	6775 (23.2)
Day 3	412 (2.8)	418 (2.8)	830 (2.8)
Day 4	251 (1.7)	85 (0.6)	336 (1.1)
Day 5	203 (1.4)	54 (0.4)	257 (0.9)
Day 6	174 (1.2)	40 (0.3)	214 (0.7)
Day 7	106 (0.7)	29 (0.2)	135 (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 14.3.1.3.2
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=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Myalgia - N1	14560	14673	29233
Day 1, 30 Minutes after Vaccination (at Study Clinic)	111 (0.8)	102 (0.7)	213 (0.7)
Day 1, after Vaccination (at Home)	435 (3.0)	1976 (13.5)	2411 (8.2)
Day 2	502 (3.4)	5929 (40.4)	6431 (22.0)
Day 3	261 (1.8)	350 (2.4)	611 (2.1)
Day 4	179 (1.2)	67 (0.5)	246 (0.8)
Day 5	120 (0.8)	32 (0.2)	152 (0.5)
Day 6	117 (0.8)	32 (0.2)	149 (0.5)
Day 7	84 (0.6)	20 (0.1)	104 (0.4)
Arthralgia - N1	14560	14673	29233
Day 1, 30 Minutes after Vaccination (at Study Clinic)	117 (0.8)	119 (0.8)	236 (0.8)
Day 1, after Vaccination (at Home)	358 (2.5)	1316 (9.0)	1674 (5.7)
Day 2	398 (2.7)	4329 (29.5)	4727 (16.2)
Day 3	227 (1.6)	338 (2.3)	565 (1.9)
Day 4	184 (1.3)	83 (0.6)	267 (0.9)
Day 5	98 (0.7)	37 (0.3)	135 (0.5)
Day 6	111 (0.8)	41 (0.3)	152 (0.5)
Day 7	76 (0.5)	21 (0.1)	97 (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=14566) n	(%)	mRNA-1273 (N=14677) n	(%)	Total (N=29243) n	(%)
Nausea/Vomiting - N1	14560		14673		29233	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	44	(0.3)	38	(0.3)	82	(0.3)
Day 1, after Vaccination (at Home)	208	(1.4)	483	(3.3)	691	(2.4)
Day 2	224	(1.5)	1777	(12.1)	2001	(6.8)
Day 3	139	(1.0)	262	(1.8)	401	(1.4)
Day 4	99	(0.7)	96	(0.7)	195	(0.7)
Day 5	74	(0.5)	51	(0.3)	125	(0.4)
Day 6	78	(0.5)	45	(0.3)	123	(0.4)
Day 7	68	(0.5)	33	(0.2)	101	(0.3)
Chills - N1	14560		14673		29233	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	59	(0.4)	47	(0.3)	106	(0.4)
Day 1, after Vaccination (at Home)	206	(1.4)	1101	(7.5)	1307	(4.5)
Day 2	200	(1.4)	4869	(33.2)	5069	(17.3)
Day 3	99	(0.7)	359	(2.4)	458	(1.6)
Day 4	75	(0.5)	47	(0.3)	122	(0.4)
Day 5	68	(0.5)	16	(0.1)	84	(0.3)
Day 6	57	(0.4)	24	(0.2)	81	(0.3)
Day 7	45	(0.3)	19	(0.1)	64	(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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Solicited Adverse Reactions - N1	15163	15179	30342
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2691 (17.7)	2624 (17.3)	5315 (17.5)
Day 1, after Vaccination (at Home)	2838 (18.7)	8867 (58.4)	11705 (38.6)
Day 2	1705 (11.2)	2729 (18.0)	4434 (14.6)
Day 3	741 (4.9)	105 (0.7)	846 (2.8)
Day 4	434 (2.9)	18 (0.1)	452 (1.5)
Day 5	310 (2.0)	23 (0.2)	333 (1.1)
Day 6	212 (1.4)	14 (<0.1)	226 (0.7)
Day 7	177 (1.2)	20 (0.1)	197 (0.6)
Solicited Local Adverse Reactions - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2023 (13.3)	1987 (13.1)	4010 (13.2)
Day 1, after Vaccination (at Home)	1152 (7.6)	8843 (58.3)	9995 (32.9)
Day 2	669 (4.4)	3037 (20.0)	3706 (12.2)
Day 3	267 (1.8)	116 (0.8)	383 (1.3)
Day 4	139 (0.9)	15 (<0.1)	154 (0.5)
Day 5	94 (0.6)	10 (<0.1)	104 (0.3)
Day 6	61 (0.4)	9 (<0.1)	70 (0.2)
Day 7	45 (0.3)	10 (<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 14.3.1.3.3
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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Pain - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1960 (12.9)	1913 (12.6)	3873 (12.8)
Day 1, after Vaccination (at Home)	1068 (7.0)	8851 (58.3)	9919 (32.7)
Day 2	565 (3.7)	3061 (20.2)	3626 (12.0)
Day 3	205 (1.4)	110 (0.7)	315 (1.0)
Day 4	98 (0.6)	11 (<0.1)	109 (0.4)
Day 5	67 (0.4)	5 (<0.1)	72 (0.2)
Day 6	44 (0.3)	7 (<0.1)	51 (0.2)
Day 7	30 (0.2)	7 (<0.1)	37 (0.1)
Erythema (Redness) - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (<0.1)	14 (<0.1)	24 (<0.1)
Day 1, after Vaccination (at Home)	38 (0.3)	159 (1.0)	197 (0.6)
Day 2	26 (0.2)	660 (4.3)	686 (2.3)
Day 3	20 (0.1)	541 (3.6)	561 (1.8)
Day 4	7 (<0.1)	118 (0.8)	125 (0.4)
Day 5	8 (<0.1)	19 (0.1)	27 (<0.1)
Day 6	6 (<0.1)	7 (<0.1)	13 (<0.1)
Day 7	2 (<0.1)	4 (<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 14.3.1.3.3
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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Swelling (Hardness) - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	21 (0.1)	30 (0.2)	51 (0.2)
Day 1, after Vaccination (at Home)	22 (0.1)	593 (3.9)	615 (2.0)
Day 2	27 (0.2)	1200 (7.9)	1227 (4.0)
Day 3	9 (<0.1)	317 (2.1)	326 (1.1)
Day 4	5 (<0.1)	71 (0.5)	76 (0.3)
Day 5	5 (<0.1)	11 (<0.1)	16 (<0.1)
Day 6	2 (<0.1)	6 (<0.1)	8 (<0.1)
Day 7	4 (<0.1)	4 (<0.1)	8 (<0.1)
Lymphadenopathy - N1 [1]	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	155 (1.0)	169 (1.1)	324 (1.1)
Day 1, after Vaccination (at Home)	257 (1.7)	775 (5.1)	1032 (3.4)
Day 2	264 (1.7)	1139 (7.5)	1403 (4.6)
Day 3	151 (1.0)	500 (3.3)	651 (2.1)
Day 4	90 (0.6)	196 (1.3)	286 (0.9)
Day 5	83 (0.5)	67 (0.4)	150 (0.5)
Day 6	57 (0.4)	67 (0.4)	124 (0.4)
Day 7	41 (0.3)	98 (0.6)	139 (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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Solicited Systemic Adverse Reactions - N1	15163	15179	30342
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1110 (7.3)	1057 (7.0)	2167 (7.1)
Day 1, after Vaccination (at Home)	2915 (19.2)	5236 (34.5)	8151 (26.9)
Day 2	1911 (12.6)	5753 (37.9)	7664 (25.3)
Day 3	848 (5.6)	404 (2.7)	1252 (4.1)
Day 4	474 (3.1)	122 (0.8)	596 (2.0)
Day 5	361 (2.4)	82 (0.5)	443 (1.5)
Day 6	275 (1.8)	63 (0.4)	338 (1.1)
Day 7	218 (1.4)	53 (0.3)	271 (0.9)
Fever - N1	15162	15178	30340
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)	219 (1.4)	228 (0.8)
Day 2	13 (<0.1)	1927 (12.7)	1940 (6.4)
Day 3	15 (<0.1)	177 (1.2)	192 (0.6)
Day 4	9 (<0.1)	7 (<0.1)	16 (<0.1)
Day 5	14 (<0.1)	11 (<0.1)	25 (<0.1)
Day 6	12 (<0.1)	3 (<0.1)	15 (<0.1)
Day 7	10 (<0.1)	5 (<0.1)	15 (<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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Headache - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	587 (3.9)	581 (3.8)	1168 (3.8)
Day 1, after Vaccination (at Home)	1592 (10.5)	2873 (18.9)	4465 (14.7)
Day 2	1355 (8.9)	5196 (34.2)	6551 (21.6)
Day 3	746 (4.9)	534 (3.5)	1280 (4.2)
Day 4	450 (3.0)	221 (1.5)	671 (2.2)
Day 5	333 (2.2)	163 (1.1)	496 (1.6)
Day 6	284 (1.9)	149 (1.0)	433 (1.4)
Day 7	256 (1.7)	108 (0.7)	364 (1.2)
Fatigue - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	420 (2.8)	441 (2.9)	861 (2.8)
Day 1, after Vaccination (at Home)	2049 (13.5)	3762 (24.8)	5811 (19.2)
Day 2	1411 (9.3)	5616 (37.0)	7027 (23.2)
Day 3	642 (4.2)	470 (3.1)	1112 (3.7)
Day 4	354 (2.3)	123 (0.8)	477 (1.6)
Day 5	274 (1.8)	80 (0.5)	354 (1.2)
Day 6	242 (1.6)	78 (0.5)	320 (1.1)
Day 7	152 (1.0)	57 (0.4)	209 (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=15163) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30342) n (%)
Myalgia - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	223 (1.5)	214 (1.4)	437 (1.4)
Day 1, after Vaccination (at Home)	766 (5.1)	2509 (16.5)	3275 (10.8)
Day 2	872 (5.8)	5930 (39.1)	6802 (22.4)
Day 3	428 (2.8)	421 (2.8)	849 (2.8)
Day 4	307 (2.0)	102 (0.7)	409 (1.3)
Day 5	197 (1.3)	58 (0.4)	255 (0.8)
Day 6	173 (1.1)	61 (0.4)	234 (0.8)
Day 7	147 (1.0)	39 (0.3)	186 (0.6)
Arthralgia - N1	15162	15179	30341
Day 1, 30 Minutes after Vaccination (at Study Clinic)	210 (1.4)	210 (1.4)	420 (1.4)
Day 1, after Vaccination (at Home)	588 (3.9)	1646 (10.8)	2234 (7.4)
Day 2	731 (4.8)	4401 (29.0)	5132 (16.9)
Day 3	393 (2.6)	459 (3.0)	852 (2.8)
Day 4	277 (1.8)	137 (0.9)	414 (1.4)
Day 5	173 (1.1)	70 (0.5)	243 (0.8)
Day 6	174 (1.1)	68 (0.4)	242 (0.8)
Day 7	120 (0.8)	53 (0.3)	173 (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=15163) n	(%)	mRNA-1273 (N=15179) n	(%)	Total (N=30342) n	(%)
Nausea/Vomiting - N1	15162		15179		30341	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	89	(0.6)	77	(0.5)	166	(0.5)
Day 1, after Vaccination (at Home)	346	(2.3)	654	(4.3)	1000	(3.3)
Day 2	418	(2.8)	1948	(12.8)	2366	(7.8)
Day 3	254	(1.7)	380	(2.5)	634	(2.1)
Day 4	185	(1.2)	171	(1.1)	356	(1.2)
Day 5	148	(1.0)	92	(0.6)	240	(0.8)
Day 6	151	(1.0)	88	(0.6)	239	(0.8)
Day 7	125	(0.8)	74	(0.5)	199	(0.7)
Chills - N1	15162		15179		30341	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	139	(0.9)	117	(0.8)	256	(0.8)
Day 1, after Vaccination (at Home)	362	(2.4)	1282	(8.4)	1644	(5.4)
Day 2	346	(2.3)	4882	(32.2)	5228	(17.2)
Day 3	196	(1.3)	425	(2.8)	621	(2.0)
Day 4	125	(0.8)	70	(0.5)	195	(0.6)
Day 5	127	(0.8)	40	(0.3)	167	(0.6)
Day 6	96	(0.6)	39	(0.3)	135	(0.4)
Day 7	79	(0.5)	36	(0.2)	115	(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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Solicited Adverse Reactions - N1	11407	11406	22813
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1341 (11.8)	1332 (11.7)	2673 (11.7)
Day 1, after Vaccination (at Home)	1710 (15.0)	5534 (48.5)	7244 (31.8)
Day 2	1224 (10.7)	3107 (27.2)	4331 (19.0)
Day 3	572 (5.0)	169 (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	177 (1.6)	26 (0.2)	203 (0.9)
Day 7	152 (1.3)	25 (0.2)	177 (0.8)
Solicited Local Adverse Reactions - N1	11405	11402	22807
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)	5357 (47.0)	5985 (26.2)
Day 2	442 (3.9)	3408 (29.9)	3850 (16.9)
Day 3	163 (1.4)	159 (1.4)	322 (1.4)
Day 4	88 (0.8)	29 (0.3)	117 (0.5)
Day 5	67 (0.6)	12 (0.1)	79 (0.3)
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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Pain - N1	11405	11402	22807
Day 1, 30 Minutes after Vaccination (at Study Clinic)	945 (8.3)	939 (8.2)	1884 (8.3)
Day 1, after Vaccination (at Home)	578 (5.1)	5332 (46.8)	5910 (25.9)
Day 2	379 (3.3)	3429 (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	41 (0.4)	8 (<0.1)	49 (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	11405	11402	22807
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	8 (<0.1)	10 (<0.1)
Day 1, after Vaccination (at Home)	16 (0.1)	43 (0.4)	59 (0.3)
Day 2	12 (0.1)	186 (1.6)	198 (0.9)
Day 3	7 (<0.1)	84 (0.7)	91 (0.4)
Day 4	4 (<0.1)	13 (0.1)	17 (<0.1)
Day 5	1 (<0.1)	7 (<0.1)	8 (<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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Swelling (Hardness) - N1	11405	11402	22807
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	10 (<0.1)	18 (<0.1)
Day 1, after Vaccination (at Home)	9 (<0.1)	171 (1.5)	180 (0.8)
Day 2	9 (<0.1)	485 (4.3)	494 (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)	3 (<0.1)	6 (<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]	11405	11402	22807
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)	416 (3.6)	538 (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)	47 (0.4)	101 (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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Solicited Systemic Adverse Reactions - N1	11407	11406	22813
Day 1, 30 Minutes after Vaccination (at Study Clinic)	561 (4.9)	528 (4.6)	1089 (4.8)
Day 1, after Vaccination (at Home)	1627 (14.3)	2324 (20.4)	3951 (17.3)
Day 2	1270 (11.1)	2231 (19.6)	3501 (15.3)
Day 3	605 (5.3)	666 (5.8)	1271 (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	201 (1.8)	168 (1.5)	369 (1.6)
Day 7	177 (1.6)	151 (1.3)	328 (1.4)
Fever - N1	11405	11404	22809
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)	13 (0.1)	15 (<0.1)
Day 2	5 (<0.1)	55 (0.5)	60 (0.3)
Day 3	7 (<0.1)	24 (0.2)	31 (0.1)
Day 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Day 5	8 (<0.1)	4 (<0.1)	12 (<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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Headache - N1	11405	11402	22807
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)	1092 (9.6)	1911 (8.4)
Day 2	788 (6.9)	1263 (11.1)	2051 (9.0)
Day 3	443 (3.9)	575 (5.0)	1018 (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	11405	11402	22807
Day 1, 30 Minutes after Vaccination (at Study Clinic)	197 (1.7)	206 (1.8)	403 (1.8)
Day 1, after Vaccination (at Home)	1112 (9.8)	1508 (13.2)	2620 (11.5)
Day 2	868 (7.6)	1644 (14.4)	2512 (11.0)
Day 3	422 (3.7)	514 (4.5)	936 (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	122 (1.1)	92 (0.8)	214 (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=11407) n	(%)	mRNA-1273 (N=11406) n	(%)	Total (N=22813) n	(%)
Myalgia - N1	11405		11402		22807	
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)	725	(6.4)	1084	(4.8)
Day 2	467	(4.1)	1200	(10.5)	1667	(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	94	(0.8)	59	(0.5)	153	(0.7)
Day 7	86	(0.8)	60	(0.5)	146	(0.6)
Arthralgia - N1	11405		11402		22807	
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)	746	(6.5)	1115	(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=11407) n	(%)	mRNA-1273 (N=11406) n	(%)	Total (N=22813) n	(%)
Nausea/Vomiting - N1	11405		11402		22807	
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)	65	(0.6)	159	(0.7)
Day 7	71	(0.6)	58	(0.5)	129	(0.6)
Chills - N1	11405		11402		22807	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	74	(0.6)	63	(0.6)	137	(0.6)
Day 1, after Vaccination (at Home)	161	(1.4)	225	(2.0)	386	(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	71	(0.6)	46	(0.4)	117	(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 (%)
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)	437 (11.7)	1233 (32.8)	1670 (22.2)
Day 2	383 (10.2)	1386 (36.8)	1769 (23.6)
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)	138 (3.7)	1028 (27.3)	1166 (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)	3 (<0.1)	9 (0.2)	12 (0.2)
Day 2	7 (0.2)	42 (1.1)	49 (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)	2 (<0.1)	19 (0.5)	21 (0.3)
Day 2	10 (0.3)	106 (2.8)	116 (1.5)
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)	377 (10.1)	584 (15.5)	961 (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)	54 (1.4)	125 (1.7)
Day 7	52 (1.4)	40 (1.1)	92 (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)	162 (4.3)	258 (6.9)	420 (5.6)
Day 2	173 (4.6)	285 (7.6)	458 (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)	42 (1.1)	92 (1.2)
Day 7	38 (1.0)	39 (1.0)	77 (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)	273 (7.3)	393 (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	12 (0.3)	19 (0.5)	31 (0.4)
Day 6	25 (0.7)	15 (0.4)	40 (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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Solicited Adverse Reactions - N1	10918	10985	21903
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1319 (12.1)	1217 (11.1)	2536 (11.6)
Day 1, after Vaccination (at Home)	1466 (13.4)	6498 (59.2)	7964 (36.4)
Day 2	927 (8.5)	2385 (21.7)	3312 (15.1)
Day 3	445 (4.1)	89 (0.8)	534 (2.4)
Day 4	261 (2.4)	18 (0.2)	279 (1.3)
Day 5	211 (1.9)	7 (<0.1)	218 (1.0)
Day 6	153 (1.4)	8 (<0.1)	161 (0.7)
Day 7	120 (1.1)	9 (<0.1)	129 (0.6)
Solicited Local Adverse Reactions - N1	10914	10984	21898
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1056 (9.7)	947 (8.6)	2003 (9.1)
Day 1, after Vaccination (at Home)	601 (5.5)	6400 (58.3)	7001 (32.0)
Day 2	296 (2.7)	2439 (22.2)	2735 (12.5)
Day 3	138 (1.3)	101 (0.9)	239 (1.1)
Day 4	58 (0.5)	17 (0.2)	75 (0.3)
Day 5	46 (0.4)	3 (<0.1)	49 (0.2)
Day 6	23 (0.2)	4 (<0.1)	27 (0.1)
Day 7	26 (0.2)	4 (<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 14.3.1.3.5
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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Pain - N1	10914	10984	21898
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1032 (9.5)	914 (8.3)	1946 (8.9)
Day 1, after Vaccination (at Home)	557 (5.1)	6387 (58.1)	6944 (31.7)
Day 2	240 (2.2)	2449 (22.3)	2689 (12.3)
Day 3	111 (1.0)	100 (0.9)	211 (1.0)
Day 4	36 (0.3)	15 (0.1)	51 (0.2)
Day 5	32 (0.3)	2 (<0.1)	34 (0.2)
Day 6	19 (0.2)	4 (<0.1)	23 (0.1)
Day 7	13 (0.1)	2 (<0.1)	15 (<0.1)
Erythema (Redness) - N1	10914	10984	21898
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (<0.1)	3 (<0.1)	10 (<0.1)
Day 1, after Vaccination (at Home)	14 (0.1)	96 (0.9)	110 (0.5)
Day 2	8 (<0.1)	389 (3.5)	397 (1.8)
Day 3	7 (<0.1)	399 (3.6)	406 (1.9)
Day 4	2 (<0.1)	83 (0.8)	85 (0.4)
Day 5	2 (<0.1)	9 (<0.1)	11 (<0.1)
Day 6	2 (<0.1)	2 (<0.1)	4 (<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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Swelling (Hardness) - N1	10914	10984	21898
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (0.1)	22 (0.1)
Day 1, after Vaccination (at Home)	7 (<0.1)	392 (3.6)	399 (1.8)
Day 2	9 (<0.1)	692 (6.3)	701 (3.2)
Day 3	5 (<0.1)	233 (2.1)	238 (1.1)
Day 4	1 (<0.1)	49 (0.4)	50 (0.2)
Day 5	1 (<0.1)	5 (<0.1)	6 (<0.1)
Day 6	2 (<0.1)	4 (<0.1)	6 (<0.1)
Day 7	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lymphadenopathy - N1 [1]	10914	10984	21898
Day 1, 30 Minutes after Vaccination (at Study Clinic)	49 (0.4)	61 (0.6)	110 (0.5)
Day 1, after Vaccination (at Home)	124 (1.1)	432 (3.9)	556 (2.5)
Day 2	123 (1.1)	740 (6.7)	863 (3.9)
Day 3	69 (0.6)	347 (3.2)	416 (1.9)
Day 4	45 (0.4)	130 (1.2)	175 (0.8)
Day 5	31 (0.3)	32 (0.3)	63 (0.3)
Day 6	15 (0.1)	16 (0.1)	31 (0.1)
Day 7	14 (0.1)	17 (0.2)	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 14.3.1.3.5
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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Solicited Systemic Adverse Reactions - N1	10917	10985	21902
Day 1, 30 Minutes after Vaccination (at Study Clinic)	419 (3.8)	415 (3.8)	834 (3.8)
Day 1, after Vaccination (at Home)	1400 (12.8)	3344 (30.4)	4744 (21.7)
Day 2	1007 (9.2)	4804 (43.7)	5811 (26.5)
Day 3	497 (4.6)	275 (2.5)	772 (3.5)
Day 4	303 (2.8)	69 (0.6)	372 (1.7)
Day 5	240 (2.2)	32 (0.3)	272 (1.2)
Day 6	182 (1.7)	36 (0.3)	218 (1.0)
Day 7	144 (1.3)	24 (0.2)	168 (0.8)
Fever - N1	10912	10979	21891
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)	179 (1.6)	184 (0.8)
Day 2	6 (<0.1)	1572 (14.3)	1578 (7.2)
Day 3	7 (<0.1)	145 (1.3)	152 (0.7)
Day 4	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 5	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 6	7 (<0.1)	1 (<0.1)	8 (<0.1)
Day 7	6 (<0.1)	3 (<0.1)	9 (<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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Headache - N1	10914	10984	21898
Day 1, 30 Minutes after Vaccination (at Study Clinic)	207 (1.9)	217 (2.0)	424 (1.9)
Day 1, after Vaccination (at Home)	760 (7.0)	1740 (15.8)	2500 (11.4)
Day 2	610 (5.6)	4231 (38.5)	4841 (22.1)
Day 3	401 (3.7)	354 (3.2)	755 (3.4)
Day 4	276 (2.5)	132 (1.2)	408 (1.9)
Day 5	191 (1.8)	97 (0.9)	288 (1.3)
Day 6	164 (1.5)	72 (0.7)	236 (1.1)
Day 7	151 (1.4)	55 (0.5)	206 (0.9)
Fatigue - N1	10912	10984	21896
Day 1, 30 Minutes after Vaccination (at Study Clinic)	168 (1.5)	191 (1.7)	359 (1.6)
Day 1, after Vaccination (at Home)	909 (8.3)	2328 (21.2)	3237 (14.8)
Day 2	717 (6.6)	4443 (40.4)	5160 (23.6)
Day 3	328 (3.0)	319 (2.9)	647 (3.0)
Day 4	185 (1.7)	62 (0.6)	247 (1.1)
Day 5	167 (1.5)	39 (0.4)	206 (0.9)
Day 6	137 (1.3)	30 (0.3)	167 (0.8)
Day 7	76 (0.7)	18 (0.2)	94 (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=10918) n	(%)	mRNA-1273 (N=10985) n	(%)	Total (N=21903) n	(%)
Myalgia - N1	10912		10984		21896	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	78	(0.7)	73	(0.7)	151	(0.7)
Day 1, after Vaccination (at Home)	360	(3.3)	1621	(14.8)	1981	(9.0)
Day 2	371	(3.4)	4695	(42.7)	5066	(23.1)
Day 3	205	(1.9)	274	(2.5)	479	(2.2)
Day 4	148	(1.4)	50	(0.5)	198	(0.9)
Day 5	89	(0.8)	23	(0.2)	112	(0.5)
Day 6	91	(0.8)	19	(0.2)	110	(0.5)
Day 7	69	(0.6)	14	(0.1)	83	(0.4)
Arthralgia - N1	10912		10984		21896	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	75	(0.7)	81	(0.7)	156	(0.7)
Day 1, after Vaccination (at Home)	282	(2.6)	1054	(9.6)	1336	(6.1)
Day 2	286	(2.6)	3462	(31.5)	3748	(17.1)
Day 3	174	(1.6)	269	(2.4)	443	(2.0)
Day 4	139	(1.3)	59	(0.5)	198	(0.9)
Day 5	79	(0.7)	24	(0.2)	103	(0.5)
Day 6	79	(0.7)	29	(0.3)	108	(0.5)
Day 7	58	(0.5)	15	(0.1)	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 14.3.1.3.5
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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Nausea/Vomiting - N1	10912	10984	21896
Day 1, 30 Minutes after Vaccination (at Study Clinic)	35 (0.3)	27 (0.2)	62 (0.3)
Day 1, after Vaccination (at Home)	187 (1.7)	413 (3.8)	600 (2.7)
Day 2	190 (1.7)	1497 (13.6)	1687 (7.7)
Day 3	121 (1.1)	221 (2.0)	342 (1.6)
Day 4	82 (0.8)	83 (0.8)	165 (0.8)
Day 5	66 (0.6)	45 (0.4)	111 (0.5)
Day 6	69 (0.6)	36 (0.3)	105 (0.5)
Day 7	51 (0.5)	26 (0.2)	77 (0.4)
Chills - N1	10912	10984	21896
Day 1, 30 Minutes after Vaccination (at Study Clinic)	47 (0.4)	34 (0.3)	81 (0.4)
Day 1, after Vaccination (at Home)	176 (1.6)	941 (8.6)	1117 (5.1)
Day 2	155 (1.4)	3999 (36.4)	4154 (19.0)
Day 3	80 (0.7)	284 (2.6)	364 (1.7)
Day 4	62 (0.6)	34 (0.3)	96 (0.4)
Day 5	54 (0.5)	14 (0.1)	68 (0.3)
Day 6	48 (0.4)	22 (0.2)	70 (0.3)
Day 7	36 (0.3)	13 (0.1)	49 (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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Solicited Adverse Reactions - N1	3648	3692	7340
Day 1, 30 Minutes after Vaccination (at Study Clinic)	242 (6.6)	238 (6.4)	480 (6.5)
Day 1, after Vaccination (at Home)	418 (11.5)	1721 (46.6)	2139 (29.1)
Day 2	296 (8.1)	1267 (34.3)	1563 (21.3)
Day 3	130 (3.6)	52 (1.4)	182 (2.5)
Day 4	87 (2.4)	11 (0.3)	98 (1.3)
Day 5	63 (1.7)	7 (0.2)	70 (1.0)
Day 6	50 (1.4)	4 (0.1)	54 (0.7)
Day 7	44 (1.2)	3 (<0.1)	47 (0.6)
Solicited Local Adverse Reactions - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	137 (3.8)	162 (4.4)	299 (4.1)
Day 1, after Vaccination (at Home)	156 (4.3)	1592 (43.2)	1748 (23.8)
Day 2	112 (3.1)	1263 (34.2)	1375 (18.7)
Day 3	42 (1.2)	55 (1.5)	97 (1.3)
Day 4	24 (0.7)	9 (0.2)	33 (0.4)
Day 5	9 (0.2)	5 (0.1)	14 (0.2)
Day 6	8 (0.2)	4 (0.1)	12 (0.2)
Day 7	3 (<0.1)	1 (<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 14.3.1.3.5
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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Pain - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	129 (3.5)	154 (4.2)	283 (3.9)
Day 1, after Vaccination (at Home)	146 (4.0)	1582 (42.9)	1728 (23.6)
Day 2	92 (2.5)	1265 (34.3)	1357 (18.5)
Day 3	33 (0.9)	55 (1.5)	88 (1.2)
Day 4	23 (0.6)	8 (0.2)	31 (0.4)
Day 5	6 (0.2)	3 (<0.1)	9 (0.1)
Day 6	5 (0.1)	2 (<0.1)	7 (<0.1)
Day 7	3 (<0.1)	1 (<0.1)	4 (<0.1)
Erythema (Redness) - N1	3648	3689	7337
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)	18 (0.5)	24 (0.3)
Day 2	1 (<0.1)	122 (3.3)	123 (1.7)
Day 3	3 (<0.1)	96 (2.6)	99 (1.3)
Day 4	0	30 (0.8)	30 (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	2 (<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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Swelling (Hardness) - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	4 (0.1)	7 (<0.1)
Day 1, after Vaccination (at Home)	4 (0.1)	81 (2.2)	85 (1.2)
Day 2	3 (<0.1)	230 (6.2)	233 (3.2)
Day 3	1 (<0.1)	63 (1.7)	64 (0.9)
Day 4	2 (<0.1)	18 (0.5)	20 (0.3)
Day 5	0	4 (0.1)	4 (<0.1)
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	14 (0.4)	15 (0.4)	29 (0.4)
Day 1, after Vaccination (at Home)	20 (0.5)	62 (1.7)	82 (1.1)
Day 2	31 (0.8)	148 (4.0)	179 (2.4)
Day 3	16 (0.4)	53 (1.4)	69 (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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Solicited Systemic Adverse Reactions - N1	3648	3692	7340
Day 1, 30 Minutes after Vaccination (at Study Clinic)	126 (3.5)	102 (2.8)	228 (3.1)
Day 1, after Vaccination (at Home)	346 (9.5)	812 (22.0)	1158 (15.8)
Day 2	277 (7.6)	1578 (42.7)	1855 (25.3)
Day 3	127 (3.5)	99 (2.7)	226 (3.1)
Day 4	88 (2.4)	25 (0.7)	113 (1.5)
Day 5	65 (1.8)	14 (0.4)	79 (1.1)
Day 6	56 (1.5)	15 (0.4)	71 (1.0)
Day 7	46 (1.3)	8 (0.2)	54 (0.7)
Fever - N1	3647	3690	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (<0.1)	1 (<0.1)
Day 1, after Vaccination (at Home)	0	27 (0.7)	27 (0.4)
Day 2	2 (<0.1)	320 (8.7)	322 (4.4)
Day 3	0	20 (0.5)	20 (0.3)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	1 (<0.1)	0	1 (<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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Headache - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	57 (1.6)	45 (1.2)	102 (1.4)
Day 1, after Vaccination (at Home)	145 (4.0)	378 (10.2)	523 (7.1)
Day 2	173 (4.7)	1111 (30.1)	1284 (17.5)
Day 3	93 (2.5)	86 (2.3)	179 (2.4)
Day 4	53 (1.5)	29 (0.8)	82 (1.1)
Day 5	42 (1.2)	20 (0.5)	62 (0.8)
Day 6	44 (1.2)	25 (0.7)	69 (0.9)
Day 7	43 (1.2)	10 (0.3)	53 (0.7)
Fatigue - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	49 (1.3)	40 (1.1)	89 (1.2)
Day 1, after Vaccination (at Home)	227 (6.2)	526 (14.3)	753 (10.3)
Day 2	187 (5.1)	1428 (38.7)	1615 (22.0)
Day 3	84 (2.3)	99 (2.7)	183 (2.5)
Day 4	66 (1.8)	23 (0.6)	89 (1.2)
Day 5	36 (1.0)	15 (0.4)	51 (0.7)
Day 6	37 (1.0)	10 (0.3)	47 (0.6)
Day 7	30 (0.8)	11 (0.3)	41 (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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Myalgia - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	33 (0.9)	29 (0.8)	62 (0.8)
Day 1, after Vaccination (at Home)	75 (2.1)	355 (9.6)	430 (5.9)
Day 2	131 (3.6)	1234 (33.5)	1365 (18.6)
Day 3	56 (1.5)	76 (2.1)	132 (1.8)
Day 4	31 (0.8)	17 (0.5)	48 (0.7)
Day 5	31 (0.8)	9 (0.2)	40 (0.5)
Day 6	26 (0.7)	13 (0.4)	39 (0.5)
Day 7	15 (0.4)	6 (0.2)	21 (0.3)
Arthralgia - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	42 (1.2)	38 (1.0)	80 (1.1)
Day 1, after Vaccination (at Home)	76 (2.1)	262 (7.1)	338 (4.6)
Day 2	112 (3.1)	867 (23.5)	979 (13.3)
Day 3	53 (1.5)	69 (1.9)	122 (1.7)
Day 4	45 (1.2)	24 (0.7)	69 (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	18 (0.5)	6 (0.2)	24 (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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Nausea/Vomiting - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (0.2)	11 (0.3)	20 (0.3)
Day 1, after Vaccination (at Home)	21 (0.6)	70 (1.9)	91 (1.2)
Day 2	34 (0.9)	280 (7.6)	314 (4.3)
Day 3	18 (0.5)	41 (1.1)	59 (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 (0.2)	9 (0.2)	18 (0.2)
Day 7	17 (0.5)	7 (0.2)	24 (0.3)
Chills - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (0.3)	13 (0.4)	25 (0.3)
Day 1, after Vaccination (at Home)	30 (0.8)	160 (4.3)	190 (2.6)
Day 2	45 (1.2)	870 (23.6)	915 (12.5)
Day 3	19 (0.5)	75 (2.0)	94 (1.3)
Day 4	13 (0.4)	13 (0.4)	26 (0.4)
Day 5	14 (0.4)	2 (<0.1)	16 (0.2)
Day 6	9 (0.2)	2 (<0.1)	11 (0.1)
Day 7	9 (0.2)	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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Solicited Adverse Reactions - N1	11413	11412	22825
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2234 (19.6)	2190 (19.2)	4424 (19.4)
Day 1, after Vaccination (at Home)	2197 (19.2)	6888 (60.4)	9085 (39.8)
Day 2	1253 (11.0)	1705 (14.9)	2958 (13.0)
Day 3	551 (4.8)	58 (0.5)	609 (2.7)
Day 4	317 (2.8)	9 (<0.1)	326 (1.4)
Day 5	238 (2.1)	14 (0.1)	252 (1.1)
Day 6	156 (1.4)	8 (<0.1)	164 (0.7)
Day 7	139 (1.2)	15 (0.1)	154 (0.7)
Solicited Local Adverse Reactions - N1	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1746 (15.3)	1693 (14.8)	3439 (15.1)
Day 1, after Vaccination (at Home)	912 (8.0)	6991 (61.3)	7903 (34.6)
Day 2	475 (4.2)	1894 (16.6)	2369 (10.4)
Day 3	198 (1.7)	69 (0.6)	267 (1.2)
Day 4	100 (0.9)	12 (0.1)	112 (0.5)
Day 5	71 (0.6)	5 (<0.1)	76 (0.3)
Day 6	42 (0.4)	4 (<0.1)	46 (0.2)
Day 7	34 (0.3)	8 (<0.1)	42 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Pain - N1	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1697 (14.9)	1633 (14.3)	3330 (14.6)
Day 1, after Vaccination (at Home)	847 (7.4)	7008 (61.4)	7855 (34.4)
Day 2	407 (3.6)	1911 (16.7)	2318 (10.2)
Day 3	157 (1.4)	64 (0.6)	221 (1.0)
Day 4	64 (0.6)	10 (<0.1)	74 (0.3)
Day 5	49 (0.4)	3 (<0.1)	52 (0.2)
Day 6	33 (0.3)	4 (<0.1)	37 (0.2)
Day 7	21 (0.2)	6 (<0.1)	27 (0.1)
Erythema (Redness) - N1	11412	11412	22824
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)	132 (1.2)	161 (0.7)
Day 2	18 (0.2)	510 (4.5)	528 (2.3)
Day 3	12 (0.1)	428 (3.8)	440 (1.9)
Day 4	6 (<0.1)	89 (0.8)	95 (0.4)
Day 5	3 (<0.1)	13 (0.1)	16 (<0.1)
Day 6	5 (<0.1)	3 (<0.1)	8 (<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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Swelling (Hardness) - N1	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	17 (0.1)	23 (0.2)	40 (0.2)
Day 1, after Vaccination (at Home)	16 (0.1)	498 (4.4)	514 (2.3)
Day 2	17 (0.1)	930 (8.1)	947 (4.1)
Day 3	5 (<0.1)	239 (2.1)	244 (1.1)
Day 4	2 (<0.1)	49 (0.4)	51 (0.2)
Day 5	4 (<0.1)	7 (<0.1)	11 (<0.1)
Day 6	2 (<0.1)	6 (<0.1)	8 (<0.1)
Day 7	4 (<0.1)	3 (<0.1)	7 (<0.1)
Lymphadenopathy - N1 [1]	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	120 (1.1)	128 (1.1)	248 (1.1)
Day 1, after Vaccination (at Home)	217 (1.9)	665 (5.8)	882 (3.9)
Day 2	199 (1.7)	948 (8.3)	1147 (5.0)
Day 3	120 (1.1)	426 (3.7)	546 (2.4)
Day 4	74 (0.6)	162 (1.4)	236 (1.0)
Day 5	72 (0.6)	56 (0.5)	128 (0.6)
Day 6	40 (0.4)	58 (0.5)	98 (0.4)
Day 7	33 (0.3)	91 (0.8)	124 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Solicited Systemic Adverse Reactions - N1	11413	11412	22825
Day 1, 30 Minutes after Vaccination (at Study Clinic)	873 (7.6)	853 (7.5)	1726 (7.6)
Day 1, after Vaccination (at Home)	2351 (20.6)	4149 (36.4)	6500 (28.5)
Day 2	1469 (12.9)	4302 (37.7)	5771 (25.3)
Day 3	645 (5.7)	277 (2.4)	922 (4.0)
Day 4	346 (3.0)	95 (0.8)	441 (1.9)
Day 5	284 (2.5)	57 (0.5)	341 (1.5)
Day 6	212 (1.9)	44 (0.4)	256 (1.1)
Day 7	168 (1.5)	40 (0.4)	208 (0.9)
Fever - N1	11412	11411	22823
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)	189 (1.7)	195 (0.9)
Day 2	11 (<0.1)	1607 (14.1)	1618 (7.1)
Day 3	14 (0.1)	157 (1.4)	171 (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	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 14.3.1.3.6
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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Headache - N1	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	464 (4.1)	475 (4.2)	939 (4.1)
Day 1, after Vaccination (at Home)	1328 (11.6)	2326 (20.4)	3654 (16.0)
Day 2	1083 (9.5)	4100 (35.9)	5183 (22.7)
Day 3	594 (5.2)	405 (3.5)	999 (4.4)
Day 4	362 (3.2)	182 (1.6)	544 (2.4)
Day 5	259 (2.3)	131 (1.1)	390 (1.7)
Day 6	230 (2.0)	119 (1.0)	349 (1.5)
Day 7	206 (1.8)	81 (0.7)	287 (1.3)
Fatigue - N1	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	334 (2.9)	363 (3.2)	697 (3.1)
Day 1, after Vaccination (at Home)	1650 (14.5)	3006 (26.3)	4656 (20.4)
Day 2	1094 (9.6)	4228 (37.0)	5322 (23.3)
Day 3	505 (4.4)	349 (3.1)	854 (3.7)
Day 4	250 (2.2)	87 (0.8)	337 (1.5)
Day 5	219 (1.9)	58 (0.5)	277 (1.2)
Day 6	179 (1.6)	55 (0.5)	234 (1.0)
Day 7	111 (1.0)	42 (0.4)	153 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Myalgia - N1	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	170 (1.5)	164 (1.4)	334 (1.5)
Day 1, after Vaccination (at Home)	620 (5.4)	2038 (17.9)	2658 (11.6)
Day 2	671 (5.9)	4692 (41.1)	5363 (23.5)
Day 3	321 (2.8)	316 (2.8)	637 (2.8)
Day 4	249 (2.2)	67 (0.6)	316 (1.4)
Day 5	150 (1.3)	41 (0.4)	191 (0.8)
Day 6	135 (1.2)	36 (0.3)	171 (0.7)
Day 7	114 (1.0)	30 (0.3)	144 (0.6)
Arthralgia - N1	11412	11412	22824
Day 1, 30 Minutes after Vaccination (at Study Clinic)	148 (1.3)	149 (1.3)	297 (1.3)
Day 1, after Vaccination (at Home)	461 (4.0)	1308 (11.5)	1769 (7.8)
Day 2	535 (4.7)	3506 (30.7)	4041 (17.7)
Day 3	290 (2.5)	347 (3.0)	637 (2.8)
Day 4	212 (1.9)	89 (0.8)	301 (1.3)
Day 5	126 (1.1)	45 (0.4)	171 (0.7)
Day 6	130 (1.1)	49 (0.4)	179 (0.8)
Day 7	95 (0.8)	39 (0.3)	134 (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=11413) n	(%)	mRNA-1273 (N=11412) n	(%)	Total (N=22825) n	(%)
Nausea/Vomiting - N1	11412		11412		22824	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	76	(0.7)	58	(0.5)	134	(0.6)
Day 1, after Vaccination (at Home)	308	(2.7)	569	(5.0)	877	(3.8)
Day 2	345	(3.0)	1637	(14.3)	1982	(8.7)
Day 3	211	(1.8)	310	(2.7)	521	(2.3)
Day 4	157	(1.4)	148	(1.3)	305	(1.3)
Day 5	130	(1.1)	73	(0.6)	203	(0.9)
Day 6	120	(1.1)	68	(0.6)	188	(0.8)
Day 7	96	(0.8)	58	(0.5)	154	(0.7)
Chills - N1	11412		11412		22824	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	115	(1.0)	94	(0.8)	209	(0.9)
Day 1, after Vaccination (at Home)	301	(2.6)	1089	(9.5)	1390	(6.1)
Day 2	274	(2.4)	4007	(35.1)	4281	(18.8)
Day 3	160	(1.4)	329	(2.9)	489	(2.1)
Day 4	104	(0.9)	47	(0.4)	151	(0.7)
Day 5	106	(0.9)	34	(0.3)	140	(0.6)
Day 6	77	(0.7)	34	(0.3)	111	(0.5)
Day 7	67	(0.6)	27	(0.2)	94	(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=3767) n (%)	Total (N=7517) n (%)
Solicited Adverse Reactions - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	457 (12.2)	434 (11.5)	891 (11.9)
Day 1, after Vaccination (at Home)	641 (17.1)	1979 (52.5)	2620 (34.9)
Day 2	452 (12.1)	1024 (27.2)	1476 (19.6)
Day 3	190 (5.1)	47 (1.2)	237 (3.2)
Day 4	117 (3.1)	9 (0.2)	126 (1.7)
Day 5	72 (1.9)	9 (0.2)	81 (1.1)
Day 6	56 (1.5)	6 (0.2)	62 (0.8)
Day 7	38 (1.0)	5 (0.1)	43 (0.6)
Solicited Local Adverse Reactions - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	277 (7.4)	294 (7.8)	571 (7.6)
Day 1, after Vaccination (at Home)	240 (6.4)	1852 (49.2)	2092 (27.8)
Day 2	194 (5.2)	1143 (30.3)	1337 (17.8)
Day 3	69 (1.8)	47 (1.2)	116 (1.5)
Day 4	39 (1.0)	3 (<0.1)	42 (0.6)
Day 5	23 (0.6)	5 (0.1)	28 (0.4)
Day 6	19 (0.5)	5 (0.1)	24 (0.3)
Day 7	11 (0.3)	2 (<0.1)	13 (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=3767) n (%)	Total (N=7517) n (%)
Pain - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	263 (7.0)	280 (7.4)	543 (7.2)
Day 1, after Vaccination (at Home)	221 (5.9)	1843 (48.9)	2064 (27.5)
Day 2	158 (4.2)	1150 (30.5)	1308 (17.4)
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	11 (0.3)	3 (<0.1)	14 (0.2)
Day 7	9 (0.2)	1 (<0.1)	10 (0.1)
Erythema (Redness) - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	9 (0.2)	27 (0.7)	36 (0.5)
Day 2	8 (0.2)	150 (4.0)	158 (2.1)
Day 3	8 (0.2)	113 (3.0)	121 (1.6)
Day 4	1 (<0.1)	29 (0.8)	30 (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	2 (<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 14.3.1.3.6
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=3767) n (%)	Total (N=7517) n (%)
Swelling (Hardness) - N1	3750	3767	7517
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)	95 (2.5)	101 (1.3)
Day 2	10 (0.3)	270 (7.2)	280 (3.7)
Day 3	4 (0.1)	78 (2.1)	82 (1.1)
Day 4	3 (<0.1)	22 (0.6)	25 (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	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	35 (0.9)	41 (1.1)	76 (1.0)
Day 1, after Vaccination (at Home)	40 (1.1)	110 (2.9)	150 (2.0)
Day 2	65 (1.7)	191 (5.1)	256 (3.4)
Day 3	31 (0.8)	74 (2.0)	105 (1.4)
Day 4	16 (0.4)	34 (0.9)	50 (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=3767) n (%)	Total (N=7517) n (%)
Solicited Systemic Adverse Reactions - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	237 (6.3)	204 (5.4)	441 (5.9)
Day 1, after Vaccination (at Home)	564 (15.0)	1087 (28.9)	1651 (22.0)
Day 2	442 (11.8)	1451 (38.5)	1893 (25.2)
Day 3	203 (5.4)	127 (3.4)	330 (4.4)
Day 4	128 (3.4)	27 (0.7)	155 (2.1)
Day 5	77 (2.1)	25 (0.7)	102 (1.4)
Day 6	63 (1.7)	19 (0.5)	82 (1.1)
Day 7	50 (1.3)	13 (0.3)	63 (0.8)
Fever - N1	3750	3767	7517
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)	30 (0.8)	33 (0.4)
Day 2	2 (<0.1)	320 (8.5)	322 (4.3)
Day 3	1 (<0.1)	20 (0.5)	21 (0.3)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	2 (<0.1)	3 (<0.1)	5 (<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=3767) n (%)	Total (N=7517) n (%)
Headache - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	123 (3.3)	106 (2.8)	229 (3.0)
Day 1, after Vaccination (at Home)	264 (7.0)	547 (14.5)	811 (10.8)
Day 2	272 (7.3)	1096 (29.1)	1368 (18.2)
Day 3	152 (4.1)	129 (3.4)	281 (3.7)
Day 4	88 (2.3)	39 (1.0)	127 (1.7)
Day 5	74 (2.0)	32 (0.8)	106 (1.4)
Day 6	54 (1.4)	30 (0.8)	84 (1.1)
Day 7	50 (1.3)	27 (0.7)	77 (1.0)
Fatigue - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	86 (2.3)	78 (2.1)	164 (2.2)
Day 1, after Vaccination (at Home)	399 (10.6)	756 (20.1)	1155 (15.4)
Day 2	317 (8.5)	1388 (36.8)	1705 (22.7)
Day 3	137 (3.7)	121 (3.2)	258 (3.4)
Day 4	104 (2.8)	36 (1.0)	140 (1.9)
Day 5	55 (1.5)	22 (0.6)	77 (1.0)
Day 6	63 (1.7)	23 (0.6)	86 (1.1)
Day 7	41 (1.1)	15 (0.4)	56 (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: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3750) n (%)	mRNA-1273 (N=3767) n (%)	Total (N=7517) n (%)
Myalgia - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	53 (1.4)	50 (1.3)	103 (1.4)
Day 1, after Vaccination (at Home)	146 (3.9)	471 (12.5)	617 (8.2)
Day 2	201 (5.4)	1238 (32.9)	1439 (19.1)
Day 3	107 (2.9)	105 (2.8)	212 (2.8)
Day 4	58 (1.5)	35 (0.9)	93 (1.2)
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)	9 (0.2)	42 (0.6)
Arthralgia - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	62 (1.7)	61 (1.6)	123 (1.6)
Day 1, after Vaccination (at Home)	127 (3.4)	338 (9.0)	465 (6.2)
Day 2	196 (5.2)	895 (23.8)	1091 (14.5)
Day 3	103 (2.7)	112 (3.0)	215 (2.9)
Day 4	65 (1.7)	48 (1.3)	113 (1.5)
Day 5	47 (1.3)	25 (0.7)	72 (1.0)
Day 6	44 (1.2)	19 (0.5)	63 (0.8)
Day 7	25 (0.7)	14 (0.4)	39 (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=3767) n (%)	Total (N=7517) n (%)
Nausea/Vomiting - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	13 (0.3)	19 (0.5)	32 (0.4)
Day 1, after Vaccination (at Home)	38 (1.0)	85 (2.3)	123 (1.6)
Day 2	73 (1.9)	311 (8.3)	384 (5.1)
Day 3	43 (1.1)	70 (1.9)	113 (1.5)
Day 4	28 (0.7)	23 (0.6)	51 (0.7)
Day 5	18 (0.5)	19 (0.5)	37 (0.5)
Day 6	31 (0.8)	20 (0.5)	51 (0.7)
Day 7	29 (0.8)	16 (0.4)	45 (0.6)
Chills - N1	3750	3767	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	24 (0.6)	23 (0.6)	47 (0.6)
Day 1, after Vaccination (at Home)	61 (1.6)	193 (5.1)	254 (3.4)
Day 2	72 (1.9)	875 (23.2)	947 (12.6)
Day 3	36 (1.0)	96 (2.5)	132 (1.8)
Day 4	21 (0.6)	23 (0.6)	44 (0.6)
Day 5	21 (0.6)	6 (0.2)	27 (0.4)
Day 6	19 (0.5)	5 (0.1)	24 (0.3)
Day 7	12 (0.3)	9 (0.2)	21 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Solicited Adverse Reactions - N1	14583	14538	29121
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1546 (10.6)	1516 (10.4)	3062 (10.5)
Day 1, after Vaccination (at Home)	2080 (14.3)	6525 (44.9)	8605 (29.5)
Day 2	1540 (10.6)	4299 (29.6)	5839 (20.1)
Day 3	723 (5.0)	271 (1.9)	994 (3.4)
Day 4	400 (2.7)	68 (0.5)	468 (1.6)
Day 5	310 (2.1)	38 (0.3)	348 (1.2)
Day 6	235 (1.6)	45 (0.3)	280 (1.0)
Day 7	189 (1.3)	38 (0.3)	227 (0.8)
Solicited Local Adverse Reactions - N1	14579	14534	29113
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1102 (7.6)	1092 (7.5)	2194 (7.5)
Day 1, after Vaccination (at Home)	742 (5.1)	6162 (42.4)	6904 (23.7)
Day 2	560 (3.8)	4704 (32.4)	5264 (18.1)
Day 3	209 (1.4)	239 (1.6)	448 (1.5)
Day 4	111 (0.8)	40 (0.3)	151 (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)	16 (0.1)	49 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Pain - N1	14579	14534	29113
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1063 (7.3)	1053 (7.2)	2116 (7.3)
Day 1, after Vaccination (at Home)	679 (4.7)	6129 (42.2)	6808 (23.4)
Day 2	474 (3.3)	4726 (32.5)	5200 (17.9)
Day 3	156 (1.1)	244 (1.7)	400 (1.4)
Day 4	79 (0.5)	34 (0.2)	113 (0.4)
Day 5	51 (0.3)	9 (<0.1)	60 (0.2)
Day 6	36 (0.2)	3 (<0.1)	39 (0.1)
Day 7	25 (0.2)	9 (<0.1)	34 (0.1)
Erythema (Redness) - N1	14579	14533	29112
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	9 (<0.1)	11 (<0.1)
Day 1, after Vaccination (at Home)	19 (0.1)	50 (0.3)	69 (0.2)
Day 2	18 (0.1)	219 (1.5)	237 (0.8)
Day 3	11 (<0.1)	106 (0.7)	117 (0.4)
Day 4	4 (<0.1)	13 (<0.1)	17 (<0.1)
Day 5	5 (<0.1)	7 (<0.1)	12 (<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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Swelling (Hardness) - N1	14579	14533	29112
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	10 (<0.1)	180 (1.2)	190 (0.7)
Day 2	17 (0.1)	574 (3.9)	591 (2.0)
Day 3	5 (<0.1)	99 (0.7)	104 (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	1 (<0.1)	1 (<0.1)
Day 7	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lymphadenopathy - N1 [1]	14579	14533	29112
Day 1, 30 Minutes after Vaccination (at Study Clinic)	95 (0.7)	94 (0.6)	189 (0.6)
Day 1, after Vaccination (at Home)	142 (1.0)	334 (2.3)	476 (1.6)
Day 2	159 (1.1)	452 (3.1)	611 (2.1)
Day 3	99 (0.7)	217 (1.5)	316 (1.1)
Day 4	62 (0.4)	89 (0.6)	151 (0.5)
Day 5	56 (0.4)	53 (0.4)	109 (0.4)
Day 6	44 (0.3)	88 (0.6)	132 (0.5)
Day 7	32 (0.2)	138 (0.9)	170 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Solicited Systemic Adverse Reactions - N1	14583	14537	29120
Day 1, 30 Minutes after Vaccination (at Study Clinic)	663 (4.5)	622 (4.3)	1285 (4.4)
Day 1, after Vaccination (at Home)	1942 (13.3)	2800 (19.3)	4742 (16.3)
Day 2	1557 (10.7)	2719 (18.7)	4276 (14.7)
Day 3	752 (5.2)	860 (5.9)	1612 (5.5)
Day 4	430 (2.9)	315 (2.2)	745 (2.6)
Day 5	343 (2.4)	234 (1.6)	577 (2.0)
Day 6	264 (1.8)	216 (1.5)	480 (1.6)
Day 7	216 (1.5)	188 (1.3)	404 (1.4)
Fever - N1	14582	14535	29117
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	1 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	14 (<0.1)	19 (<0.1)
Day 2	4 (<0.1)	30 (0.2)	34 (0.1)
Day 3	5 (<0.1)	21 (0.1)	26 (<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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Headache - N1	14578	14533	29111
Day 1, 30 Minutes after Vaccination (at Study Clinic)	351 (2.4)	349 (2.4)	700 (2.4)
Day 1, after Vaccination (at Home)	953 (6.5)	1291 (8.9)	2244 (7.7)
Day 2	921 (6.3)	1457 (10.0)	2378 (8.2)
Day 3	526 (3.6)	683 (4.7)	1209 (4.2)
Day 4	344 (2.4)	272 (1.9)	616 (2.1)
Day 5	296 (2.0)	238 (1.6)	534 (1.8)
Day 6	261 (1.8)	222 (1.5)	483 (1.7)
Day 7	213 (1.5)	211 (1.5)	424 (1.5)
Fatigue - N1	14578	14533	29111
Day 1, 30 Minutes after Vaccination (at Study Clinic)	230 (1.6)	238 (1.6)	468 (1.6)
Day 1, after Vaccination (at Home)	1335 (9.2)	1818 (12.5)	3153 (10.8)
Day 2	1054 (7.2)	2014 (13.9)	3068 (10.5)
Day 3	514 (3.5)	667 (4.6)	1181 (4.1)
Day 4	284 (1.9)	246 (1.7)	530 (1.8)
Day 5	233 (1.6)	149 (1.0)	382 (1.3)
Day 6	191 (1.3)	150 (1.0)	341 (1.2)
Day 7	147 (1.0)	118 (0.8)	265 (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=14583) n	(%)	mRNA-1273 (N=14538) n	(%)	Total (N=29121) n	(%)
Myalgia - N1	14578		14533		29111	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	119	(0.8)	127	(0.9)	246	(0.8)
Day 1, after Vaccination (at Home)	436	(3.0)	856	(5.9)	1292	(4.4)
Day 2	563	(3.9)	1366	(9.4)	1929	(6.6)
Day 3	278	(1.9)	466	(3.2)	744	(2.6)
Day 4	218	(1.5)	160	(1.1)	378	(1.3)
Day 5	150	(1.0)	98	(0.7)	248	(0.9)
Day 6	114	(0.8)	93	(0.6)	207	(0.7)
Day 7	109	(0.7)	78	(0.5)	187	(0.6)
Arthralgia - N1	14578		14533		29111	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	94	(0.6)	103	(0.7)	197	(0.7)
Day 1, after Vaccination (at Home)	309	(2.1)	526	(3.6)	835	(2.9)
Day 2	473	(3.2)	879	(6.0)	1352	(4.6)
Day 3	276	(1.9)	422	(2.9)	698	(2.4)
Day 4	195	(1.3)	169	(1.2)	364	(1.3)
Day 5	144	(1.0)	100	(0.7)	244	(0.8)
Day 6	124	(0.9)	91	(0.6)	215	(0.7)
Day 7	92	(0.6)	91	(0.6)	183	(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=14583) n	(%)	mRNA-1273 (N=14538) n	(%)	Total (N=29121) n	(%)
Nausea/Vomiting - N1	14578		14533		29111	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	48	(0.3)	40	(0.3)	88	(0.3)
Day 1, after Vaccination (at Home)	169	(1.2)	211	(1.5)	380	(1.3)
Day 2	244	(1.7)	368	(2.5)	612	(2.1)
Day 3	164	(1.1)	234	(1.6)	398	(1.4)
Day 4	115	(0.8)	120	(0.8)	235	(0.8)
Day 5	99	(0.7)	74	(0.5)	173	(0.6)
Day 6	114	(0.8)	78	(0.5)	192	(0.7)
Day 7	80	(0.5)	68	(0.5)	148	(0.5)
Chills - N1	14578		14533		29111	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	83	(0.6)	69	(0.5)	152	(0.5)
Day 1, after Vaccination (at Home)	186	(1.3)	253	(1.7)	439	(1.5)
Day 2	189	(1.3)	406	(2.8)	595	(2.0)
Day 3	125	(0.9)	229	(1.6)	354	(1.2)
Day 4	74	(0.5)	67	(0.5)	141	(0.5)
Day 5	77	(0.5)	55	(0.4)	132	(0.5)
Day 6	59	(0.4)	31	(0.2)	90	(0.3)
Day 7	43	(0.3)	34	(0.2)	77	(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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Solicited Adverse Reactions - N1	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	27 (8.0)	26 (7.6)	53 (7.8)
Day 1, after Vaccination (at Home)	35 (10.4)	119 (34.8)	154 (22.7)
Day 2	36 (10.7)	103 (30.1)	139 (20.5)
Day 3	13 (3.9)	9 (2.6)	22 (3.2)
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	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	19 (5.6)	15 (4.4)	34 (5.0)
Day 1, after Vaccination (at Home)	16 (4.7)	107 (31.3)	123 (18.1)
Day 2	10 (3.0)	110 (32.2)	120 (17.7)
Day 3	5 (1.5)	11 (3.2)	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	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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Pain - N1	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	19 (5.6)	15 (4.4)	34 (5.0)
Day 1, after Vaccination (at Home)	15 (4.5)	107 (31.3)	122 (18.0)
Day 2	9 (2.7)	107 (31.3)	116 (17.1)
Day 3	4 (1.2)	13 (3.8)	17 (2.5)
Day 4	3 (0.9)	1 (0.3)	4 (0.6)
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	337	342	679
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Swelling (Hardness) - N1	337	342	679
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)	12 (3.5)	13 (1.9)
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]	337	342	679
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)	7 (2.0)	9 (1.3)
Day 2	1 (0.3)	21 (6.1)	22 (3.2)
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	4 (1.2)	0	4 (0.6)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Solicited Systemic Adverse Reactions - N1	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (3.0)	16 (4.7)	26 (3.8)
Day 1, after Vaccination (at Home)	29 (8.6)	57 (16.7)	86 (12.7)
Day 2	37 (11.0)	113 (33.0)	150 (22.1)
Day 3	17 (5.0)	13 (3.8)	30 (4.4)
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	336	342	678
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)	25 (7.3)	26 (3.8)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Headache - N1	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (1.5)	6 (1.8)	11 (1.6)
Day 1, after Vaccination (at Home)	14 (4.2)	32 (9.4)	46 (6.8)
Day 2	23 (6.8)	63 (18.4)	86 (12.7)
Day 3	11 (3.3)	13 (3.8)	24 (3.5)
Day 4	10 (3.0)	8 (2.3)	18 (2.7)
Day 5	7 (2.1)	8 (2.3)	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	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (0.9)	8 (2.3)	11 (1.6)
Day 1, after Vaccination (at Home)	16 (4.7)	31 (9.1)	47 (6.9)
Day 2	21 (6.2)	75 (21.9)	96 (14.1)
Day 3	14 (4.2)	10 (2.9)	24 (3.5)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Myalgia - N1	337	342	679
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)	27 (7.9)	31 (4.6)
Day 2	17 (5.0)	77 (22.5)	94 (13.8)
Day 3	8 (2.4)	11 (3.2)	19 (2.8)
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	337	342	679
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 (8.4)
Day 3	10 (3.0)	11 (3.2)	21 (3.1)
Day 4	6 (1.8)	3 (0.9)	9 (1.3)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Nausea/Vomiting - N1	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	5 (1.5)	3 (0.9)	8 (1.2)
Day 2	4 (1.2)	22 (6.4)	26 (3.8)
Day 3	3 (0.9)	8 (2.3)	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	337	342	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	2 (0.6)	3 (0.4)
Day 1, after Vaccination (at Home)	5 (1.5)	12 (3.5)	17 (2.5)
Day 2	7 (2.1)	53 (15.5)	60 (8.8)
Day 3	6 (1.8)	8 (2.3)	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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Adverse Reactions - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	23 (9.8)	30 (10.4)	53 (10.1)
Day 1, after Vaccination (at Home)	32 (13.6)	123 (42.7)	155 (29.6)
Day 2	31 (13.2)	91 (31.6)	122 (23.3)
Day 3	11 (4.7)	8 (2.8)	19 (3.6)
Day 4	8 (3.4)	4 (1.4)	12 (2.3)
Day 5	9 (3.8)	1 (0.3)	10 (1.9)
Day 6	6 (2.6)	0	6 (1.1)
Day 7	4 (1.7)	1 (0.3)	5 (1.0)
Solicited Local Adverse Reactions - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	18 (7.7)	22 (7.6)	40 (7.6)
Day 1, after Vaccination (at Home)	8 (3.4)	116 (40.3)	124 (23.7)
Day 2	10 (4.3)	97 (33.7)	107 (20.5)
Day 3	3 (1.3)	5 (1.7)	8 (1.5)
Day 4	2 (0.9)	2 (0.7)	4 (0.8)
Day 5	2 (0.9)	0	2 (0.4)
Day 6	3 (1.3)	1 (0.3)	4 (0.8)
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Pain - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	18 (7.7)	20 (6.9)	38 (7.3)
Day 1, after Vaccination (at Home)	7 (3.0)	115 (39.9)	122 (23.3)
Day 2	8 (3.4)	97 (33.7)	105 (20.1)
Day 3	1 (0.4)	4 (1.4)	5 (1.0)
Day 4	1 (0.4)	2 (0.7)	3 (0.6)
Day 5	2 (0.9)	0	2 (0.4)
Day 6	1 (0.4)	1 (0.3)	2 (0.4)
Day 7	1 (0.4)	0	1 (0.2)
Erythema (Redness) - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.3)	1 (0.2)
Day 1, after Vaccination (at Home)	0	1 (0.3)	1 (0.2)
Day 2	0	6 (2.1)	6 (1.1)
Day 3	0	4 (1.4)	4 (0.8)
Day 4	0	0	0
Day 5	0	0	0
Day 6	1 (0.4)	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 14.3.1.3.7
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=235) n	Placebo (N=235) (%)	mRNA-1273 (N=288) n	mRNA-1273 (N=288) (%)	Total (N=523) n	Total (N=523) (%)
Swelling (Hardness) - N1	235		288		523	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0		0		0	
Day 1, after Vaccination (at Home)	0		6	(2.1)	6	(1.1)
Day 2	1	(0.4)	5	(1.7)	6	(1.1)
Day 3	0		7	(2.4)	7	(1.3)
Day 4	0		0		0	
Day 5	0		0		0	
Day 6	0		0		0	
Day 7	0		0		0	
Lymphadenopathy - N1 [1]	235		288		523	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2	(0.9)	1	(0.3)	3	(0.6)
Day 1, after Vaccination (at Home)	3	(1.3)	7	(2.4)	10	(1.9)
Day 2	2	(0.9)	17	(5.9)	19	(3.6)
Day 3	3	(1.3)	2	(0.7)	5	(1.0)
Day 4	1	(0.4)	4	(1.4)	5	(1.0)
Day 5	0		2	(0.7)	2	(0.4)
Day 6	3	(1.3)	1	(0.3)	4	(0.8)
Day 7	1	(0.4)	1	(0.3)	2	(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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Systemic Adverse Reactions - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (4.3)	10 (3.5)	20 (3.8)
Day 1, after Vaccination (at Home)	33 (14.0)	51 (17.7)	84 (16.1)
Day 2	28 (11.9)	57 (19.8)	85 (16.3)
Day 3	14 (6.0)	14 (4.9)	28 (5.4)
Day 4	8 (3.4)	10 (3.5)	18 (3.4)
Day 5	9 (3.8)	8 (2.8)	17 (3.3)
Day 6	5 (2.1)	5 (1.7)	10 (1.9)
Day 7	4 (1.7)	1 (0.3)	5 (1.0)
Fever - N1	235	287	522
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (0.3)	1 (0.2)
Day 2	0	1 (0.3)	1 (0.2)
Day 3	0	2 (0.7)	2 (0.4)
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 14.3.1.3.7
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Headache - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (3.4)	5 (1.7)	13 (2.5)
Day 1, after Vaccination (at Home)	14 (6.0)	27 (9.4)	41 (7.8)
Day 2	17 (7.2)	28 (9.7)	45 (8.6)
Day 3	14 (6.0)	14 (4.9)	28 (5.4)
Day 4	9 (3.8)	6 (2.1)	15 (2.9)
Day 5	5 (2.1)	5 (1.7)	10 (1.9)
Day 6	6 (2.6)	9 (3.1)	15 (2.9)
Day 7	7 (3.0)	3 (1.0)	10 (1.9)
Fatigue - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (1.3)	2 (0.7)	5 (1.0)
Day 1, after Vaccination (at Home)	21 (8.9)	27 (9.4)	48 (9.2)
Day 2	18 (7.7)	43 (14.9)	61 (11.7)
Day 3	6 (2.6)	11 (3.8)	17 (3.3)
Day 4	6 (2.6)	5 (1.7)	11 (2.1)
Day 5	10 (4.3)	7 (2.4)	17 (3.3)
Day 6	6 (2.6)	4 (1.4)	10 (1.9)
Day 7	3 (1.3)	2 (0.7)	5 (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: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Myalgia - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (1.3)	1 (0.3)	4 (0.8)
Day 1, after Vaccination (at Home)	10 (4.3)	20 (6.9)	30 (5.7)
Day 2	7 (3.0)	30 (10.4)	37 (7.1)
Day 3	6 (2.6)	9 (3.1)	15 (2.9)
Day 4	4 (1.7)	4 (1.4)	8 (1.5)
Day 5	4 (1.7)	7 (2.4)	11 (2.1)
Day 6	3 (1.3)	1 (0.3)	4 (0.8)
Day 7	0	1 (0.3)	1 (0.2)
Arthralgia - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (1.7)	0	4 (0.8)
Day 1, after Vaccination (at Home)	6 (2.6)	6 (2.1)	12 (2.3)
Day 2	10 (4.3)	18 (6.3)	28 (5.4)
Day 3	6 (2.6)	6 (2.1)	12 (2.3)
Day 4	4 (1.7)	5 (1.7)	9 (1.7)
Day 5	2 (0.9)	8 (2.8)	10 (1.9)
Day 6	3 (1.3)	1 (0.3)	4 (0.8)
Day 7	1 (0.4)	1 (0.3)	2 (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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Nausea/Vomiting - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.4)	1 (0.3)	2 (0.4)
Day 1, after Vaccination (at Home)	1 (0.4)	2 (0.7)	3 (0.6)
Day 2	3 (1.3)	6 (2.1)	9 (1.7)
Day 3	1 (0.4)	6 (2.1)	7 (1.3)
Day 4	2 (0.9)	2 (0.7)	4 (0.8)
Day 5	3 (1.3)	5 (1.7)	8 (1.5)
Day 6	2 (0.9)	2 (0.7)	4 (0.8)
Day 7	2 (0.9)	3 (1.0)	5 (1.0)
Chills - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.9)	2 (0.7)	4 (0.8)
Day 1, after Vaccination (at Home)	4 (1.7)	7 (2.4)	11 (2.1)
Day 2	2 (0.9)	11 (3.8)	13 (2.5)
Day 3	0	4 (1.4)	4 (0.8)
Day 4	2 (0.9)	0	2 (0.4)
Day 5	2 (0.9)	3 (1.0)	5 (1.0)
Day 6	1 (0.4)	1 (0.3)	2 (0.4)
Day 7	2 (0.9)	1 (0.3)	3 (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 14.3.1.3.8
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Solicited Adverse Reactions - N1	14119	14183	28302
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1510 (10.7)	1415 (10.0)	2925 (10.3)
Day 1, after Vaccination (at Home)	1836 (13.0)	7951 (56.1)	9787 (34.6)
Day 2	1188 (8.4)	3535 (24.9)	4723 (16.7)
Day 3	558 (4.0)	136 (1.0)	694 (2.5)
Day 4	339 (2.4)	28 (0.2)	367 (1.3)
Day 5	266 (1.9)	13 (<0.1)	279 (1.0)
Day 6	197 (1.4)	12 (<0.1)	209 (0.7)
Day 7	162 (1.1)	11 (<0.1)	173 (0.6)
Solicited Local Adverse Reactions - N1	14116	14179	28295
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1152 (8.2)	1081 (7.6)	2233 (7.9)
Day 1, after Vaccination (at Home)	733 (5.2)	7732 (54.5)	8465 (29.9)
Day 2	397 (2.8)	3585 (25.3)	3982 (14.1)
Day 3	176 (1.2)	152 (1.1)	328 (1.2)
Day 4	81 (0.6)	24 (0.2)	105 (0.4)
Day 5	53 (0.4)	8 (<0.1)	61 (0.2)
Day 6	29 (0.2)	8 (<0.1)	37 (0.1)
Day 7	29 (0.2)	4 (<0.1)	33 (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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Pain - N1	14116	14179	28295
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1120 (7.9)	1040 (7.3)	2160 (7.6)
Day 1, after Vaccination (at Home)	682 (4.8)	7712 (54.4)	8394 (29.7)
Day 2	324 (2.3)	3597 (25.4)	3921 (13.9)
Day 3	143 (1.0)	152 (1.1)	295 (1.0)
Day 4	58 (0.4)	22 (0.2)	80 (0.3)
Day 5	37 (0.3)	5 (<0.1)	42 (0.1)
Day 6	23 (0.2)	6 (<0.1)	29 (0.1)
Day 7	16 (0.1)	2 (<0.1)	18 (<0.1)
Erythema (Redness) - N1	14116	14179	28295
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (<0.1)	4 (<0.1)	11 (<0.1)
Day 1, after Vaccination (at Home)	19 (0.1)	111 (0.8)	130 (0.5)
Day 2	9 (<0.1)	499 (3.5)	508 (1.8)
Day 3	9 (<0.1)	485 (3.4)	494 (1.7)
Day 4	2 (<0.1)	108 (0.8)	110 (0.4)
Day 5	3 (<0.1)	14 (<0.1)	17 (<0.1)
Day 6	2 (<0.1)	3 (<0.1)	5 (<0.1)
Day 7	1 (<0.1)	3 (<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 14.3.1.3.8
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Swelling (Hardness) - N1	14116	14179	28295
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (<0.1)	17 (0.1)	29 (0.1)
Day 1, after Vaccination (at Home)	11 (<0.1)	461 (3.3)	472 (1.7)
Day 2	11 (<0.1)	901 (6.4)	912 (3.2)
Day 3	6 (<0.1)	288 (2.0)	294 (1.0)
Day 4	3 (<0.1)	66 (0.5)	69 (0.2)
Day 5	0	8 (<0.1)	8 (<0.1)
Day 6	2 (<0.1)	4 (<0.1)	6 (<0.1)
Day 7	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lymphadenopathy - N1 [1]	14116	14179	28295
Day 1, 30 Minutes after Vaccination (at Study Clinic)	60 (0.4)	75 (0.5)	135 (0.5)
Day 1, after Vaccination (at Home)	140 (1.0)	473 (3.3)	613 (2.2)
Day 2	147 (1.0)	852 (6.0)	999 (3.5)
Day 3	82 (0.6)	392 (2.8)	474 (1.7)
Day 4	48 (0.3)	148 (1.0)	196 (0.7)
Day 5	37 (0.3)	39 (0.3)	76 (0.3)
Day 6	17 (0.1)	21 (0.1)	38 (0.1)
Day 7	15 (0.1)	18 (0.1)	33 (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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Solicited Systemic Adverse Reactions - N1	14118	14183	28301
Day 1, 30 Minutes after Vaccination (at Study Clinic)	525 (3.7)	503 (3.5)	1028 (3.6)
Day 1, after Vaccination (at Home)	1698 (12.0)	4012 (28.3)	5710 (20.2)
Day 2	1243 (8.8)	6194 (43.7)	7437 (26.3)
Day 3	606 (4.3)	367 (2.6)	973 (3.4)
Day 4	379 (2.7)	90 (0.6)	469 (1.7)
Day 5	297 (2.1)	44 (0.3)	341 (1.2)
Day 6	233 (1.7)	48 (0.3)	281 (1.0)
Day 7	187 (1.3)	32 (0.2)	219 (0.8)
Fever - N1	14113	14176	28289
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)	197 (1.4)	202 (0.7)
Day 2	8 (<0.1)	1851 (13.1)	1859 (6.6)
Day 3	7 (<0.1)	162 (1.1)	169 (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	6 (<0.1)	3 (<0.1)	9 (<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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Headache - N1	14116	14179	28295
Day 1, 30 Minutes after Vaccination (at Study Clinic)	256 (1.8)	257 (1.8)	513 (1.8)
Day 1, after Vaccination (at Home)	875 (6.2)	2043 (14.4)	2918 (10.3)
Day 2	760 (5.4)	5189 (36.6)	5949 (21.0)
Day 3	478 (3.4)	434 (3.1)	912 (3.2)
Day 4	321 (2.3)	154 (1.1)	475 (1.7)
Day 5	227 (1.6)	112 (0.8)	339 (1.2)
Day 6	205 (1.5)	94 (0.7)	299 (1.1)
Day 7	189 (1.3)	65 (0.5)	254 (0.9)
Fatigue - N1	14114	14179	28293
Day 1, 30 Minutes after Vaccination (at Study Clinic)	207 (1.5)	225 (1.6)	432 (1.5)
Day 1, after Vaccination (at Home)	1103 (7.8)	2767 (19.5)	3870 (13.7)
Day 2	873 (6.2)	5703 (40.2)	6576 (23.2)
Day 3	401 (2.8)	412 (2.9)	813 (2.9)
Day 4	244 (1.7)	81 (0.6)	325 (1.1)
Day 5	191 (1.4)	54 (0.4)	245 (0.9)
Day 6	170 (1.2)	39 (0.3)	209 (0.7)
Day 7	105 (0.7)	29 (0.2)	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 14.3.1.3.8
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Myalgia - N1	14114	14179	28293
Day 1, 30 Minutes after Vaccination (at Study Clinic)	107 (0.8)	99 (0.7)	206 (0.7)
Day 1, after Vaccination (at Home)	417 (3.0)	1900 (13.4)	2317 (8.2)
Day 2	484 (3.4)	5743 (40.5)	6227 (22.0)
Day 3	249 (1.8)	342 (2.4)	591 (2.1)
Day 4	170 (1.2)	63 (0.4)	233 (0.8)
Day 5	115 (0.8)	32 (0.2)	147 (0.5)
Day 6	116 (0.8)	30 (0.2)	146 (0.5)
Day 7	80 (0.6)	20 (0.1)	100 (0.4)
Arthralgia - N1	14114	14179	28293
Day 1, 30 Minutes after Vaccination (at Study Clinic)	115 (0.8)	115 (0.8)	230 (0.8)
Day 1, after Vaccination (at Home)	343 (2.4)	1261 (8.9)	1604 (5.7)
Day 2	384 (2.7)	4200 (29.6)	4584 (16.2)
Day 3	217 (1.5)	330 (2.3)	547 (1.9)
Day 4	178 (1.3)	81 (0.6)	259 (0.9)
Day 5	97 (0.7)	37 (0.3)	134 (0.5)
Day 6	107 (0.8)	38 (0.3)	145 (0.5)
Day 7	75 (0.5)	21 (0.1)	96 (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: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14119) n	Placebo (N=14119) (%)	mRNA-1273 (N=14183) n	mRNA-1273 (N=14183) (%)	Total (N=28302) n	Total (N=28302) (%)
Nausea/Vomiting - N1	14114		14179		28293	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	44	(0.3)	38	(0.3)	82	(0.3)
Day 1, after Vaccination (at Home)	206	(1.5)	460	(3.2)	666	(2.4)
Day 2	217	(1.5)	1724	(12.2)	1941	(6.9)
Day 3	134	(0.9)	256	(1.8)	390	(1.4)
Day 4	95	(0.7)	94	(0.7)	189	(0.7)
Day 5	73	(0.5)	51	(0.4)	124	(0.4)
Day 6	76	(0.5)	44	(0.3)	120	(0.4)
Day 7	67	(0.5)	33	(0.2)	100	(0.4)
Chills - N1	14114		14179		28293	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	57	(0.4)	46	(0.3)	103	(0.4)
Day 1, after Vaccination (at Home)	198	(1.4)	1062	(7.5)	1260	(4.5)
Day 2	193	(1.4)	4730	(33.4)	4923	(17.4)
Day 3	96	(0.7)	351	(2.5)	447	(1.6)
Day 4	70	(0.5)	45	(0.3)	115	(0.4)
Day 5	64	(0.5)	16	(0.1)	80	(0.3)
Day 6	57	(0.4)	23	(0.2)	80	(0.3)
Day 7	43	(0.3)	19	(0.1)	62	(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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Solicited Adverse Reactions - N1	232	230	462
Day 1, 30 Minutes after Vaccination (at Study Clinic)	22 (9.5)	15 (6.5)	37 (8.0)
Day 1, after Vaccination (at Home)	25 (10.8)	108 (47.0)	133 (28.8)
Day 2	18 (7.8)	58 (25.2)	76 (16.5)
Day 3	5 (2.2)	2 (0.9)	7 (1.5)
Day 4	4 (1.7)	1 (0.4)	5 (1.1)
Day 5	3 (1.3)	1 (0.4)	4 (0.9)
Day 6	3 (1.3)	0	3 (0.6)
Day 7	1 (0.4)	1 (0.4)	2 (0.4)
Solicited Local Adverse Reactions - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	15 (6.5)	9 (3.9)	24 (5.2)
Day 1, after Vaccination (at Home)	16 (6.9)	104 (45.2)	120 (26.0)
Day 2	7 (3.0)	53 (23.0)	60 (13.0)
Day 3	1 (0.4)	3 (1.3)	4 (0.9)
Day 4	1 (0.4)	2 (0.9)	3 (0.7)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	1 (0.4)	0	1 (0.2)
Day 7	0	1 (0.4)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Pain - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	15 (6.5)	9 (3.9)	24 (5.2)
Day 1, after Vaccination (at Home)	15 (6.5)	103 (44.8)	118 (25.6)
Day 2	4 (1.7)	53 (23.0)	57 (12.4)
Day 3	0	2 (0.9)	2 (0.4)
Day 4	1 (0.4)	1 (0.4)	2 (0.4)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	0	0	0
Day 7	0	1 (0.4)	1 (0.2)
Erythema (Redness) - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	4 (1.7)	4 (0.9)
Day 3	1 (0.4)	1 (0.4)	2 (0.4)
Day 4	0	3 (1.3)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Swelling (Hardness) - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	3 (1.3)	3 (0.7)
Day 2	0	4 (1.7)	4 (0.9)
Day 3	0	2 (0.9)	2 (0.4)
Day 4	0	1 (0.4)	1 (0.2)
Day 5	1 (0.4)	1 (0.4)	2 (0.4)
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	2 (0.9)	10 (4.3)	12 (2.6)
Day 2	5 (2.2)	12 (5.2)	17 (3.7)
Day 3	1 (0.4)	3 (1.3)	4 (0.9)
Day 4	0	5 (2.2)	5 (1.1)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	2 (0.9)	0	2 (0.4)
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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Solicited Systemic Adverse Reactions - N1	232	230	462
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (4.7)	7 (3.0)	18 (3.9)
Day 1, after Vaccination (at Home)	20 (8.6)	63 (27.4)	83 (18.0)
Day 2	22 (9.5)	72 (31.3)	94 (20.3)
Day 3	7 (3.0)	2 (0.9)	9 (1.9)
Day 4	4 (1.7)	2 (0.9)	6 (1.3)
Day 5	3 (1.3)	2 (0.9)	5 (1.1)
Day 6	3 (1.3)	2 (0.9)	5 (1.1)
Day 7	1 (0.4)	0	1 (0.2)
Fever - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.4)	1 (0.2)
Day 1, after Vaccination (at Home)	0	4 (1.7)	4 (0.9)
Day 2	0	23 (10.0)	23 (5.0)
Day 3	0	2 (0.9)	2 (0.4)
Day 4	0	1 (0.4)	1 (0.2)
Day 5	0	0	0
Day 6	1 (0.4)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Headache - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	6 (2.6)	2 (0.9)	8 (1.7)
Day 1, after Vaccination (at Home)	11 (4.8)	32 (13.9)	43 (9.3)
Day 2	9 (3.9)	54 (23.5)	63 (13.7)
Day 3	6 (2.6)	2 (0.9)	8 (1.7)
Day 4	3 (1.3)	2 (0.9)	5 (1.1)
Day 5	3 (1.3)	2 (0.9)	5 (1.1)
Day 6	3 (1.3)	3 (1.3)	6 (1.3)
Day 7	2 (0.9)	0	2 (0.4)
Fatigue - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (2.2)	4 (1.7)	9 (2.0)
Day 1, after Vaccination (at Home)	15 (6.5)	34 (14.8)	49 (10.6)
Day 2	13 (5.6)	63 (27.4)	76 (16.5)
Day 3	8 (3.5)	3 (1.3)	11 (2.4)
Day 4	6 (2.6)	0	6 (1.3)
Day 5	5 (2.2)	0	5 (1.1)
Day 6	1 (0.4)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Myalgia - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (0.9)	2 (0.4)
Day 1, after Vaccination (at Home)	7 (3.0)	32 (13.9)	39 (8.5)
Day 2	9 (3.9)	75 (32.6)	84 (18.2)
Day 3	4 (1.7)	2 (0.9)	6 (1.3)
Day 4	6 (2.6)	2 (0.9)	8 (1.7)
Day 5	2 (0.9)	0	2 (0.4)
Day 6	1 (0.4)	2 (0.9)	3 (0.7)
Day 7	3 (1.3)	0	3 (0.7)
Arthralgia - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.4)	3 (1.3)	4 (0.9)
Day 1, after Vaccination (at Home)	6 (2.6)	21 (9.1)	27 (5.9)
Day 2	7 (3.0)	44 (19.1)	51 (11.1)
Day 3	4 (1.7)	5 (2.2)	9 (2.0)
Day 4	4 (1.7)	1 (0.4)	5 (1.1)
Day 5	0	0	0
Day 6	1 (0.4)	2 (0.9)	3 (0.7)
Day 7	1 (0.4)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Nausea/Vomiting - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	12 (5.2)	12 (2.6)
Day 2	2 (0.9)	17 (7.4)	19 (4.1)
Day 3	5 (2.2)	3 (1.3)	8 (1.7)
Day 4	4 (1.7)	1 (0.4)	5 (1.1)
Day 5	0	0	0
Day 6	1 (0.4)	1 (0.4)	2 (0.4)
Day 7	1 (0.4)	0	1 (0.2)
Chills - N1	231	230	461
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.9)	0	2 (0.4)
Day 1, after Vaccination (at Home)	3 (1.3)	19 (8.3)	22 (4.8)
Day 2	2 (0.9)	54 (23.5)	56 (12.1)
Day 3	2 (0.9)	3 (1.3)	5 (1.1)
Day 4	3 (1.3)	1 (0.4)	4 (0.9)
Day 5	3 (1.3)	0	3 (0.7)
Day 6	0	1 (0.4)	1 (0.2)
Day 7	2 (0.9)	0	2 (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: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Solicited Adverse Reactions - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	29 (13.5)	25 (9.5)	54 (11.3)
Day 1, after Vaccination (at Home)	23 (10.7)	160 (60.6)	183 (38.2)
Day 2	17 (7.9)	59 (22.3)	76 (15.9)
Day 3	12 (5.6)	3 (1.1)	15 (3.1)
Day 4	5 (2.3)	0	5 (1.0)
Day 5	5 (2.3)	0	5 (1.0)
Day 6	3 (1.4)	0	3 (0.6)
Day 7	1 (0.5)	0	1 (0.2)
Solicited Local Adverse Reactions - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	26 (12.1)	19 (7.2)	45 (9.4)
Day 1, after Vaccination (at Home)	8 (3.7)	156 (59.1)	164 (34.2)
Day 2	4 (1.9)	64 (24.2)	68 (14.2)
Day 3	3 (1.4)	1 (0.4)	4 (0.8)
Day 4	0	0	0
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: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Pain - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	26 (12.1)	19 (7.2)	45 (9.4)
Day 1, after Vaccination (at Home)	6 (2.8)	154 (58.3)	160 (33.4)
Day 2	4 (1.9)	64 (24.2)	68 (14.2)
Day 3	1 (0.5)	1 (0.4)	2 (0.4)
Day 4	0	0	0
Day 5	0	0	0
Day 6	1 (0.5)	0	1 (0.2)
Day 7	0	0	0
Erythema (Redness) - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.5)	0	1 (0.2)
Day 1, after Vaccination (at Home)	1 (0.5)	3 (1.1)	4 (0.8)
Day 2	0	8 (3.0)	8 (1.7)
Day 3	0	9 (3.4)	9 (1.9)
Day 4	0	2 (0.8)	2 (0.4)
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: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=215) n	(%)	mRNA-1273 (N=264) n	(%)	Total (N=479) n	(%)
Swelling (Hardness) - N1	215		264		479	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0		0		0	
Day 1, after Vaccination (at Home)	0		9	(3.4)	9	(1.9)
Day 2	1	(0.5)	17	(6.4)	18	(3.8)
Day 3	0		6	(2.3)	6	(1.3)
Day 4	0		0		0	
Day 5	0		0		0	
Day 6	0		0		0	
Day 7	0		0		0	
Lymphadenopathy - N1 [1]	215		264		479	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3	(1.4)	1	(0.4)	4	(0.8)
Day 1, after Vaccination (at Home)	2	(0.9)	11	(4.2)	13	(2.7)
Day 2	2	(0.9)	24	(9.1)	26	(5.4)
Day 3	2	(0.9)	5	(1.9)	7	(1.5)
Day 4	0		1	(0.4)	1	(0.2)
Day 5	1	(0.5)	0		1	(0.2)
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Solicited Systemic Adverse Reactions - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (4.2)	7 (2.7)	16 (3.3)
Day 1, after Vaccination (at Home)	28 (13.0)	81 (30.7)	109 (22.8)
Day 2	19 (8.8)	116 (43.9)	135 (28.2)
Day 3	11 (5.1)	5 (1.9)	16 (3.3)
Day 4	8 (3.7)	2 (0.8)	10 (2.1)
Day 5	5 (2.3)	0	5 (1.0)
Day 6	2 (0.9)	1 (0.4)	3 (0.6)
Day 7	2 (0.9)	0	2 (0.4)
Fever - N1	215	263	478
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	5 (1.9)	5 (1.0)
Day 2	0	18 (6.8)	18 (3.8)
Day 3	0	1 (0.4)	1 (0.2)
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Headache - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.9)	3 (1.1)	5 (1.0)
Day 1, after Vaccination (at Home)	19 (8.8)	43 (16.3)	62 (12.9)
Day 2	14 (6.5)	99 (37.5)	113 (23.6)
Day 3	10 (4.7)	4 (1.5)	14 (2.9)
Day 4	5 (2.3)	5 (1.9)	10 (2.1)
Day 5	3 (1.4)	3 (1.1)	6 (1.3)
Day 6	0	0	0
Day 7	3 (1.4)	0	3 (0.6)
Fatigue - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (2.3)	2 (0.8)	7 (1.5)
Day 1, after Vaccination (at Home)	18 (8.4)	53 (20.1)	71 (14.8)
Day 2	18 (8.4)	105 (39.8)	123 (25.7)
Day 3	3 (1.4)	3 (1.1)	6 (1.3)
Day 4	1 (0.5)	4 (1.5)	5 (1.0)
Day 5	7 (3.3)	0	7 (1.5)
Day 6	3 (1.4)	1 (0.4)	4 (0.8)
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: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Myalgia - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (1.9)	1 (0.4)	5 (1.0)
Day 1, after Vaccination (at Home)	11 (5.1)	44 (16.7)	55 (11.5)
Day 2	9 (4.2)	111 (42.0)	120 (25.1)
Day 3	8 (3.7)	6 (2.3)	14 (2.9)
Day 4	3 (1.4)	2 (0.8)	5 (1.0)
Day 5	3 (1.4)	0	3 (0.6)
Day 6	0	0	0
Day 7	1 (0.5)	0	1 (0.2)
Arthralgia - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.5)	1 (0.4)	2 (0.4)
Day 1, after Vaccination (at Home)	9 (4.2)	34 (12.9)	43 (9.0)
Day 2	7 (3.3)	85 (32.2)	92 (19.2)
Day 3	6 (2.8)	3 (1.1)	9 (1.9)
Day 4	2 (0.9)	1 (0.4)	3 (0.6)
Day 5	1 (0.5)	0	1 (0.2)
Day 6	3 (1.4)	1 (0.4)	4 (0.8)
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Nausea/Vomiting - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	2 (0.9)	11 (4.2)	13 (2.7)
Day 2	5 (2.3)	36 (13.6)	41 (8.6)
Day 3	0	3 (1.1)	3 (0.6)
Day 4	0	1 (0.4)	1 (0.2)
Day 5	1 (0.5)	0	1 (0.2)
Day 6	1 (0.5)	0	1 (0.2)
Day 7	0	0	0
Chills - N1	215	264	479
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.4)	1 (0.2)
Day 1, after Vaccination (at Home)	5 (2.3)	20 (7.6)	25 (5.2)
Day 2	5 (2.3)	85 (32.2)	90 (18.8)
Day 3	1 (0.5)	5 (1.9)	6 (1.3)
Day 4	2 (0.9)	1 (0.4)	3 (0.6)
Day 5	1 (0.5)	0	1 (0.2)
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: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Solicited Adverse Reactions - N1	14591	14548	29139
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2608 (17.9)	2534 (17.4)	5142 (17.6)
Day 1, after Vaccination (at Home)	2756 (18.9)	8537 (58.7)	11293 (38.8)
Day 2	1635 (11.2)	2608 (17.9)	4243 (14.6)
Day 3	719 (4.9)	97 (0.7)	816 (2.8)
Day 4	421 (2.9)	17 (0.1)	438 (1.5)
Day 5	300 (2.1)	22 (0.2)	322 (1.1)
Day 6	205 (1.4)	14 (<0.1)	219 (0.8)
Day 7	164 (1.1)	18 (0.1)	182 (0.6)
Solicited Local Adverse Reactions - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1957 (13.4)	1924 (13.2)	3881 (13.3)
Day 1, after Vaccination (at Home)	1116 (7.6)	8519 (58.6)	9635 (33.1)
Day 2	645 (4.4)	2902 (19.9)	3547 (12.2)
Day 3	261 (1.8)	107 (0.7)	368 (1.3)
Day 4	134 (0.9)	12 (<0.1)	146 (0.5)
Day 5	91 (0.6)	9 (<0.1)	100 (0.3)
Day 6	57 (0.4)	9 (<0.1)	66 (0.2)
Day 7	43 (0.3)	8 (<0.1)	51 (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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Pain - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1894 (13.0)	1852 (12.7)	3746 (12.9)
Day 1, after Vaccination (at Home)	1037 (7.1)	8527 (58.6)	9564 (32.8)
Day 2	546 (3.7)	2925 (20.1)	3471 (11.9)
Day 3	202 (1.4)	103 (0.7)	305 (1.0)
Day 4	95 (0.7)	9 (<0.1)	104 (0.4)
Day 5	62 (0.4)	5 (<0.1)	67 (0.2)
Day 6	43 (0.3)	7 (<0.1)	50 (0.2)
Day 7	28 (0.2)	5 (<0.1)	33 (0.1)
Erythema (Redness) - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	37 (0.3)	155 (1.1)	192 (0.7)
Day 2	25 (0.2)	641 (4.4)	666 (2.3)
Day 3	18 (0.1)	528 (3.6)	546 (1.9)
Day 4	6 (<0.1)	112 (0.8)	118 (0.4)
Day 5	8 (<0.1)	18 (0.1)	26 (<0.1)
Day 6	4 (<0.1)	6 (<0.1)	10 (<0.1)
Day 7	2 (<0.1)	4 (<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 14.3.1.3.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Swelling (Hardness) - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	21 (0.1)	30 (0.2)	51 (0.2)
Day 1, after Vaccination (at Home)	21 (0.1)	574 (3.9)	595 (2.0)
Day 2	25 (0.2)	1168 (8.0)	1193 (4.1)
Day 3	9 (<0.1)	307 (2.1)	316 (1.1)
Day 4	5 (<0.1)	70 (0.5)	75 (0.3)
Day 5	4 (<0.1)	9 (<0.1)	13 (<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]	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	150 (1.0)	165 (1.1)	315 (1.1)
Day 1, after Vaccination (at Home)	248 (1.7)	741 (5.1)	989 (3.4)
Day 2	255 (1.7)	1081 (7.4)	1336 (4.6)
Day 3	144 (1.0)	483 (3.3)	627 (2.2)
Day 4	89 (0.6)	185 (1.3)	274 (0.9)
Day 5	79 (0.5)	63 (0.4)	142 (0.5)
Day 6	51 (0.3)	66 (0.5)	117 (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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Solicited Systemic Adverse Reactions - N1	14591	14548	29139
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1073 (7.4)	1019 (7.0)	2092 (7.2)
Day 1, after Vaccination (at Home)	2831 (19.4)	5041 (34.7)	7872 (27.0)
Day 2	1836 (12.6)	5535 (38.0)	7371 (25.3)
Day 3	821 (5.6)	392 (2.7)	1213 (4.2)
Day 4	458 (3.1)	115 (0.8)	573 (2.0)
Day 5	350 (2.4)	79 (0.5)	429 (1.5)
Day 6	268 (1.8)	61 (0.4)	329 (1.1)
Day 7	204 (1.4)	51 (0.4)	255 (0.9)
Fever - N1	14591	14548	29139
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (<0.1)	2 (<0.1)	6 (<0.1)
Day 1, after Vaccination (at Home)	9 (<0.1)	208 (1.4)	217 (0.7)
Day 2	12 (<0.1)	1870 (12.9)	1882 (6.5)
Day 3	12 (<0.1)	171 (1.2)	183 (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	10 (<0.1)	5 (<0.1)	15 (<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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Headache - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	566 (3.9)	565 (3.9)	1131 (3.9)
Day 1, after Vaccination (at Home)	1546 (10.6)	2759 (19.0)	4305 (14.8)
Day 2	1306 (9.0)	5024 (34.5)	6330 (21.7)
Day 3	717 (4.9)	519 (3.6)	1236 (4.2)
Day 4	432 (3.0)	209 (1.4)	641 (2.2)
Day 5	320 (2.2)	155 (1.1)	475 (1.6)
Day 6	276 (1.9)	140 (1.0)	416 (1.4)
Day 7	239 (1.6)	106 (0.7)	345 (1.2)
Fatigue - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	406 (2.8)	425 (2.9)	831 (2.9)
Day 1, after Vaccination (at Home)	1991 (13.6)	3641 (25.0)	5632 (19.3)
Day 2	1357 (9.3)	5429 (37.3)	6786 (23.3)
Day 3	619 (4.2)	457 (3.1)	1076 (3.7)
Day 4	342 (2.3)	118 (0.8)	460 (1.6)
Day 5	258 (1.8)	76 (0.5)	334 (1.1)
Day 6	234 (1.6)	74 (0.5)	308 (1.1)
Day 7	146 (1.0)	53 (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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Myalgia - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	215 (1.5)	208 (1.4)	423 (1.5)
Day 1, after Vaccination (at Home)	738 (5.1)	2401 (16.5)	3139 (10.8)
Day 2	838 (5.7)	5715 (39.3)	6553 (22.5)
Day 3	412 (2.8)	404 (2.8)	816 (2.8)
Day 4	290 (2.0)	97 (0.7)	387 (1.3)
Day 5	189 (1.3)	55 (0.4)	244 (0.8)
Day 6	169 (1.2)	58 (0.4)	227 (0.8)
Day 7	140 (1.0)	36 (0.2)	176 (0.6)
Arthralgia - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	203 (1.4)	203 (1.4)	406 (1.4)
Day 1, after Vaccination (at Home)	567 (3.9)	1571 (10.8)	2138 (7.3)
Day 2	699 (4.8)	4251 (29.2)	4950 (17.0)
Day 3	376 (2.6)	442 (3.0)	818 (2.8)
Day 4	266 (1.8)	132 (0.9)	398 (1.4)
Day 5	171 (1.2)	64 (0.4)	235 (0.8)
Day 6	169 (1.2)	66 (0.5)	235 (0.8)
Day 7	112 (0.8)	51 (0.4)	163 (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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Nausea/Vomiting - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	88 (0.6)	76 (0.5)	164 (0.6)
Day 1, after Vaccination (at Home)	338 (2.3)	626 (4.3)	964 (3.3)
Day 2	405 (2.8)	1877 (12.9)	2282 (7.8)
Day 3	247 (1.7)	367 (2.5)	614 (2.1)
Day 4	179 (1.2)	165 (1.1)	344 (1.2)
Day 5	141 (1.0)	87 (0.6)	228 (0.8)
Day 6	146 (1.0)	85 (0.6)	231 (0.8)
Day 7	118 (0.8)	69 (0.5)	187 (0.6)
Chills - N1	14590	14548	29138
Day 1, 30 Minutes after Vaccination (at Study Clinic)	134 (0.9)	112 (0.8)	246 (0.8)
Day 1, after Vaccination (at Home)	346 (2.4)	1226 (8.4)	1572 (5.4)
Day 2	330 (2.3)	4717 (32.4)	5047 (17.3)
Day 3	190 (1.3)	411 (2.8)	601 (2.1)
Day 4	118 (0.8)	68 (0.5)	186 (0.6)
Day 5	121 (0.8)	38 (0.3)	159 (0.5)
Day 6	95 (0.7)	38 (0.3)	133 (0.5)
Day 7	73 (0.5)	34 (0.2)	107 (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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Solicited Adverse Reactions - N1	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	42 (12.5)	40 (11.7)	82 (12.1)
Day 1, after Vaccination (at Home)	44 (13.1)	156 (45.5)	200 (29.4)
Day 2	33 (9.8)	78 (22.7)	111 (16.3)
Day 3	13 (3.9)	5 (1.5)	18 (2.6)
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)	2 (0.6)	11 (1.6)
Solicited Local Adverse Reactions - N1	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	30 (8.9)	24 (7.0)	54 (7.9)
Day 1, after Vaccination (at Home)	24 (7.1)	152 (44.3)	176 (25.9)
Day 2	12 (3.6)	82 (23.9)	94 (13.8)
Day 3	3 (0.9)	7 (2.0)	10 (1.5)
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)	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 14.3.1.3.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Pain - N1	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	30 (8.9)	24 (7.0)	54 (7.9)
Day 1, after Vaccination (at Home)	22 (6.5)	152 (44.3)	174 (25.6)
Day 2	9 (2.7)	82 (23.9)	91 (13.4)
Day 3	2 (0.6)	6 (1.7)	8 (1.2)
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)	2 (0.6)	4 (0.6)
Erythema (Redness) - N1	337	343	680
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)	6 (1.7)	7 (1.0)
Day 3	2 (0.6)	3 (0.9)	5 (0.7)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Swelling (Hardness) - N1	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	1 (0.3)	6 (1.7)	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]	337	343	680
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)	16 (4.7)	20 (2.9)
Day 2	5 (1.5)	27 (7.9)	32 (4.7)
Day 3	4 (1.2)	13 (3.8)	17 (2.5)
Day 4	0	9 (2.6)	9 (1.3)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	3 (0.9)	0	3 (0.4)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Solicited Systemic Adverse Reactions - N1	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	20 (5.9)	22 (6.4)	42 (6.2)
Day 1, after Vaccination (at Home)	40 (11.9)	95 (27.7)	135 (19.9)
Day 2	38 (11.3)	108 (31.5)	146 (21.5)
Day 3	16 (4.7)	7 (2.0)	23 (3.4)
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	336	343	679
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (0.6)	2 (0.3)
Day 1, after Vaccination (at Home)	0	5 (1.5)	5 (0.7)
Day 2	1 (0.3)	39 (11.4)	40 (5.9)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Headache - N1	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (3.3)	8 (2.3)	19 (2.8)
Day 1, after Vaccination (at Home)	21 (6.2)	55 (16.0)	76 (11.2)
Day 2	26 (7.7)	80 (23.3)	106 (15.6)
Day 3	12 (3.6)	7 (2.0)	19 (2.8)
Day 4	9 (2.7)	6 (1.7)	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	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (2.1)	12 (3.5)	19 (2.8)
Day 1, after Vaccination (at Home)	26 (7.7)	54 (15.7)	80 (11.8)
Day 2	25 (7.4)	87 (25.4)	112 (16.5)
Day 3	18 (5.3)	9 (2.6)	27 (4.0)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Myalgia - N1	337	343	680
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)	55 (16.0)	66 (9.7)
Day 2	21 (6.2)	101 (29.4)	122 (17.9)
Day 3	8 (2.4)	9 (2.6)	17 (2.5)
Day 4	11 (3.3)	2 (0.6)	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	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.6)	6 (1.7)	8 (1.2)
Day 1, after Vaccination (at Home)	9 (2.7)	37 (10.8)	46 (6.8)
Day 2	17 (5.0)	65 (19.0)	82 (12.1)
Day 3	9 (2.7)	12 (3.5)	21 (3.1)
Day 4	7 (2.1)	2 (0.6)	9 (1.3)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Nausea/Vomiting - N1	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	5 (1.5)	15 (4.4)	20 (2.9)
Day 2	6 (1.8)	31 (9.0)	37 (5.4)
Day 3	7 (2.1)	9 (2.6)	16 (2.4)
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	337	343	680
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (0.9)	2 (0.6)	5 (0.7)
Day 1, after Vaccination (at Home)	8 (2.4)	29 (8.5)	37 (5.4)
Day 2	9 (2.7)	80 (23.3)	89 (13.1)
Day 3	6 (1.8)	9 (2.6)	15 (2.2)
Day 4	4 (1.2)	1 (0.3)	5 (0.7)
Day 5	4 (1.2)	1 (0.3)	5 (0.7)
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Adverse Reactions - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	41 (17.4)	50 (17.4)	91 (17.4)
Day 1, after Vaccination (at Home)	38 (16.2)	174 (60.4)	212 (40.5)
Day 2	37 (15.7)	43 (14.9)	80 (15.3)
Day 3	9 (3.8)	3 (1.0)	12 (2.3)
Day 4	4 (1.7)	0	4 (0.8)
Day 5	7 (3.0)	1 (0.3)	8 (1.5)
Day 6	5 (2.1)	0	5 (1.0)
Day 7	4 (1.7)	0	4 (0.8)
Solicited Local Adverse Reactions - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	36 (15.3)	39 (13.5)	75 (14.3)
Day 1, after Vaccination (at Home)	12 (5.1)	172 (59.7)	184 (35.2)
Day 2	12 (5.1)	53 (18.4)	65 (12.4)
Day 3	3 (1.3)	2 (0.7)	5 (1.0)
Day 4	2 (0.9)	0	2 (0.4)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	3 (1.3)	0	3 (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 14.3.1.3.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Pain - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	36 (15.3)	37 (12.8)	73 (14.0)
Day 1, after Vaccination (at Home)	9 (3.8)	172 (59.7)	181 (34.6)
Day 2	10 (4.3)	54 (18.8)	64 (12.2)
Day 3	1 (0.4)	1 (0.3)	2 (0.4)
Day 4	1 (0.4)	0	1 (0.2)
Day 5	2 (0.9)	0	2 (0.4)
Day 6	1 (0.4)	0	1 (0.2)
Day 7	0	0	0
Erythema (Redness) - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.4)	1 (0.3)	2 (0.4)
Day 1, after Vaccination (at Home)	1 (0.4)	3 (1.0)	4 (0.8)
Day 2	0	13 (4.5)	13 (2.5)
Day 3	0	10 (3.5)	10 (1.9)
Day 4	0	2 (0.7)	2 (0.4)
Day 5	0	0	0
Day 6	2 (0.9)	0	2 (0.4)
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Swelling (Hardness) - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	13 (4.5)	13 (2.5)
Day 2	1 (0.4)	18 (6.3)	19 (3.6)
Day 3	0	8 (2.8)	8 (1.5)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Lymphadenopathy - N1 [1]	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (2.1)	2 (0.7)	7 (1.3)
Day 1, after Vaccination (at Home)	5 (2.1)	18 (6.3)	23 (4.4)
Day 2	4 (1.7)	31 (10.8)	35 (6.7)
Day 3	3 (1.3)	4 (1.4)	7 (1.3)
Day 4	1 (0.4)	2 (0.7)	3 (0.6)
Day 5	0	2 (0.7)	2 (0.4)
Day 6	3 (1.3)	1 (0.3)	4 (0.8)
Day 7	1 (0.4)	1 (0.3)	2 (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: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Systemic Adverse Reactions - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	17 (7.2)	16 (5.6)	33 (6.3)
Day 1, after Vaccination (at Home)	44 (18.7)	100 (34.7)	144 (27.5)
Day 2	37 (15.7)	110 (38.2)	147 (28.1)
Day 3	11 (4.7)	5 (1.7)	16 (3.1)
Day 4	5 (2.1)	2 (0.7)	7 (1.3)
Day 5	9 (3.8)	2 (0.7)	11 (2.1)
Day 6	4 (1.7)	1 (0.3)	5 (1.0)
Day 7	4 (1.7)	1 (0.3)	5 (1.0)
Fever - N1	235	287	522
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	6 (2.1)	6 (1.1)
Day 2	0	18 (6.3)	18 (3.4)
Day 3	0	2 (0.7)	2 (0.4)
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 14.3.1.3.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Headache - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (4.3)	8 (2.8)	18 (3.4)
Day 1, after Vaccination (at Home)	25 (10.6)	59 (20.5)	84 (16.1)
Day 2	23 (9.8)	92 (31.9)	115 (22.0)
Day 3	17 (7.2)	8 (2.8)	25 (4.8)
Day 4	9 (3.8)	6 (2.1)	15 (2.9)
Day 5	7 (3.0)	3 (1.0)	10 (1.9)
Day 6	4 (1.7)	6 (2.1)	10 (1.9)
Day 7	8 (3.4)	1 (0.3)	9 (1.7)
Fatigue - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (3.0)	4 (1.4)	11 (2.1)
Day 1, after Vaccination (at Home)	32 (13.6)	67 (23.3)	99 (18.9)
Day 2	29 (12.3)	100 (34.7)	129 (24.7)
Day 3	5 (2.1)	4 (1.4)	9 (1.7)
Day 4	3 (1.3)	4 (1.4)	7 (1.3)
Day 5	11 (4.7)	2 (0.7)	13 (2.5)
Day 6	6 (2.6)	3 (1.0)	9 (1.7)
Day 7	2 (0.9)	2 (0.7)	4 (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 14.3.1.3.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Myalgia - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (3.0)	2 (0.7)	9 (1.7)
Day 1, after Vaccination (at Home)	17 (7.2)	53 (18.4)	70 (13.4)
Day 2	13 (5.5)	114 (39.6)	127 (24.3)
Day 3	8 (3.4)	8 (2.8)	16 (3.1)
Day 4	6 (2.6)	3 (1.0)	9 (1.7)
Day 5	4 (1.7)	2 (0.7)	6 (1.1)
Day 6	2 (0.9)	1 (0.3)	3 (0.6)
Day 7	1 (0.4)	1 (0.3)	2 (0.4)
Arthralgia - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (2.1)	1 (0.3)	6 (1.1)
Day 1, after Vaccination (at Home)	12 (5.1)	38 (13.2)	50 (9.6)
Day 2	15 (6.4)	85 (29.5)	100 (19.1)
Day 3	8 (3.4)	5 (1.7)	13 (2.5)
Day 4	4 (1.7)	3 (1.0)	7 (1.3)
Day 5	2 (0.9)	4 (1.4)	6 (1.1)
Day 6	3 (1.3)	1 (0.3)	4 (0.8)
Day 7	1 (0.4)	1 (0.3)	2 (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: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Nausea/Vomiting - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.4)	1 (0.3)	2 (0.4)
Day 1, after Vaccination (at Home)	3 (1.3)	13 (4.5)	16 (3.1)
Day 2	7 (3.0)	40 (13.9)	47 (9.0)
Day 3	0	4 (1.4)	4 (0.8)
Day 4	2 (0.9)	2 (0.7)	4 (0.8)
Day 5	3 (1.3)	3 (1.0)	6 (1.1)
Day 6	1 (0.4)	2 (0.7)	3 (0.6)
Day 7	1 (0.4)	3 (1.0)	4 (0.8)
Chills - N1	235	288	523
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.9)	3 (1.0)	5 (1.0)
Day 1, after Vaccination (at Home)	8 (3.4)	27 (9.4)	35 (6.7)
Day 2	7 (3.0)	85 (29.5)	92 (17.6)
Day 3	0	5 (1.7)	5 (1.0)
Day 4	3 (1.3)	1 (0.3)	4 (0.8)
Day 5	2 (0.9)	1 (0.3)	3 (0.6)
Day 6	1 (0.4)	0	1 (0.2)
Day 7	2 (0.9)	1 (0.3)	3 (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 14.3.1.4.4
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=11407)	mRNA-1273 (N=11406)	Total (N=22813)
Solicited Adverse Reactions			
n	5738	10261	15999
Mean (SD)	3.1 (3.67)	3.5 (3.15)	3.3 (3.35)
Median	2.0	3.0	3.0
Min, Max	1, 74	1, 56	1, 74
Solicited Local Adverse Reactions			
n	2430	9960	12390
Mean (SD)	1.9 (2.22)	2.7 (1.99)	2.5 (2.06)
Median	1.0	2.0	2.0
Min, Max	1, 34	1, 45	1, 45
Pain			
n	2177	9908	12085
Mean (SD)	1.7 (1.79)	2.5 (1.40)	2.4 (1.51)
Median	1.0	2.0	2.0
Min, Max	1, 34	1, 34	1, 34
Erythema (Redness)			
n	47	344	391
Mean (SD)	2.4 (3.70)	2.5 (4.02)	2.5 (3.98)
Median	1.0	2.0	1.0
Min, Max	1, 17	1, 45	1, 45

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=11407)	mRNA-1273 (N=11406)	Total (N=22813)
Swelling (Hardness)			
n	34	767	801
Mean (SD)	3.4 (4.90)	2.1 (2.19)	2.1 (2.38)
Median	1.0	2.0	2.0
Min, Max	1, 24	1, 29	1, 29
Lymphadenopathy [1]			
n	567	1322	1889
Mean (SD)	2.2 (3.00)	2.4 (2.93)	2.3 (2.95)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 31	1, 33
Solicited Systemic Adverse Reactions			
n	5065	6503	11568
Mean (SD)	3.0 (3.71)	2.9 (3.43)	3.0 (3.55)
Median	2.0	2.0	2.0
Min, Max	1, 73	1, 56	1, 73
Fever			
n	37	105	142
Mean (SD)	1.4 (0.59)	1.3 (0.74)	1.3 (0.70)
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=11407)	mRNA-1273 (N=11406)	Total (N=22813)
Headache			
n	3304	4030	7334
Mean (SD)	2.1 (2.38)	2.1 (2.11)	2.1 (2.23)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 35	1, 35
Fatigue			
n	3282	4384	7666
Mean (SD)	2.7 (3.27)	2.6 (3.24)	2.7 (3.25)
Median	2.0	2.0	2.0
Min, Max	1, 44	1, 43	1, 44
Myalgia			
n	1628	2699	4327
Mean (SD)	2.5 (3.29)	2.2 (3.00)	2.3 (3.12)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 56	1, 56
Arthralgia			
n	1327	1893	3220
Mean (SD)	3.0 (4.52)	2.5 (3.67)	2.7 (4.05)
Median	2.0	1.0	1.0
Min, Max	1, 73	1, 56	1, 73

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=11407)	mRNA-1273 (N=11406)	Total (N=22813)
Nausea/Vomiting			
n	908	1068	1976
Mean (SD)	1.8 (2.31)	1.7 (1.59)	1.7 (1.95)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 28	1, 33
Chills			
n	730	1051	1781
Mean (SD)	1.7 (1.79)	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)	3.4 (5.62)	3.2 (3.66)	3.2 (4.42)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 84	1, 88
Solicited Local Adverse Reactions			
n	567	2805	3372
Mean (SD)	2.2 (3.74)	2.3 (1.65)	2.3 (2.15)
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 (1.22)	2.1 (1.62)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 29	1, 51
Erythema (Redness)			
n	20	86	106
Mean (SD)	5.2 (8.45)	2.7 (4.54)	3.2 (5.52)
Median	1.0	2.0	1.0
Min, Max	1, 28	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	18	165	183
Mean (SD)	8.2 (10.92)	1.9 (1.94)	2.5 (4.24)
Median	2.0	1.0	1.0
Min, Max	1, 28	1, 22	1, 28
Lymphadenopathy [1]			
n	155	231	386
Mean (SD)	1.8 (2.08)	1.9 (2.62)	1.8 (2.42)
Median	1.0	1.0	1.0
Min, Max	1, 16	1, 24	1, 24
Solicited Systemic Adverse Reactions			
n	1334	1817	3151
Mean (SD)	3.4 (5.63)	3.0 (4.44)	3.2 (4.98)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
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	723	921	1644
Mean (SD)	2.0 (2.40)	2.0 (2.43)	2.0 (2.42)
Median	1.0	1.0	1.0
Min, Max	1, 30	1, 42	1, 42
Fatigue			
n	851	1251	2102
Mean (SD)	3.1 (5.16)	2.8 (4.53)	2.9 (4.80)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Myalgia			
n	443	742	1185
Mean (SD)	3.2 (4.96)	2.5 (3.96)	2.7 (4.37)
Median	1.0	1.0	1.0
Min, Max	1, 44	1, 75	1, 75
Arthralgia			
n	456	618	1074
Mean (SD)	3.6 (6.21)	3.1 (5.19)	3.3 (5.65)
Median	2.0	1.0	1.0
Min, Max	1, 84	1, 75	1, 84

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 (1.49)	1.6 (1.29)	1.6 (1.38)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 10	1, 11
Chills			
n	148	202	350
Mean (SD)	1.5 (1.30)	1.6 (1.94)	1.6 (1.70)
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=10918)	mRNA-1273 (N=10985)	Total (N=21903)
Solicited Adverse Reactions			
n	4902	10231	15133
Mean (SD)	3.3 (5.29)	4.1 (4.77)	3.8 (4.96)
Median	2.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Solicited Local Adverse Reactions			
n	2244	9915	12159
Mean (SD)	2.1 (3.98)	3.3 (2.97)	3.0 (3.22)
Median	1.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Pain			
n	2040	9873	11913
Mean (SD)	1.8 (3.20)	3.1 (2.21)	2.9 (2.46)
Median	1.0	3.0	3.0
Min, Max	1, 72	1, 72	1, 72
Erythema (Redness)			
n	43	982	1025
Mean (SD)	3.4 (9.48)	2.6 (4.03)	2.6 (4.39)
Median	1.0	2.0	2.0
Min, Max	1, 63	1, 93	1, 93

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=10918)	mRNA-1273 (N=10985)	Total (N=21903)
Swelling (Hardness)			
n	36	1389	1425
Mean (SD)	2.4 (2.75)	2.6 (4.23)	2.6 (4.20)
Median	1.0	2.0	2.0
Min, Max	1, 13	1, 93	1, 93
Lymphadenopathy [1]			
n	470	1775	2245
Mean (SD)	2.7 (5.72)	2.5 (3.42)	2.5 (4.01)
Median	1.0	2.0	2.0
Min, Max	1, 90	1, 68	1, 90
Solicited Systemic Adverse Reactions			
n	4192	8999	13191
Mean (SD)	3.3 (5.14)	3.2 (4.44)	3.2 (4.67)
Median	2.0	2.0	2.0
Min, Max	1, 90	1, 84	1, 90
Fever			
n	39	1908	1947
Mean (SD)	1.2 (0.51)	1.2 (1.84)	1.2 (1.82)
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=10918)	mRNA-1273 (N=10985)	Total (N=21903)
Headache			
n	2760	6898	9658
Mean (SD)	2.3 (2.91)	2.3 (2.89)	2.3 (2.89)
Median	1.0	2.0	2.0
Min, Max	1, 72	1, 78	1, 78
Fatigue			
n	2687	7430	10117
Mean (SD)	2.9 (4.74)	2.6 (3.62)	2.7 (3.95)
Median	2.0	2.0	2.0
Min, Max	1, 83	1, 78	1, 83
Myalgia			
n	1411	6769	8180
Mean (SD)	3.0 (5.24)	2.1 (2.98)	2.3 (3.49)
Median	2.0	2.0	2.0
Min, Max	1, 72	1, 79	1, 79
Arthralgia			
n	1172	4993	6165
Mean (SD)	3.5 (6.28)	2.2 (3.39)	2.5 (4.13)
Median	2.0	1.0	1.0
Min, Max	1, 90	1, 82	1, 90

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=10918)	mRNA-1273 (N=10985)	Total (N=21903)
Nausea/Vomiting			
n	801	2348	3149
Mean (SD)	2.0 (4.08)	1.7 (2.30)	1.8 (2.86)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 78	1, 78
Chills			
n	658	5341	5999
Mean (SD)	2.0 (3.38)	1.5 (1.62)	1.5 (1.90)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 76	1, 76

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=3648)	mRNA-1273 (N=3692)	Total (N=7340)
Solicited Adverse Reactions			
n	1330	3303	4633
Mean (SD)	3.7 (7.09)	3.8 (4.96)	3.8 (5.65)
Median	2.0	3.0	3.0
Min, Max	1, 71	1, 78	1, 78
Solicited Local Adverse Reactions			
n	491	3091	3582
Mean (SD)	2.1 (4.30)	3.0 (2.62)	2.9 (2.92)
Median	1.0	3.0	2.0
Min, Max	1, 69	1, 78	1, 78
Pain			
n	437	3070	3507
Mean (SD)	1.8 (3.50)	2.8 (2.07)	2.7 (2.32)
Median	1.0	3.0	2.0
Min, Max	1, 69	1, 78	1, 78
Erythema (Redness)			
n	13	275	288
Mean (SD)	4.9 (14.14)	3.0 (3.35)	3.1 (4.39)
Median	1.0	2.0	2.0
Min, Max	1, 52	1, 40	1, 52

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=3648)	mRNA-1273 (N=3692)	Total (N=7340)
Swelling (Hardness)			
n	13	400	413
Mean (SD)	3.7 (8.52)	2.6 (3.76)	2.6 (3.98)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 70	1, 70
Lymphadenopathy [1]			
n	97	315	412
Mean (SD)	2.3 (2.01)	1.8 (1.37)	1.9 (1.55)
Median	1.0	1.0	1.0
Min, Max	1, 14	1, 9	1, 14
Solicited Systemic Adverse Reactions			
n	1131	2653	3784
Mean (SD)	3.8 (7.16)	3.1 (5.03)	3.3 (5.76)
Median	2.0	2.0	2.0
Min, Max	1, 71	1, 78	1, 78
Fever			
n	4	370	374
Mean (SD)	1.5 (0.58)	1.1 (0.26)	1.1 (0.27)
Median	1.5	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=3648)	mRNA-1273 (N=3692)	Total (N=7340)
Headache			
n	650	1704	2354
Mean (SD)	2.4 (4.58)	2.0 (3.12)	2.1 (3.58)
Median	1.0	1.0	1.0
Min, Max	1, 63	1, 77	1, 77
Fatigue			
n	716	2152	2868
Mean (SD)	3.3 (6.13)	2.6 (4.13)	2.8 (4.72)
Median	2.0	2.0	2.0
Min, Max	1, 70	1, 72	1, 72
Myalgia			
n	398	1739	2137
Mean (SD)	3.9 (8.43)	2.1 (3.61)	2.4 (4.93)
Median	2.0	1.0	1.0
Min, Max	1, 71	1, 77	1, 77
Arthralgia			
n	397	1291	1688
Mean (SD)	4.4 (8.66)	2.4 (4.02)	2.9 (5.54)
Median	2.0	1.0	1.0
Min, Max	1, 71	1, 74	1, 74

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=3648)	mRNA-1273 (N=3692)	Total (N=7340)
Nausea/Vomiting			
n	133	437	570
Mean (SD)	1.5 (1.48)	1.7 (2.63)	1.6 (2.41)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 45	1, 45
Chills			
n	151	1141	1292
Mean (SD)	1.8 (2.30)	1.4 (1.19)	1.4 (1.37)
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=11413)	mRNA-1273 (N=11412)	Total (N=22825)
Solicited Adverse Reactions			
n	7085	10887	17972
Mean (SD)	3.6 (5.16)	4.6 (5.12)	4.2 (5.16)
Median	2.0	4.0	3.0
Min, Max	1, 90	1, 93	1, 93
Solicited Local Adverse Reactions			
n	3578	10676	14254
Mean (SD)	2.1 (3.50)	3.5 (3.17)	3.2 (3.31)
Median	1.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Pain			
n	3275	10639	13914
Mean (SD)	1.8 (2.78)	3.2 (2.27)	2.9 (2.47)
Median	1.0	3.0	3.0
Min, Max	1, 72	1, 72	1, 72
Erythema (Redness)			
n	84	1188	1272
Mean (SD)	2.9 (7.26)	2.6 (4.21)	2.6 (4.48)
Median	1.0	2.0	2.0
Min, Max	1, 63	1, 93	1, 93

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=11413)	mRNA-1273 (N=11412)	Total (N=22825)
Swelling (Hardness)			
n	67	1755	1822
Mean (SD)	2.9 (4.00)	2.5 (4.00)	2.6 (4.00)
Median	1.0	2.0	2.0
Min, Max	1, 24	1, 93	1, 93
Lymphadenopathy [1]			
n	875	2534	3409
Mean (SD)	2.4 (4.62)	2.5 (3.37)	2.5 (3.73)
Median	1.0	2.0	1.0
Min, Max	1, 90	1, 68	1, 90
Solicited Systemic Adverse Reactions			
n	6348	9817	16165
Mean (SD)	3.5 (5.00)	3.5 (4.77)	3.5 (4.86)
Median	2.0	2.0	2.0
Min, Max	1, 90	1, 84	1, 90
Fever			
n	75	1977	2052
Mean (SD)	1.3 (0.56)	1.2 (1.81)	1.2 (1.78)
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=11413)	mRNA-1273 (N=11412)	Total (N=22825)
Headache			
n	4526	7819	12345
Mean (SD)	2.4 (2.90)	2.5 (2.97)	2.4 (2.94)
Median	2.0	2.0	2.0
Min, Max	1, 72	1, 78	1, 78
Fatigue			
n	4342	8188	12530
Mean (SD)	3.0 (4.45)	2.9 (3.96)	2.9 (4.13)
Median	2.0	2.0	2.0
Min, Max	1, 83	1, 78	1, 83
Myalgia			
n	2430	7384	9814
Mean (SD)	2.9 (4.56)	2.3 (3.26)	2.4 (3.64)
Median	2.0	2.0	2.0
Min, Max	1, 72	1, 79	1, 79
Arthralgia			
n	1997	5532	7529
Mean (SD)	3.4 (5.80)	2.4 (3.67)	2.6 (4.36)
Median	2.0	2.0	2.0
Min, Max	1, 90	1, 82	1, 90

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=11413)	mRNA-1273 (N=11412)	Total (N=22825)
Nausea/Vomiting			
n	1443	2921	4364
Mean (SD)	1.9 (3.41)	1.7 (2.22)	1.8 (2.67)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 78	1, 78
Chills			
n	1204	5661	6865
Mean (SD)	1.8 (2.67)	1.5 (1.68)	1.6 (1.90)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 76	1, 76

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=3767)	Total (N=7517)
Solicited Adverse Reactions			
n	2023	3513	5536
Mean (SD)	4.0 (7.20)	4.3 (5.52)	4.2 (6.19)
Median	2.0	3.0	3.0
Min, Max	1, 88	1, 84	1, 88
Solicited Local Adverse Reactions			
n	872	3351	4223
Mean (SD)	2.2 (4.32)	3.1 (2.73)	2.9 (3.15)
Median	1.0	3.0	2.0
Min, Max	1, 69	1, 78	1, 78
Pain			
n	762	3326	4088
Mean (SD)	1.9 (3.51)	2.9 (2.07)	2.7 (2.44)
Median	1.0	3.0	2.0
Min, Max	1, 69	1, 78	1, 78
Erythema (Redness)			
n	33	334	367
Mean (SD)	5.1 (10.84)	3.0 (3.79)	3.2 (4.86)
Median	1.0	2.0	2.0
Min, Max	1, 52	1, 40	1, 52

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=3767)	Total (N=7517)
Swelling (Hardness)			
n	28	477	505
Mean (SD)	6.3 (10.36)	2.5 (3.60)	2.7 (4.33)
Median	2.0	2.0	2.0
Min, Max	1, 32	1, 70	1, 70
Lymphadenopathy [1]			
n	223	477	700
Mean (SD)	2.0 (2.04)	1.8 (2.08)	1.9 (2.07)
Median	1.0	1.0	1.0
Min, Max	1, 16	1, 24	1, 24
Solicited Systemic Adverse Reactions			
n	1764	2953	4717
Mean (SD)	3.9 (7.16)	3.5 (5.62)	3.7 (6.25)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Fever			
n	11	376	387
Mean (SD)	1.5 (0.69)	1.1 (0.26)	1.1 (0.29)
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=3767)	Total (N=7517)
Headache			
n	1077	2006	3083
Mean (SD)	2.4 (3.96)	2.1 (3.21)	2.2 (3.49)
Median	1.0	1.0	1.0
Min, Max	1, 63	1, 77	1, 77
Fatigue			
n	1202	2439	3641
Mean (SD)	3.4 (6.16)	3.0 (4.86)	3.1 (5.33)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Myalgia			
n	683	1950	2633
Mean (SD)	3.5 (7.16)	2.3 (4.10)	2.6 (5.10)
Median	1.0	1.0	1.0
Min, Max	1, 71	1, 77	1, 77
Arthralgia			
n	669	1512	2181
Mean (SD)	4.2 (7.99)	2.8 (4.77)	3.2 (5.98)
Median	2.0	1.0	2.0
Min, Max	1, 84	1, 75	1, 84

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=3767)	Total (N=7517)
Nausea/Vomiting			
n	273	563	836
Mean (SD)	1.6 (1.48)	1.7 (2.42)	1.7 (2.16)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 45	1, 45
Chills			
n	266	1230	1496
Mean (SD)	1.7 (1.93)	1.4 (1.37)	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=14583)	mRNA-1273 (N=14538)	Total (N=29121)
Solicited Adverse Reactions			
n	7023	12800	19823
Mean (SD)	3.1 (4.15)	3.4 (3.28)	3.3 (3.62)
Median	2.0	3.0	3.0
Min, Max	1, 88	1, 84	1, 88
Solicited Local Adverse Reactions			
n	2891	12276	15167
Mean (SD)	1.9 (2.61)	2.6 (1.94)	2.5 (2.10)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 45	1, 51
Pain			
n	2563	12207	14770
Mean (SD)	1.7 (2.09)	2.4 (1.37)	2.3 (1.55)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 34	1, 51
Erythema (Redness)			
n	63	409	472
Mean (SD)	3.4 (5.78)	2.6 (4.22)	2.7 (4.46)
Median	1.0	2.0	1.5
Min, Max	1, 28	1, 45	1, 45

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=14583)	mRNA-1273 (N=14538)	Total (N=29121)
Swelling (Hardness)			
n	49	895	944
Mean (SD)	5.3 (7.96)	2.1 (2.14)	2.2 (2.84)
Median	2.0	2.0	2.0
Min, Max	1, 28	1, 29	1, 29
Lymphadenopathy [1]			
n	689	1465	2154
Mean (SD)	2.1 (2.87)	2.3 (2.93)	2.2 (2.91)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 31	1, 33
Solicited Systemic Adverse Reactions			
n	6167	7954	14121
Mean (SD)	3.1 (4.17)	2.9 (3.69)	3.0 (3.91)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Fever			
n	38	79	117
Mean (SD)	1.4 (0.64)	1.3 (0.80)	1.3 (0.75)
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=14583)	mRNA-1273 (N=14538)	Total (N=29121)
Headache			
n	3865	4723	8588
Mean (SD)	2.1 (2.40)	2.0 (2.15)	2.1 (2.27)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 42	1, 42
Fatigue			
n	3988	5400	9388
Mean (SD)	2.7 (3.71)	2.7 (3.58)	2.7 (3.64)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Myalgia			
n	1987	3244	5231
Mean (SD)	2.6 (3.65)	2.3 (3.28)	2.4 (3.43)
Median	1.0	1.0	1.0
Min, Max	1, 44	1, 75	1, 75
Arthralgia			
n	1707	2381	4088
Mean (SD)	3.1 (5.00)	2.7 (4.20)	2.9 (4.56)
Median	2.0	1.0	1.0
Min, Max	1, 84	1, 75	1, 84

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=14583)	mRNA-1273 (N=14538)	Total (N=29121)
Nausea/Vomiting			
n	1033	1193	2226
Mean (SD)	1.8 (2.23)	1.7 (1.54)	1.7 (1.89)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 28	1, 33
Chills			
n	836	1144	1980
Mean (SD)	1.6 (1.74)	1.5 (1.72)	1.6 (1.73)
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=337)	mRNA-1273 (N=342)	Total (N=679)
Solicited Adverse Reactions			
n	137	261	398
Mean (SD)	3.4 (3.23)	3.6 (3.60)	3.6 (3.48)
Median	2.0	3.0	3.0
Min, Max	1, 19	1, 30	1, 30
Solicited Local Adverse Reactions			
n	60	246	306
Mean (SD)	2.0 (1.58)	2.6 (1.84)	2.5 (1.81)
Median	1.0	2.0	2.0
Min, Max	1, 10	1, 17	1, 17
Pain			
n	56	244	300
Mean (SD)	1.6 (1.22)	2.4 (1.25)	2.2 (1.28)
Median	1.0	2.0	2.0
Min, Max	1, 8	1, 8	1, 8
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=337)	mRNA-1273 (N=342)	Total (N=679)
Swelling (Hardness)			
n	2	19	21
Mean (SD)	1.5 (0.71)	2.4 (3.24)	2.3 (3.09)
Median	1.5	1.0	1.0
Min, Max	1, 2	1, 15	1, 15
Lymphadenopathy [1]			
n	18	53	71
Mean (SD)	2.3 (2.24)	2.2 (2.33)	2.2 (2.30)
Median	1.5	1.0	1.0
Min, Max	1, 10	1, 16	1, 16
Solicited Systemic Adverse Reactions			
n	121	210	331
Mean (SD)	3.3 (3.28)	3.0 (3.75)	3.1 (3.59)
Median	2.0	2.0	2.0
Min, Max	1, 18	1, 30	1, 30
Fever			
n	6	32	38
Mean (SD)	1.3 (0.52)	1.2 (0.49)	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=337)	mRNA-1273 (N=342)	Total (N=679)
Headache			
n	82	131	213
Mean (SD)	2.2 (2.27)	2.5 (2.96)	2.4 (2.71)
Median	1.0	1.0	1.0
Min, Max	1, 15	1, 22	1, 22
Fatigue			
n	72	134	206
Mean (SD)	3.2 (3.21)	2.6 (3.35)	2.8 (3.31)
Median	2.0	2.0	2.0
Min, Max	1, 15	1, 29	1, 29
Myalgia			
n	47	124	171
Mean (SD)	3.5 (3.94)	2.2 (2.76)	2.6 (3.18)
Median	2.0	1.0	2.0
Min, Max	1, 18	1, 27	1, 27
Arthralgia			
n	40	85	125
Mean (SD)	3.4 (3.84)	1.8 (1.38)	2.3 (2.54)
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=337)	mRNA-1273 (N=342)	Total (N=679)
Nausea/Vomiting			
n	26	42	68
Mean (SD)	1.8 (1.42)	1.8 (1.94)	1.8 (1.75)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 13	1, 13
Chills			
n	27	80	107
Mean (SD)	2.0 (1.34)	1.6 (1.39)	1.7 (1.38)
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=235)	mRNA-1273 (N=288)	Total (N=523)
Solicited Adverse Reactions			
n	124	258	382
Mean (SD)	3.6 (5.38)	3.2 (2.25)	3.3 (3.58)
Median	2.0	3.0	2.0
Min, Max	1, 41	1, 20	1, 41
Solicited Local Adverse Reactions			
n	46	243	289
Mean (SD)	1.7 (1.16)	2.5 (1.39)	2.4 (1.39)
Median	1.0	2.0	2.0
Min, Max	1, 7	1, 10	1, 10
Pain			
n	39	239	278
Mean (SD)	1.6 (1.14)	2.4 (1.16)	2.2 (1.19)
Median	1.0	2.0	2.0
Min, Max	1, 7	1, 10	1, 10
Erythema (Redness)			
n	1	12	13
Mean (SD)	1.0 (NA)	2.2 (1.34)	2.1 (1.32)
Median	1.0	2.0	2.0
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: Missing

Solicited Adverse Reaction Category / Statistic	Placebo (N=235)	mRNA-1273 (N=288)	Total (N=523)
Swelling (Hardness)			
n	1	18	19
Mean (SD)	1.0 (NA)	1.8 (1.48)	1.7 (1.45)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 7	1, 7
Lymphadenopathy [1]			
n	15	35	50
Mean (SD)	1.6 (0.99)	1.9 (1.63)	1.8 (1.47)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 9	1, 9
Solicited Systemic Adverse Reactions			
n	111	156	267
Mean (SD)	3.7 (5.57)	2.7 (2.57)	3.1 (4.12)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 18	1, 41
Fever			
n	0	4	4
Mean (SD)		1.0 (0.00)	1.0 (0.00)
Median		1.0	1.0
Min, Max		1, 1	1, 1

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=235)	mRNA-1273 (N=288)	Total (N=523)
Headache			
n	80	97	177
Mean (SD)	2.1 (1.52)	2.0 (1.92)	2.0 (1.74)
Median	1.5	1.0	1.0
Min, Max	1, 8	1, 15	1, 15
Fatigue			
n	73	101	174
Mean (SD)	3.1 (5.43)	2.5 (2.73)	2.7 (4.08)
Median	2.0	1.0	1.5
Min, Max	1, 41	1, 17	1, 41
Myalgia			
n	37	73	110
Mean (SD)	4.0 (6.00)	1.9 (1.51)	2.6 (3.79)
Median	2.0	1.0	1.0
Min, Max	1, 30	1, 8	1, 30
Arthralgia			
n	36	45	81
Mean (SD)	4.3 (6.57)	1.7 (0.95)	2.8 (4.58)
Median	2.0	1.0	1.0
Min, Max	1, 32	1, 4	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=235)	mRNA-1273 (N=288)	Total (N=523)
Nausea/Vomiting			
n	15	27	42
Mean (SD)	1.5 (1.06)	1.5 (0.94)	1.5 (0.97)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 5	1, 5
Chills			
n	15	29	44
Mean (SD)	1.5 (0.92)	1.2 (0.38)	1.3 (0.62)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 2	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=14119)	mRNA-1273 (N=14183)	Total (N=28302)
Solicited Adverse Reactions			
n	6056	13101	19157
Mean (SD)	3.4 (5.72)	4.1 (4.87)	3.8 (5.16)
Median	2.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Solicited Local Adverse Reactions			
n	2650	12594	15244
Mean (SD)	2.1 (3.97)	3.2 (2.91)	3.0 (3.15)
Median	1.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Pain			
n	2403	12536	14939
Mean (SD)	1.9 (3.30)	3.0 (2.18)	2.8 (2.43)
Median	1.0	3.0	3.0
Min, Max	1, 72	1, 78	1, 78
Erythema (Redness)			
n	52	1227	1279
Mean (SD)	3.0 (8.66)	2.6 (3.89)	2.7 (4.19)
Median	1.0	2.0	2.0
Min, Max	1, 63	1, 93	1, 93

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=14119)	mRNA-1273 (N=14183)	Total (N=28302)
Swelling (Hardness)			
n	47	1746	1793
Mean (SD)	2.8 (4.99)	2.6 (4.16)	2.6 (4.18)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 93	1, 93
Lymphadenopathy [1]			
n	546	2018	2564
Mean (SD)	2.6 (5.33)	2.4 (3.25)	2.4 (3.79)
Median	1.0	2.0	2.0
Min, Max	1, 90	1, 68	1, 90
Solicited Systemic Adverse Reactions			
n	5168	11290	16458
Mean (SD)	3.4 (5.66)	3.2 (4.62)	3.2 (4.97)
Median	2.0	2.0	2.0
Min, Max	1, 90	1, 84	1, 90
Fever			
n	42	2223	2265
Mean (SD)	1.2 (0.52)	1.2 (1.71)	1.2 (1.69)
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 14.3.1.4.8
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=14119)	mRNA-1273 (N=14183)	Total (N=28302)
Headache			
n	3311	8348	11659
Mean (SD)	2.3 (3.33)	2.3 (2.95)	2.3 (3.06)
Median	1.0	2.0	2.0
Min, Max	1, 72	1, 78	1, 78
Fatigue			
n	3294	9310	12604
Mean (SD)	3.0 (5.12)	2.6 (3.77)	2.7 (4.17)
Median	2.0	2.0	2.0
Min, Max	1, 83	1, 78	1, 83
Myalgia			
n	1738	8229	9967
Mean (SD)	3.2 (6.09)	2.1 (3.15)	2.3 (3.85)
Median	2.0	1.0	2.0
Min, Max	1, 72	1, 79	1, 79
Arthralgia			
n	1516	6083	7599
Mean (SD)	3.7 (7.03)	2.3 (3.57)	2.5 (4.51)
Median	2.0	1.0	1.0
Min, Max	1, 90	1, 82	1, 90

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=14119)	mRNA-1273 (N=14183)	Total (N=28302)
Nausea/Vomiting			
n	912	2700	3612
Mean (SD)	2.0 (3.86)	1.7 (2.39)	1.8 (2.83)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 78	1, 78
Chills			
n	778	6292	7070
Mean (SD)	1.9 (3.24)	1.5 (1.57)	1.5 (1.84)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 76	1, 76

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=232)	mRNA-1273 (N=230)	Total (N=462)
Solicited Adverse Reactions			
n	81	186	267
Mean (SD)	3.9 (5.10)	3.3 (3.78)	3.5 (4.22)
Median	2.0	3.0	3.0
Min, Max	1, 33	1, 34	1, 34
Solicited Local Adverse Reactions			
n	42	172	214
Mean (SD)	2.5 (2.96)	2.8 (3.08)	2.7 (3.05)
Median	1.0	2.0	2.0
Min, Max	1, 18	1, 34	1, 34
Pain			
n	36	169	205
Mean (SD)	1.6 (0.99)	2.7 (3.09)	2.6 (2.87)
Median	1.0	2.0	2.0
Min, Max	1, 5	1, 34	1, 34
Erythema (Redness)			
n	1	8	9
Mean (SD)	2.0 (NA)	4.8 (6.27)	4.4 (5.94)
Median	2.0	3.0	3.0
Min, Max	2, 2	1, 20	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=232)	mRNA-1273 (N=230)	Total (N=462)
Swelling (Hardness)			
n	1	11	12
Mean (SD)	1.0 (NA)	4.2 (5.46)	3.9 (5.28)
Median	1.0	3.0	2.5
Min, Max	1, 1	1, 20	1, 20
Lymphadenopathy [1]			
n	11	30	41
Mean (SD)	4.6 (4.54)	2.2 (1.72)	2.9 (2.91)
Median	4.0	1.5	2.0
Min, Max	1, 17	1, 7	1, 17
Solicited Systemic Adverse Reactions			
n	71	150	221
Mean (SD)	4.0 (5.24)	2.8 (3.28)	3.2 (4.04)
Median	2.0	2.0	2.0
Min, Max	1, 32	1, 30	1, 32
Fever			
n	1	31	32
Mean (SD)	1.0 (NA)	1.0 (0.18)	1.0 (0.18)
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 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=232)	mRNA-1273 (N=230)	Total (N=462)
Headache			
n	43	97	140
Mean (SD)	2.5 (2.25)	2.6 (3.77)	2.6 (3.37)
Median	2.0	2.0	2.0
Min, Max	1, 12	1, 29	1, 29
Fatigue			
n	53	104	157
Mean (SD)	3.0 (3.59)	2.3 (1.95)	2.6 (2.63)
Median	2.0	2.0	2.0
Min, Max	1, 24	1, 12	1, 24
Myalgia			
n	32	115	147
Mean (SD)	4.5 (7.19)	2.0 (2.30)	2.6 (4.02)
Median	2.0	1.0	2.0
Min, Max	1, 32	1, 21	1, 32
Arthralgia			
n	24	76	100
Mean (SD)	4.4 (5.39)	2.3 (2.68)	2.8 (3.61)
Median	2.0	2.0	2.0
Min, Max	1, 24	1, 21	1, 24

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=232)	mRNA-1273 (N=230)	Total (N=462)
Nausea/Vomiting			
n	13	34	47
Mean (SD)	1.5 (0.78)	1.7 (1.19)	1.7 (1.09)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 6	1, 6
Chills			
n	17	78	95
Mean (SD)	2.6 (2.87)	1.6 (0.95)	1.8 (1.51)
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=215)	mRNA-1273 (N=264)	Total (N=479)
Solicited Adverse Reactions			
n	95	247	342
Mean (SD)	3.6 (6.28)	3.5 (2.37)	3.5 (3.86)
Median	2.0	3.0	3.0
Min, Max	1, 52	1, 18	1, 52
Solicited Local Adverse Reactions			
n	43	240	283
Mean (SD)	2.9 (7.77)	3.0 (1.69)	3.0 (3.38)
Median	1.0	3.0	2.0
Min, Max	1, 52	1, 13	1, 52
Pain			
n	38	238	276
Mean (SD)	1.6 (1.20)	2.8 (1.49)	2.7 (1.51)
Median	1.0	3.0	2.0
Min, Max	1, 7	1, 10	1, 10
Erythema (Redness)			
n	3	22	25
Mean (SD)	18.0 (29.44)	2.7 (2.55)	4.5 (10.19)
Median	1.0	2.0	2.0
Min, Max	1, 52	1, 13	1, 52

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=215)	mRNA-1273 (N=264)	Total (N=479)
Swelling (Hardness)			
n	1	32	33
Mean (SD)	1.0 (NA)	2.5 (1.52)	2.5 (1.52)
Median	1.0	2.0	2.0
Min, Max	1, 1	1, 6	1, 6
Lymphadenopathy [1]			
n	10	42	52
Mean (SD)	1.8 (1.03)	2.1 (1.64)	2.1 (1.54)
Median	1.5	1.0	1.0
Min, Max	1, 4	1, 7	1, 7
Solicited Systemic Adverse Reactions			
n	84	212	296
Mean (SD)	3.1 (3.97)	2.7 (2.37)	2.8 (2.91)
Median	2.0	2.0	2.0
Min, Max	1, 25	1, 18	1, 25
Fever			
n	0	24	24
Mean (SD)		1.1 (0.34)	1.1 (0.34)
Median		1.0	1.0
Min, Max		1, 2	1, 2

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=215)	mRNA-1273 (N=264)	Total (N=479)
Headache			
n	56	157	213
Mean (SD)	1.9 (1.61)	2.1 (1.61)	2.0 (1.61)
Median	1.0	2.0	1.0
Min, Max	1, 8	1, 10	1, 10
Fatigue			
n	56	168	224
Mean (SD)	2.6 (2.32)	2.3 (2.27)	2.4 (2.28)
Median	2.0	2.0	2.0
Min, Max	1, 12	1, 17	1, 17
Myalgia			
n	39	164	203
Mean (SD)	3.2 (5.30)	2.0 (1.64)	2.2 (2.78)
Median	1.0	1.5	1.0
Min, Max	1, 25	1, 14	1, 25
Arthralgia			
n	29	125	154
Mean (SD)	3.4 (4.68)	2.0 (1.60)	2.2 (2.53)
Median	2.0	1.0	2.0
Min, Max	1, 25	1, 11	1, 25

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=215)	mRNA-1273 (N=264)	Total (N=479)
Nausea/Vomiting			
n	9	51	60
Mean (SD)	1.3 (0.50)	1.5 (0.73)	1.5 (0.70)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 3
Chills			
n	14	112	126
Mean (SD)	1.3 (0.61)	1.4 (0.94)	1.4 (0.91)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 8	1, 8

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=14591)	mRNA-1273 (N=14548)	Total (N=29139)
Solicited Adverse Reactions			
n	8808	13847	22655
Mean (SD)	3.7 (5.68)	4.6 (5.27)	4.2 (5.45)
Median	2.0	4.0	3.0
Min, Max	1, 90	1, 93	1, 93
Solicited Local Adverse Reactions			
n	4304	13490	17794
Mean (SD)	2.1 (3.64)	3.4 (3.10)	3.1 (3.29)
Median	1.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Pain			
n	3907	13433	17340
Mean (SD)	1.8 (2.97)	3.2 (2.23)	2.9 (2.48)
Median	1.0	3.0	3.0
Min, Max	1, 72	1, 78	1, 78
Erythema (Redness)			
n	109	1477	1586
Mean (SD)	3.2 (7.35)	2.7 (4.15)	2.7 (4.44)
Median	1.0	2.0	2.0
Min, Max	1, 63	1, 93	1, 93

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=14591)	mRNA-1273 (N=14548)	Total (N=29139)
Swelling (Hardness)			
n	91	2167	2258
Mean (SD)	4.0 (6.80)	2.5 (3.94)	2.6 (4.10)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 93	1, 93
Lymphadenopathy [1]			
n	1054	2880	3934
Mean (SD)	2.3 (4.28)	2.4 (3.25)	2.4 (3.55)
Median	1.0	1.0	1.0
Min, Max	1, 90	1, 68	1, 90
Solicited Systemic Adverse Reactions			
n	7841	12293	20134
Mean (SD)	3.6 (5.56)	3.5 (5.03)	3.6 (5.25)
Median	2.0	2.0	2.0
Min, Max	1, 90	1, 84	1, 90
Fever			
n	79	2273	2352
Mean (SD)	1.3 (0.59)	1.2 (1.69)	1.2 (1.67)
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 14.3.1.4.9
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=14591)	mRNA-1273 (N=14548)	Total (N=29139)
Headache			
n	5402	9477	14879
Mean (SD)	2.4 (3.16)	2.4 (3.03)	2.4 (3.08)
Median	2.0	2.0	2.0
Min, Max	1, 72	1, 78	1, 78
Fatigue			
n	5353	10273	15626
Mean (SD)	3.1 (4.89)	2.9 (4.22)	3.0 (4.46)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Myalgia			
n	2991	8974	11965
Mean (SD)	3.0 (5.23)	2.3 (3.49)	2.4 (4.01)
Median	2.0	2.0	2.0
Min, Max	1, 72	1, 79	1, 79
Arthralgia			
n	2563	6780	9343
Mean (SD)	3.6 (6.48)	2.5 (3.99)	2.8 (4.83)
Median	2.0	1.0	2.0
Min, Max	1, 90	1, 82	1, 90

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=14591)	mRNA-1273 (N=14548)	Total (N=29139)
Nausea/Vomiting			
n	1662	3352	5014
Mean (SD)	1.9 (3.23)	1.7 (2.29)	1.8 (2.64)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 78	1, 78
Chills			
n	1407	6644	8051
Mean (SD)	1.8 (2.58)	1.5 (1.65)	1.5 (1.85)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 76	1, 76

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=337)	mRNA-1273 (N=343)	Total (N=680)
Solicited Adverse Reactions			
n	155	282	437
Mean (SD)	3.9 (4.43)	4.0 (4.26)	4.0 (4.31)
Median	2.0	3.0	3.0
Min, Max	1, 33	1, 34	1, 34
Solicited Local Adverse Reactions			
n	77	271	348
Mean (SD)	2.3 (2.48)	3.0 (2.85)	2.9 (2.79)
Median	1.0	3.0	2.0
Min, Max	1, 18	1, 34	1, 34
Pain			
n	70	268	338
Mean (SD)	1.7 (1.22)	2.8 (2.58)	2.6 (2.40)
Median	1.0	3.0	2.0
Min, Max	1, 8	1, 34	1, 34
Erythema (Redness)			
n	4	16	20
Mean (SD)	1.3 (0.50)	3.4 (4.63)	3.0 (4.21)
Median	1.0	2.5	1.5
Min, Max	1, 2	1, 20	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=337)	mRNA-1273 (N=343)	Total (N=680)
Swelling (Hardness)			
n	3	26	29
Mean (SD)	1.3 (0.58)	3.2 (4.47)	3.0 (4.27)
Median	1.0	1.5	1.0
Min, Max	1, 2	1, 20	1, 20
Lymphadenopathy [1]			
n	22	70	92
Mean (SD)	3.5 (3.83)	2.3 (2.24)	2.5 (2.73)
Median	2.0	1.0	1.5
Min, Max	1, 17	1, 16	1, 17
Solicited Systemic Adverse Reactions			
n	140	240	380
Mean (SD)	3.9 (4.52)	3.3 (3.99)	3.5 (4.20)
Median	2.0	2.0	2.0
Min, Max	1, 32	1, 30	1, 32
Fever			
n	7	54	61
Mean (SD)	1.3 (0.49)	1.1 (0.41)	1.2 (0.42)
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=337)	mRNA-1273 (N=343)	Total (N=680)
Headache			
n	98	165	263
Mean (SD)	2.5 (2.47)	2.8 (3.44)	2.7 (3.11)
Median	2.0	2.0	2.0
Min, Max	1, 15	1, 29	1, 29
Fatigue			
n	96	168	264
Mean (SD)	3.4 (3.69)	2.8 (3.16)	3.0 (3.37)
Median	2.0	2.0	2.0
Min, Max	1, 24	1, 29	1, 29
Myalgia			
n	64	176	240
Mean (SD)	4.2 (5.79)	2.3 (2.89)	2.8 (3.95)
Median	2.0	2.0	2.0
Min, Max	1, 32	1, 27	1, 32
Arthralgia			
n	53	126	179
Mean (SD)	3.8 (4.56)	2.2 (2.32)	2.7 (3.22)
Median	2.0	2.0	2.0
Min, Max	1, 24	1, 21	1, 24

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=337)	mRNA-1273 (N=343)	Total (N=680)
Nausea/Vomiting			
n	36	64	100
Mean (SD)	1.7 (1.28)	1.7 (1.65)	1.7 (1.52)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 13	1, 13
Chills			
n	38	124	162
Mean (SD)	2.4 (2.16)	1.7 (1.30)	1.9 (1.56)
Median	1.5	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=235)	mRNA-1273 (N=288)	Total (N=523)
Solicited Adverse Reactions			
n	145	271	416
Mean (SD)	4.2 (6.66)	4.1 (2.65)	4.1 (4.47)
Median	2.0	3.0	3.0
Min, Max	1, 52	1, 20	1, 52
Solicited Local Adverse Reactions			
n	69	266	335
Mean (SD)	2.5 (6.17)	3.2 (1.75)	3.0 (3.20)
Median	1.0	3.0	3.0
Min, Max	1, 52	1, 13	1, 52
Pain			
n	60	264	324
Mean (SD)	1.7 (1.24)	3.0 (1.47)	2.7 (1.52)
Median	1.0	3.0	2.0
Min, Max	1, 7	1, 10	1, 10
Erythema (Redness)			
n	4	29	33
Mean (SD)	13.8 (25.50)	2.7 (2.33)	4.0 (8.90)
Median	1.0	2.0	2.0
Min, Max	1, 52	1, 13	1, 52

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=235)	mRNA-1273 (N=288)	Total (N=523)
Swelling (Hardness)			
n	1	39	40
Mean (SD)	1.0 (NA)	2.4 (1.60)	2.3 (1.59)
Median	1.0	2.0	2.0
Min, Max	1, 1	1, 7	1, 7
Lymphadenopathy [1]			
n	22	61	83
Mean (SD)	1.6 (0.90)	2.2 (1.77)	2.0 (1.60)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 9	1, 9
Solicited Systemic Adverse Reactions			
n	131	237	368
Mean (SD)	3.9 (5.51)	3.1 (2.70)	3.4 (3.95)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 18	1, 41
Fever			
n	0	26	26
Mean (SD)		1.1 (0.33)	1.1 (0.33)
Median		1.0	1.0
Min, Max		1, 2	1, 2

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=235)	mRNA-1273 (N=288)	Total (N=523)
Headache			
n	103	183	286
Mean (SD)	2.1 (1.68)	2.2 (1.85)	2.2 (1.79)
Median	1.0	2.0	2.0
Min, Max	1, 8	1, 15	1, 15
Fatigue			
n	95	186	281
Mean (SD)	3.2 (4.96)	2.6 (2.68)	2.8 (3.62)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 17	1, 41
Myalgia			
n	58	184	242
Mean (SD)	3.7 (5.69)	2.1 (1.74)	2.5 (3.23)
Median	1.0	2.0	2.0
Min, Max	1, 30	1, 14	1, 30
Arthralgia			
n	50	138	188
Mean (SD)	4.0 (5.74)	2.0 (1.56)	2.5 (3.35)
Median	2.0	1.5	2.0
Min, Max	1, 32	1, 11	1, 32

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=235)	mRNA-1273 (N=288)	Total (N=523)
Nausea/Vomiting			
n	18	68	86
Mean (SD)	1.6 (0.98)	1.5 (0.82)	1.5 (0.85)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 5	1, 5
Chills			
n	25	123	148
Mean (SD)	1.4 (0.82)	1.4 (0.91)	1.4 (0.89)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 8	1, 8

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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Solicited Adverse Reactions - N1	11407	11406	22813
Any Solicited Adverse Reactions	715 (6.3)	887 (7.8)	1602 (7.0)
95% CI	5.8, 6.7	7.3, 8.3	6.7, 7.4
Grade 1	300 (2.6)	405 (3.6)	705 (3.1)
Grade 2	333 (2.9)	393 (3.4)	726 (3.2)
Grade 3	82 (0.7)	89 (0.8)	171 (0.7)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	11405	11402	22807
Any Solicited Local Adverse Reactions	87 (0.8)	305 (2.7)	392 (1.7)
95% CI	0.6, 0.9	2.4, 3.0	1.6, 1.9
Grade 1	70 (0.6)	213 (1.9)	283 (1.2)
Grade 2	14 (0.1)	74 (0.6)	88 (0.4)
Grade 3	3 (<0.1)	18 (0.2)	21 (<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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Pain - N1	11405	11402	22807
Any	40 (0.4)	77 (0.7)	117 (0.5)
Grade 1	33 (0.3)	40 (0.4)	73 (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	11405	11402	22807
Any	5 (<0.1)	15 (0.1)	20 (<0.1)
Grade 1	4 (<0.1)	7 (<0.1)	11 (<0.1)
Grade 2	0	6 (<0.1)	6 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	11405	11402	22807
Any	6 (<0.1)	22 (0.2)	28 (0.1)
Grade 1	4 (<0.1)	14 (0.1)	18 (<0.1)
Grade 2	1 (<0.1)	8 (<0.1)	9 (<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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Lymphadenopathy - N1 [1]	11405	11402	22807
Any	49 (0.4)	224 (2.0)	273 (1.2)
Grade 1	39 (0.3)	172 (1.5)	211 (0.9)
Grade 2	10 (<0.1)	43 (0.4)	53 (0.2)
Grade 3	0	9 (<0.1)	9 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	11407	11406	22813
Any Solicited Systemic Adverse Reactions	663 (5.8)	669 (5.9)	1332 (5.8)
95% CI	5.4, 6.3	5.4, 6.3	5.5, 6.2
Grade 1	255 (2.2)	245 (2.1)	500 (2.2)
Grade 2	328 (2.9)	348 (3.1)	676 (3.0)
Grade 3	80 (0.7)	76 (0.7)	156 (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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Fever - N1	11405	11404	22809
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	11405	11402	22807
Any	258 (2.3)	281 (2.5)	539 (2.4)
Grade 1	121 (1.1)	143 (1.3)	264 (1.2)
Grade 2	97 (0.9)	112 (1.0)	209 (0.9)
Grade 3	40 (0.4)	26 (0.2)	66 (0.3)
Grade 4	0	0	0
Fatigue - N1	11405	11402	22807
Any	368 (3.2)	391 (3.4)	759 (3.3)
Grade 1	112 (1.0)	109 (1.0)	221 (1.0)
Grade 2	220 (1.9)	241 (2.1)	461 (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=11407) n	Placebo (N=11407) (%)	mRNA-1273 (N=11406) n	mRNA-1273 (N=11406) (%)	Total (N=22813) n	Total (N=22813) (%)
Myalgia - N1	11405		11402		22807	
Any	176	(1.5)	163	(1.4)	339	(1.5)
Grade 1	65	(0.6)	53	(0.5)	118	(0.5)
Grade 2	92	(0.8)	84	(0.7)	176	(0.8)
Grade 3	19	(0.2)	26	(0.2)	45	(0.2)
Grade 4	0		0		0	
Arthralgia - N1	11405		11402		22807	
Any	192	(1.7)	166	(1.5)	358	(1.6)
Grade 1	82	(0.7)	68	(0.6)	150	(0.7)
Grade 2	96	(0.8)	79	(0.7)	175	(0.8)
Grade 3	14	(0.1)	19	(0.2)	33	(0.1)
Grade 4	0		0		0	
Nausea/Vomiting - N1	11405		11402		22807	
Any	56	(0.5)	52	(0.5)	108	(0.5)
Grade 1	32	(0.3)	28	(0.2)	60	(0.3)
Grade 2	23	(0.2)	24	(0.2)	47	(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=11407) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22813) n (%)
Chills - N1	11405	11402	22807
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	215 (5.7)	226 (6.0)	441 (5.9)
95% CI	5.0, 6.5	5.3, 6.8	5.4, 6.4
Grade 1	111 (3.0)	104 (2.8)	215 (2.9)
Grade 2	88 (2.3)	101 (2.7)	189 (2.5)
Grade 3	16 (0.4)	21 (0.6)	37 (0.5)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	3746	3762	7508
Any Solicited Local Adverse Reactions	26 (0.7)	26 (0.7)	52 (0.7)
95% CI	0.5, 1.0	0.5, 1.0	0.5, 0.9
Grade 1	16 (0.4)	17 (0.5)	33 (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)	9 (0.2)	20 (0.3)
Grade 1	8 (0.2)	5 (0.1)	13 (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	5 (0.1)	6 (0.2)	11 (0.1)
Grade 1	4 (0.1)	3 (<0.1)	7 (<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	194 (5.2)	208 (5.5)	402 (5.4)
95% CI	4.5, 5.9	4.8, 6.3	4.9, 5.9
Grade 1	99 (2.6)	90 (2.4)	189 (2.5)
Grade 2	80 (2.1)	98 (2.6)	178 (2.4)
Grade 3	15 (0.4)	20 (0.5)	35 (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	106 (2.8)	132 (3.5)	238 (3.2)
Grade 1	46 (1.2)	45 (1.2)	91 (1.2)
Grade 2	49 (1.3)	74 (2.0)	123 (1.6)
Grade 3	11 (0.3)	13 (0.3)	24 (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)	31 (0.8)	68 (0.9)
Grade 2	31 (0.8)	27 (0.7)	58 (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)	83 (2.2)	173 (2.3)
Grade 1	55 (1.5)	37 (1.0)	92 (1.2)
Grade 2	30 (0.8)	39 (1.0)	69 (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	11 (0.3)	10 (0.3)	21 (0.3)
Grade 1	8 (0.2)	5 (0.1)	13 (0.2)
Grade 2	3 (<0.1)	3 (<0.1)	6 (<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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Solicited Adverse Reactions - N1	10918	10985	21903
Any Solicited Adverse Reactions	585 (5.4)	772 (7.0)	1357 (6.2)
95% CI	4.9, 5.8	6.6, 7.5	5.9, 6.5
Grade 1	237 (2.2)	165 (1.5)	402 (1.8)
Grade 2	271 (2.5)	389 (3.5)	660 (3.0)
Grade 3	77 (0.7)	218 (2.0)	295 (1.3)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	10914	10984	21898
Any Solicited Local Adverse Reactions	89 (0.8)	230 (2.1)	319 (1.5)
95% CI	0.7, 1.0	1.8, 2.4	1.3, 1.6
Grade 1	72 (0.7)	86 (0.8)	158 (0.7)
Grade 2	10 (<0.1)	93 (0.8)	103 (0.5)
Grade 3	7 (<0.1)	51 (0.5)	58 (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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Pain - N1	10914	10984	21898
Any	44 (0.4)	116 (1.1)	160 (0.7)
Grade 1	32 (0.3)	37 (0.3)	69 (0.3)
Grade 2	6 (<0.1)	57 (0.5)	63 (0.3)
Grade 3	6 (<0.1)	22 (0.2)	28 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	10914	10984	21898
Any	3 (<0.1)	36 (0.3)	39 (0.2)
Grade 1	3 (<0.1)	3 (<0.1)	6 (<0.1)
Grade 2	0	13 (0.1)	13 (<0.1)
Grade 3	0	20 (0.2)	20 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	10914	10984	21898
Any	5 (<0.1)	37 (0.3)	42 (0.2)
Grade 1	5 (<0.1)	12 (0.1)	17 (<0.1)
Grade 2	0	14 (0.1)	14 (<0.1)
Grade 3	0	11 (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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Lymphadenopathy - N1 [1]	10914	10984	21898
Any	43 (0.4)	85 (0.8)	128 (0.6)
Grade 1	38 (0.3)	55 (0.5)	93 (0.4)
Grade 2	4 (<0.1)	23 (0.2)	27 (0.1)
Grade 3	1 (<0.1)	7 (<0.1)	8 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	10917	10985	21902
Any Solicited Systemic Adverse Reactions	536 (4.9)	639 (5.8)	1175 (5.4)
95% CI	4.5, 5.3	5.4, 6.3	5.1, 5.7
Grade 1	196 (1.8)	111 (1.0)	307 (1.4)
Grade 2	269 (2.5)	350 (3.2)	619 (2.8)
Grade 3	71 (0.7)	178 (1.6)	249 (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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Fever - N1	10912	10979	21891
Any	0	3 (<0.1)	3 (<0.1)
Grade 1	0	1 (<0.1)	1 (<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	10914	10984	21898
Any	245 (2.2)	326 (3.0)	571 (2.6)
Grade 1	117 (1.1)	79 (0.7)	196 (0.9)
Grade 2	97 (0.9)	195 (1.8)	292 (1.3)
Grade 3	31 (0.3)	52 (0.5)	83 (0.4)
Grade 4	0	0	0
Fatigue - N1	10912	10984	21896
Any	294 (2.7)	371 (3.4)	665 (3.0)
Grade 1	81 (0.7)	48 (0.4)	129 (0.6)
Grade 2	173 (1.6)	207 (1.9)	380 (1.7)
Grade 3	40 (0.4)	116 (1.1)	156 (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=10918) n	(%)	mRNA-1273 (N=10985) n	(%)	Total (N=21903) n	(%)
Myalgia - N1	10912		10984		21896	
Any	172	(1.6)	176	(1.6)	348	(1.6)
Grade 1	58	(0.5)	30	(0.3)	88	(0.4)
Grade 2	90	(0.8)	99	(0.9)	189	(0.9)
Grade 3	24	(0.2)	47	(0.4)	71	(0.3)
Grade 4	0		0		0	
Arthralgia - N1	10912		10984		21896	
Any	184	(1.7)	193	(1.8)	377	(1.7)
Grade 1	66	(0.6)	40	(0.4)	106	(0.5)
Grade 2	100	(0.9)	116	(1.1)	216	(1.0)
Grade 3	18	(0.2)	37	(0.3)	55	(0.3)
Grade 4	0		0		0	
Nausea/Vomiting - N1	10912		10984		21896	
Any	45	(0.4)	54	(0.5)	99	(0.5)
Grade 1	19	(0.2)	13	(0.1)	32	(0.1)
Grade 2	25	(0.2)	39	(0.4)	64	(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=10918) n (%)	mRNA-1273 (N=10985) n (%)	Total (N=21903) n (%)
Chills - N1	10912	10984	21896
Any	39 (0.4)	43 (0.4)	82 (0.4)
Grade 1	17 (0.2)	9 (<0.1)	26 (0.1)
Grade 2	17 (0.2)	27 (0.2)	44 (0.2)
Grade 3	5 (<0.1)	7 (<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 14.3.1.6.5
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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Solicited Adverse Reactions - N1	3648	3692	7340
Any Solicited Adverse Reactions	183 (5.0)	247 (6.7)	430 (5.9)
95% CI	4.3, 5.8	5.9, 7.5	5.3, 6.4
Grade 1	89 (2.4)	71 (1.9)	160 (2.2)
Grade 2	77 (2.1)	114 (3.1)	191 (2.6)
Grade 3	17 (0.5)	61 (1.7)	78 (1.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	3648	3689	7337
Any Solicited Local Adverse Reactions	20 (0.5)	71 (1.9)	91 (1.2)
95% CI	0.3, 0.8	1.5, 2.4	1.0, 1.5
Grade 1	15 (0.4)	30 (0.8)	45 (0.6)
Grade 2	4 (0.1)	26 (0.7)	30 (0.4)
Grade 3	1 (<0.1)	15 (0.4)	16 (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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Pain - N1	3648	3689	7337
Any	14 (0.4)	43 (1.2)	57 (0.8)
Grade 1	9 (0.2)	21 (0.6)	30 (0.4)
Grade 2	5 (0.1)	19 (0.5)	24 (0.3)
Grade 3	0	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	3648	3689	7337
Any	1 (<0.1)	24 (0.7)	25 (0.3)
Grade 1	1 (<0.1)	7 (0.2)	8 (0.1)
Grade 2	0	7 (0.2)	7 (<0.1)
Grade 3	0	10 (0.3)	10 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	3648	3689	7337
Any	1 (<0.1)	11 (0.3)	12 (0.2)
Grade 1	1 (<0.1)	6 (0.2)	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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Lymphadenopathy - N1 [1]	3648	3689	7337
Any	5 (0.1)	6 (0.2)	11 (0.1)
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	3648	3692	7340
Any Solicited Systemic Adverse Reactions	173 (4.7)	197 (5.3)	370 (5.0)
95% CI	4.1, 5.5	4.6, 6.1	4.6, 5.6
Grade 1	83 (2.3)	51 (1.4)	134 (1.8)
Grade 2	74 (2.0)	99 (2.7)	173 (2.4)
Grade 3	16 (0.4)	46 (1.2)	62 (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 14.3.1.6.5
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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Fever - N1	3647	3690	7337
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	3648	3689	7337
Any	59 (1.6)	55 (1.5)	114 (1.6)
Grade 1	35 (1.0)	21 (0.6)	56 (0.8)
Grade 2	22 (0.6)	30 (0.8)	52 (0.7)
Grade 3	2 (<0.1)	4 (0.1)	6 (<0.1)
Grade 4	0	0	0
Fatigue - N1	3648	3689	7337
Any	95 (2.6)	114 (3.1)	209 (2.8)
Grade 1	36 (1.0)	23 (0.6)	59 (0.8)
Grade 2	49 (1.3)	55 (1.5)	104 (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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Myalgia - N1	3648	3689	7337
Any	51 (1.4)	59 (1.6)	110 (1.5)
Grade 1	26 (0.7)	15 (0.4)	41 (0.6)
Grade 2	21 (0.6)	31 (0.8)	52 (0.7)
Grade 3	4 (0.1)	13 (0.4)	17 (0.2)
Grade 4	0	0	0
Arthralgia - N1	3648	3689	7337
Any	76 (2.1)	74 (2.0)	150 (2.0)
Grade 1	39 (1.1)	20 (0.5)	59 (0.8)
Grade 2	33 (0.9)	39 (1.1)	72 (1.0)
Grade 3	4 (0.1)	15 (0.4)	19 (0.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	3648	3689	7337
Any	6 (0.2)	9 (0.2)	15 (0.2)
Grade 1	2 (<0.1)	3 (<0.1)	5 (<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=3648) n (%)	mRNA-1273 (N=3692) n (%)	Total (N=7340) n (%)
Chills - N1	3648	3689	7337
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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Solicited Adverse Reactions - N1	11413	11412	22825
Any Solicited Adverse Reactions	1128 (9.9)	1433 (12.6)	2561 (11.2)
95% CI	9.3, 10.4	12.0, 13.2	10.8, 11.6
Grade 1	448 (3.9)	467 (4.1)	915 (4.0)
Grade 2	530 (4.6)	674 (5.9)	1204 (5.3)
Grade 3	150 (1.3)	292 (2.6)	442 (1.9)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	11412	11412	22824
Any Solicited Local Adverse Reactions	162 (1.4)	487 (4.3)	649 (2.8)
95% CI	1.2, 1.7	3.9, 4.7	2.6, 3.1
Grade 1	128 (1.1)	269 (2.4)	397 (1.7)
Grade 2	24 (0.2)	150 (1.3)	174 (0.8)
Grade 3	10 (<0.1)	68 (0.6)	78 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Pain - N1	11412	11412	22824
Any	79 (0.7)	178 (1.6)	257 (1.1)
Grade 1	60 (0.5)	70 (0.6)	130 (0.6)
Grade 2	11 (<0.1)	79 (0.7)	90 (0.4)
Grade 3	8 (<0.1)	29 (0.3)	37 (0.2)
Grade 4	0	0	0
Erythema (Redness) - N1	11412	11412	22824
Any	7 (<0.1)	49 (0.4)	56 (0.2)
Grade 1	6 (<0.1)	9 (<0.1)	15 (<0.1)
Grade 2	0	18 (0.2)	18 (<0.1)
Grade 3	1 (<0.1)	22 (0.2)	23 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	11412	11412	22824
Any	11 (<0.1)	58 (0.5)	69 (0.3)
Grade 1	9 (<0.1)	25 (0.2)	34 (0.1)
Grade 2	1 (<0.1)	22 (0.2)	23 (0.1)
Grade 3	1 (<0.1)	11 (<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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Lymphadenopathy - N1 [1]	11412	11412	22824
Any	84 (0.7)	285 (2.5)	369 (1.6)
Grade 1	69 (0.6)	209 (1.8)	278 (1.2)
Grade 2	14 (0.1)	60 (0.5)	74 (0.3)
Grade 3	1 (<0.1)	16 (0.1)	17 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	11413	11412	22825
Any Solicited Systemic Adverse Reactions	1042 (9.1)	1141 (10.0)	2183 (9.6)
95% CI	8.6, 9.7	9.5, 10.6	9.2, 10.0
Grade 1	376 (3.3)	296 (2.6)	672 (2.9)
Grade 2	524 (4.6)	603 (5.3)	1127 (4.9)
Grade 3	142 (1.2)	242 (2.1)	384 (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.
[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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Fever - N1	11412	11411	22823
Any	3 (<0.1)	6 (<0.1)	9 (<0.1)
Grade 1	3 (<0.1)	2 (<0.1)	5 (<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	11412	11412	22824
Any	465 (4.1)	556 (4.9)	1021 (4.5)
Grade 1	216 (1.9)	194 (1.7)	410 (1.8)
Grade 2	182 (1.6)	284 (2.5)	466 (2.0)
Grade 3	67 (0.6)	78 (0.7)	145 (0.6)
Grade 4	0	0	0
Fatigue - N1	11412	11412	22824
Any	586 (5.1)	672 (5.9)	1258 (5.5)
Grade 1	168 (1.5)	132 (1.2)	300 (1.3)
Grade 2	347 (3.0)	391 (3.4)	738 (3.2)
Grade 3	71 (0.6)	149 (1.3)	220 (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 14.3.1.6.6
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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Myalgia - N1	11412	11412	22824
Any	318 (2.8)	312 (2.7)	630 (2.8)
Grade 1	108 (0.9)	72 (0.6)	180 (0.8)
Grade 2	167 (1.5)	171 (1.5)	338 (1.5)
Grade 3	43 (0.4)	69 (0.6)	112 (0.5)
Grade 4	0	0	0
Arthralgia - N1	11412	11412	22824
Any	333 (2.9)	314 (2.8)	647 (2.8)
Grade 1	122 (1.1)	83 (0.7)	205 (0.9)
Grade 2	179 (1.6)	181 (1.6)	360 (1.6)
Grade 3	32 (0.3)	50 (0.4)	82 (0.4)
Grade 4	0	0	0
Nausea/Vomiting - N1	11412	11412	22824
Any	91 (0.8)	99 (0.9)	190 (0.8)
Grade 1	46 (0.4)	37 (0.3)	83 (0.4)
Grade 2	43 (0.4)	60 (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=11413) n (%)	mRNA-1273 (N=11412) n (%)	Total (N=22825) n (%)
Chills - N1	11412	11412	22824
Any	75 (0.7)	68 (0.6)	143 (0.6)
Grade 1	37 (0.3)	16 (0.1)	53 (0.2)
Grade 2	32 (0.3)	44 (0.4)	76 (0.3)
Grade 3	6 (<0.1)	8 (<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 14.3.1.6.6
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=3767) n (%)	Total (N=7517) n (%)
Solicited Adverse Reactions - N1	3750	3767	7517
Any Solicited Adverse Reactions	335 (8.9)	418 (11.1)	753 (10.0)
95% CI	8.0, 9.9	10.1, 12.1	9.3, 10.7
Grade 1	167 (4.5)	146 (3.9)	313 (4.2)
Grade 2	136 (3.6)	192 (5.1)	328 (4.4)
Grade 3	32 (0.9)	79 (2.1)	111 (1.5)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	3750	3767	7517
Any Solicited Local Adverse Reactions	42 (1.1)	92 (2.4)	134 (1.8)
95% CI	0.8, 1.5	2.0, 3.0	1.5, 2.1
Grade 1	27 (0.7)	43 (1.1)	70 (0.9)
Grade 2	13 (0.3)	31 (0.8)	44 (0.6)
Grade 3	2 (<0.1)	18 (0.5)	20 (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=3767) n (%)	Total (N=7517) n (%)
Pain - N1	3750	3767	7517
Any	24 (0.6)	49 (1.3)	73 (1.0)
Grade 1	16 (0.4)	24 (0.6)	40 (0.5)
Grade 2	8 (0.2)	21 (0.6)	29 (0.4)
Grade 3	0	4 (0.1)	4 (<0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	3750	3767	7517
Any	6 (0.2)	30 (0.8)	36 (0.5)
Grade 1	5 (0.1)	10 (0.3)	15 (0.2)
Grade 2	1 (<0.1)	9 (0.2)	10 (0.1)
Grade 3	0	11 (0.3)	11 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	3750	3767	7517
Any	6 (0.2)	13 (0.3)	19 (0.3)
Grade 1	4 (0.1)	7 (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=3767) n (%)	Total (N=7517) n (%)
Lymphadenopathy - N1 [1]	3750	3767	7517
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	3767	7517
Any Solicited Systemic Adverse Reactions	306 (8.2)	357 (9.5)	663 (8.8)
95% CI	7.3, 9.1	8.6, 10.5	8.2, 9.5
Grade 1	151 (4.0)	119 (3.2)	270 (3.6)
Grade 2	125 (3.3)	174 (4.6)	299 (4.0)
Grade 3	30 (0.8)	63 (1.7)	93 (1.2)
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=3767) n	(%)	Total (N=7517) n	(%)
Fever - N1	3750		3767		7517	
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		3767		7517	
Any	103	(2.7)	105	(2.8)	208	(2.8)
Grade 1	62	(1.7)	50	(1.3)	112	(1.5)
Grade 2	34	(0.9)	42	(1.1)	76	(1.0)
Grade 3	7	(0.2)	13	(0.3)	20	(0.3)
Grade 4	0		0		0	
Fatigue - N1	3750		3767		7517	
Any	169	(4.5)	222	(5.9)	391	(5.2)
Grade 1	67	(1.8)	58	(1.5)	125	(1.7)
Grade 2	81	(2.2)	115	(3.1)	196	(2.6)
Grade 3	21	(0.6)	49	(1.3)	70	(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=3767) n	(%)	Total (N=7517) n	(%)
Myalgia - N1	3750		3767		7517	
Any	103	(2.7)	111	(2.9)	214	(2.8)
Grade 1	50	(1.3)	39	(1.0)	89	(1.2)
Grade 2	46	(1.2)	53	(1.4)	99	(1.3)
Grade 3	7	(0.2)	19	(0.5)	26	(0.3)
Grade 4	0		0		0	
Arthralgia - N1	3750		3767		7517	
Any	143	(3.8)	140	(3.7)	283	(3.8)
Grade 1	79	(2.1)	49	(1.3)	128	(1.7)
Grade 2	56	(1.5)	70	(1.9)	126	(1.7)
Grade 3	8	(0.2)	21	(0.6)	29	(0.4)
Grade 4	0		0		0	
Nausea/Vomiting - N1	3750		3767		7517	
Any	16	(0.4)	19	(0.5)	35	(0.5)
Grade 1	9	(0.2)	8	(0.2)	17	(0.2)
Grade 2	7	(0.2)	5	(0.1)	12	(0.2)
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=3767) n (%)	Total (N=7517) n (%)
Chills - N1	3750	3767	7517
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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Solicited Adverse Reactions - N1	14583	14538	29121
Any Solicited Adverse Reactions	885 (6.1)	1068 (7.3)	1953 (6.7)
95% CI	5.7, 6.5	6.9, 7.8	6.4, 7.0
Grade 1	392 (2.7)	495 (3.4)	887 (3.0)
Grade 2	403 (2.8)	469 (3.2)	872 (3.0)
Grade 3	90 (0.6)	104 (0.7)	194 (0.7)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	14579	14534	29113
Any Solicited Local Adverse Reactions	108 (0.7)	321 (2.2)	429 (1.5)
95% CI	0.6, 0.9	2.0, 2.5	1.3, 1.6
Grade 1	81 (0.6)	222 (1.5)	303 (1.0)
Grade 2	23 (0.2)	79 (0.5)	102 (0.4)
Grade 3	4 (<0.1)	20 (0.1)	24 (<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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Pain - N1	14579	14534	29113
Any	50 (0.3)	83 (0.6)	133 (0.5)
Grade 1	40 (0.3)	43 (0.3)	83 (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	14579	14533	29112
Any	10 (<0.1)	20 (0.1)	30 (0.1)
Grade 1	8 (<0.1)	9 (<0.1)	17 (<0.1)
Grade 2	1 (<0.1)	8 (<0.1)	9 (<0.1)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	14579	14533	29112
Any	12 (<0.1)	23 (0.2)	35 (0.1)
Grade 1	8 (<0.1)	14 (<0.1)	22 (<0.1)
Grade 2	2 (<0.1)	9 (<0.1)	11 (<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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Lymphadenopathy - N1 [1]	14579	14533	29112
Any	52 (0.4)	228 (1.6)	280 (1.0)
Grade 1	38 (0.3)	176 (1.2)	214 (0.7)
Grade 2	14 (<0.1)	42 (0.3)	56 (0.2)
Grade 3	0	10 (<0.1)	10 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14583	14537	29120
Any Solicited Systemic Adverse Reactions	816 (5.6)	840 (5.8)	1656 (5.7)
95% CI	5.2, 6.0	5.4, 6.2	5.4, 6.0
Grade 1	339 (2.3)	328 (2.3)	667 (2.3)
Grade 2	390 (2.7)	422 (2.9)	812 (2.8)
Grade 3	87 (0.6)	90 (0.6)	177 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Fever - N1	14582	14535	29117
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	14578	14533	29111
Any	295 (2.0)	318 (2.2)	613 (2.1)
Grade 1	151 (1.0)	170 (1.2)	321 (1.1)
Grade 2	103 (0.7)	116 (0.8)	219 (0.8)
Grade 3	41 (0.3)	32 (0.2)	73 (0.3)
Grade 4	0	0	0
Fatigue - N1	14578	14533	29111
Any	449 (3.1)	501 (3.4)	950 (3.3)
Grade 1	147 (1.0)	150 (1.0)	297 (1.0)
Grade 2	259 (1.8)	300 (2.1)	559 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Myalgia - N1	14578	14533	29111
Any	230 (1.6)	214 (1.5)	444 (1.5)
Grade 1	97 (0.7)	79 (0.5)	176 (0.6)
Grade 2	113 (0.8)	105 (0.7)	218 (0.7)
Grade 3	20 (0.1)	30 (0.2)	50 (0.2)
Grade 4	0	0	0
Arthralgia - N1	14578	14533	29111
Any	267 (1.8)	244 (1.7)	511 (1.8)
Grade 1	133 (0.9)	105 (0.7)	238 (0.8)
Grade 2	117 (0.8)	114 (0.8)	231 (0.8)
Grade 3	17 (0.1)	25 (0.2)	42 (0.1)
Grade 4	0	0	0
Nausea/Vomiting - N1	14578	14533	29111
Any	65 (0.4)	59 (0.4)	124 (0.4)
Grade 1	39 (0.3)	31 (0.2)	70 (0.2)
Grade 2	25 (0.2)	26 (0.2)	51 (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=14583) n (%)	mRNA-1273 (N=14538) n (%)	Total (N=29121) n (%)
Chills - N1	14578	14533	29111
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Solicited Adverse Reactions - N1	337	342	679
Any Solicited Adverse Reactions	25 (7.4)	22 (6.4)	47 (6.9)
95% CI	4.9, 10.8	4.1, 9.6	5.1, 9.1
Grade 1	7 (2.1)	6 (1.8)	13 (1.9)
Grade 2	12 (3.6)	12 (3.5)	24 (3.5)
Grade 3	6 (1.8)	4 (1.2)	10 (1.5)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	337	342	679
Any Solicited Local Adverse Reactions	4 (1.2)	5 (1.5)	9 (1.3)
95% CI	0.3, 3.0	0.5, 3.4	0.6, 2.5
Grade 1	4 (1.2)	3 (0.9)	7 (1.0)
Grade 2	0	1 (0.3)	1 (0.1)
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Pain - N1	337	342	679
Any	1 (0.3)	2 (0.6)	3 (0.4)
Grade 1	1 (0.3)	1 (0.3)	2 (0.3)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	337	342	679
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	337	342	679
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Lymphadenopathy - N1 [1]	337	342	679
Any	4 (1.2)	3 (0.9)	7 (1.0)
Grade 1	4 (1.2)	1 (0.3)	5 (0.7)
Grade 2	0	2 (0.6)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	337	342	679
Any Solicited Systemic Adverse Reactions	22 (6.5)	18 (5.3)	40 (5.9)
95% CI	4.1, 9.7	3.1, 8.2	4.2, 7.9
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Fever - N1	336	342	678
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	337	342	679
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	337	342	679
Any	15 (4.5)	9 (2.6)	24 (3.5)
Grade 1	3 (0.9)	2 (0.6)	5 (0.7)
Grade 2	10 (3.0)	6 (1.8)	16 (2.4)
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=337) n	(%)	mRNA-1273 (N=342) n	(%)	Total (N=679) n	(%)
Myalgia - N1	337		342		679	
Any	11	(3.3)	7	(2.0)	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	337		342		679	
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	337		342		679	
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=337) n (%)	mRNA-1273 (N=342) n (%)	Total (N=679) n (%)
Chills - N1	337	342	679
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Adverse Reactions - N1	235	288	523
Any Solicited Adverse Reactions	20 (8.5)	23 (8.0)	43 (8.2)
95% CI	5.3, 12.8	5.1, 11.7	6.0, 10.9
Grade 1	12 (5.1)	8 (2.8)	20 (3.8)
Grade 2	6 (2.6)	13 (4.5)	19 (3.6)
Grade 3	2 (0.9)	2 (0.7)	4 (0.8)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	235	288	523
Any Solicited Local Adverse Reactions	1 (0.4)	5 (1.7)	6 (1.1)
95% CI	0.0, 2.3	0.6, 4.0	0.4, 2.5
Grade 1	1 (0.4)	5 (1.7)	6 (1.1)
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: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Pain - N1	235	288	523
Any	0	1 (0.3)	1 (0.2)
Grade 1	0	1 (0.3)	1 (0.2)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Erythema (Redness) - N1	235	288	523
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	235	288	523
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Lymphadenopathy - N1 [1]	235	288	523
Any	1 (0.4)	4 (1.4)	5 (1.0)
Grade 1	1 (0.4)	4 (1.4)	5 (1.0)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	235	288	523
Any Solicited Systemic Adverse Reactions	19 (8.1)	19 (6.6)	38 (7.3)
95% CI	4.9, 12.3	4.0, 10.1	5.2, 9.8
Grade 1	11 (4.7)	4 (1.4)	15 (2.9)
Grade 2	6 (2.6)	13 (4.5)	19 (3.6)
Grade 3	2 (0.9)	2 (0.7)	4 (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 14.3.1.6.7
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Fever - N1	235	287	522
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	235	288	523
Any	8 (3.4)	6 (2.1)	14 (2.7)
Grade 1	3 (1.3)	3 (1.0)	6 (1.1)
Grade 2	4 (1.7)	3 (1.0)	7 (1.3)
Grade 3	1 (0.4)	0	1 (0.2)
Grade 4	0	0	0
Fatigue - N1	235	288	523
Any	10 (4.3)	13 (4.5)	23 (4.4)
Grade 1	8 (3.4)	2 (0.7)	10 (1.9)
Grade 2	0	9 (3.1)	9 (1.7)
Grade 3	2 (0.9)	2 (0.7)	4 (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 14.3.1.6.7
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Myalgia - N1	235	288	523
Any	6 (2.6)	6 (2.1)	12 (2.3)
Grade 1	3 (1.3)	2 (0.7)	5 (1.0)
Grade 2	2 (0.9)	2 (0.7)	4 (0.8)
Grade 3	1 (0.4)	2 (0.7)	3 (0.6)
Grade 4	0	0	0
Arthralgia - N1	235	288	523
Any	7 (3.0)	2 (0.7)	9 (1.7)
Grade 1	3 (1.3)	0	3 (0.6)
Grade 2	3 (1.3)	1 (0.3)	4 (0.8)
Grade 3	1 (0.4)	1 (0.3)	2 (0.4)
Grade 4	0	0	0
Nausea/Vomiting - N1	235	288	523
Any	1 (0.4)	2 (0.7)	3 (0.6)
Grade 1	1 (0.4)	2 (0.7)	3 (0.6)
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Chills - N1	235	288	523
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Solicited Adverse Reactions - N1	14119	14183	28302
Any Solicited Adverse Reactions	740 (5.2)	991 (7.0)	1731 (6.1)
95% CI	4.9, 5.6	6.6, 7.4	5.8, 6.4
Grade 1	310 (2.2)	233 (1.6)	543 (1.9)
Grade 2	339 (2.4)	484 (3.4)	823 (2.9)
Grade 3	91 (0.6)	273 (1.9)	364 (1.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	14116	14179	28295
Any Solicited Local Adverse Reactions	101 (0.7)	292 (2.1)	393 (1.4)
95% CI	0.6, 0.9	1.8, 2.3	1.3, 1.5
Grade 1	81 (0.6)	114 (0.8)	195 (0.7)
Grade 2	13 (<0.1)	114 (0.8)	127 (0.4)
Grade 3	7 (<0.1)	64 (0.5)	71 (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: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Pain - N1	14116	14179	28295
Any	56 (0.4)	152 (1.1)	208 (0.7)
Grade 1	40 (0.3)	57 (0.4)	97 (0.3)
Grade 2	11 (<0.1)	71 (0.5)	82 (0.3)
Grade 3	5 (<0.1)	24 (0.2)	29 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	14116	14179	28295
Any	3 (<0.1)	58 (0.4)	61 (0.2)
Grade 1	3 (<0.1)	10 (<0.1)	13 (<0.1)
Grade 2	0	20 (0.1)	20 (<0.1)
Grade 3	0	28 (0.2)	28 (<0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	14116	14179	28295
Any	6 (<0.1)	46 (0.3)	52 (0.2)
Grade 1	6 (<0.1)	16 (0.1)	22 (<0.1)
Grade 2	0	16 (0.1)	16 (<0.1)
Grade 3	0	14 (<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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Lymphadenopathy - N1 [1]	14116	14179	28295
Any	43 (0.3)	89 (0.6)	132 (0.5)
Grade 1	38 (0.3)	58 (0.4)	96 (0.3)
Grade 2	3 (<0.1)	24 (0.2)	27 (<0.1)
Grade 3	2 (<0.1)	7 (<0.1)	9 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14118	14183	28301
Any Solicited Systemic Adverse Reactions	685 (4.9)	812 (5.7)	1497 (5.3)
95% CI	4.5, 5.2	5.3, 6.1	5.0, 5.6
Grade 1	267 (1.9)	160 (1.1)	427 (1.5)
Grade 2	334 (2.4)	431 (3.0)	765 (2.7)
Grade 3	84 (0.6)	220 (1.6)	304 (1.1)
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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Fever - N1	14113	14176	28289
Any	0	3 (<0.1)	3 (<0.1)
Grade 1	0	1 (<0.1)	1 (<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	14116	14179	28295
Any	293 (2.1)	367 (2.6)	660 (2.3)
Grade 1	145 (1.0)	96 (0.7)	241 (0.9)
Grade 2	116 (0.8)	217 (1.5)	333 (1.2)
Grade 3	32 (0.2)	54 (0.4)	86 (0.3)
Grade 4	0	0	0
Fatigue - N1	14114	14179	28293
Any	376 (2.7)	474 (3.3)	850 (3.0)
Grade 1	112 (0.8)	71 (0.5)	183 (0.6)
Grade 2	216 (1.5)	253 (1.8)	469 (1.7)
Grade 3	48 (0.3)	150 (1.1)	198 (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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Myalgia - N1	14114	14179	28293
Any	213 (1.5)	228 (1.6)	441 (1.6)
Grade 1	81 (0.6)	45 (0.3)	126 (0.4)
Grade 2	105 (0.7)	124 (0.9)	229 (0.8)
Grade 3	27 (0.2)	59 (0.4)	86 (0.3)
Grade 4	0	0	0
Arthralgia - N1	14114	14179	28293
Any	249 (1.8)	260 (1.8)	509 (1.8)
Grade 1	99 (0.7)	60 (0.4)	159 (0.6)
Grade 2	129 (0.9)	149 (1.1)	278 (1.0)
Grade 3	21 (0.1)	51 (0.4)	72 (0.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	14114	14179	28293
Any	51 (0.4)	63 (0.4)	114 (0.4)
Grade 1	21 (0.1)	16 (0.1)	37 (0.1)
Grade 2	29 (0.2)	41 (0.3)	70 (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=14119) n (%)	mRNA-1273 (N=14183) n (%)	Total (N=28302) n (%)
Chills - N1	14114	14179	28293
Any	48 (0.3)	52 (0.4)	100 (0.4)
Grade 1	22 (0.2)	11 (<0.1)	33 (0.1)
Grade 2	21 (0.1)	33 (0.2)	54 (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 14.3.1.6.8
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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Solicited Adverse Reactions - N1	232	230	462
Any Solicited Adverse Reactions	16 (6.9)	9 (3.9)	25 (5.4)
95% CI	4.0, 11.0	1.8, 7.3	3.5, 7.9
Grade 1	7 (3.0)	1 (0.4)	8 (1.7)
Grade 2	8 (3.4)	7 (3.0)	15 (3.2)
Grade 3	1 (0.4)	1 (0.4)	2 (0.4)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	231	230	461
Any Solicited Local Adverse Reactions	4 (1.7)	3 (1.3)	7 (1.5)
95% CI	0.5, 4.4	0.3, 3.8	0.6, 3.1
Grade 1	3 (1.3)	1 (0.4)	4 (0.9)
Grade 2	1 (0.4)	1 (0.4)	2 (0.4)
Grade 3	0	1 (0.4)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Pain - N1	231	230	461
Any	0	3 (1.3)	3 (0.7)
Grade 1	0	1 (0.4)	1 (0.2)
Grade 2	0	1 (0.4)	1 (0.2)
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Erythema (Redness) - N1	231	230	461
Any	0	1 (0.4)	1 (0.2)
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	231	230	461
Any	0	2 (0.9)	2 (0.4)
Grade 1	0	2 (0.9)	2 (0.4)
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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Lymphadenopathy - N1 [1]	231	230	461
Any	4 (1.7)	1 (0.4)	5 (1.1)
Grade 1	3 (1.3)	1 (0.4)	4 (0.9)
Grade 2	1 (0.4)	0	1 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	232	230	462
Any Solicited Systemic Adverse Reactions	14 (6.0)	8 (3.5)	22 (4.8)
95% CI	3.3, 9.9	1.5, 6.7	3.0, 7.1
Grade 1	5 (2.2)	1 (0.4)	6 (1.3)
Grade 2	8 (3.4)	7 (3.0)	15 (3.2)
Grade 3	1 (0.4)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Fever - N1	231	230	461
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	231	230	461
Any	5 (2.2)	6 (2.6)	11 (2.4)
Grade 1	2 (0.9)	2 (0.9)	4 (0.9)
Grade 2	3 (1.3)	4 (1.7)	7 (1.5)
Grade 3	0	0	0
Grade 4	0	0	0
Fatigue - N1	231	230	461
Any	8 (3.5)	4 (1.7)	12 (2.6)
Grade 1	2 (0.9)	0	2 (0.4)
Grade 2	5 (2.2)	4 (1.7)	9 (2.0)
Grade 3	1 (0.4)	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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Myalgia - N1	231	230	461
Any	6 (2.6)	3 (1.3)	9 (2.0)
Grade 1	2 (0.9)	0	2 (0.4)
Grade 2	4 (1.7)	3 (1.3)	7 (1.5)
Grade 3	0	0	0
Grade 4	0	0	0
Arthralgia - N1	231	230	461
Any	7 (3.0)	3 (1.3)	10 (2.2)
Grade 1	4 (1.7)	0	4 (0.9)
Grade 2	3 (1.3)	3 (1.3)	6 (1.3)
Grade 3	0	0	0
Grade 4	0	0	0
Nausea/Vomiting - N1	231	230	461
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=232) n (%)	mRNA-1273 (N=230) n (%)	Total (N=462) n (%)
Chills - N1	231	230	461
Any	3 (1.3)	0	3 (0.7)
Grade 1	2 (0.9)	0	2 (0.4)
Grade 2	1 (0.4)	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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Solicited Adverse Reactions - N1	215	264	479
Any Solicited Adverse Reactions	12 (5.6)	19 (7.2)	31 (6.5)
95% CI	2.9, 9.5	4.4, 11.0	4.4, 9.1
Grade 1	9 (4.2)	2 (0.8)	11 (2.3)
Grade 2	1 (0.5)	12 (4.5)	13 (2.7)
Grade 3	2 (0.9)	5 (1.9)	7 (1.5)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	215	264	479
Any Solicited Local Adverse Reactions	4 (1.9)	6 (2.3)	10 (2.1)
95% CI	0.5, 4.7	0.8, 4.9	1.0, 3.8
Grade 1	3 (1.4)	1 (0.4)	4 (0.8)
Grade 2	0	4 (1.5)	4 (0.8)
Grade 3	1 (0.5)	1 (0.4)	2 (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 14.3.1.6.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Pain - N1	215	264	479
Any	2 (0.9)	4 (1.5)	6 (1.3)
Grade 1	1 (0.5)	0	1 (0.2)
Grade 2	0	4 (1.5)	4 (0.8)
Grade 3	1 (0.5)	0	1 (0.2)
Grade 4	0	0	0
Erythema (Redness) - N1	215	264	479
Any	1 (0.5)	1 (0.4)	2 (0.4)
Grade 1	1 (0.5)	0	1 (0.2)
Grade 2	0	0	0
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	215	264	479
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Lymphadenopathy - N1 [1]	215	264	479
Any	1 (0.5)	1 (0.4)	2 (0.4)
Grade 1	1 (0.5)	1 (0.4)	2 (0.4)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	215	264	479
Any Solicited Systemic Adverse Reactions	10 (4.7)	16 (6.1)	26 (5.4)
95% CI	2.3, 8.4	3.5, 9.7	3.6, 7.9
Grade 1	7 (3.3)	1 (0.4)	8 (1.7)
Grade 2	1 (0.5)	11 (4.2)	12 (2.5)
Grade 3	2 (0.9)	4 (1.5)	6 (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 14.3.1.6.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Fever - N1	215	263	478
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	215	264	479
Any	6 (2.8)	8 (3.0)	14 (2.9)
Grade 1	5 (2.3)	2 (0.8)	7 (1.5)
Grade 2	0	4 (1.5)	4 (0.8)
Grade 3	1 (0.5)	2 (0.8)	3 (0.6)
Grade 4	0	0	0
Fatigue - N1	215	264	479
Any	5 (2.3)	7 (2.7)	12 (2.5)
Grade 1	3 (1.4)	0	3 (0.6)
Grade 2	1 (0.5)	5 (1.9)	6 (1.3)
Grade 3	1 (0.5)	2 (0.8)	3 (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 14.3.1.6.8
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Myalgia - N1	215	264	479
Any	4 (1.9)	4 (1.5)	8 (1.7)
Grade 1	1 (0.5)	0	1 (0.2)
Grade 2	2 (0.9)	3 (1.1)	5 (1.0)
Grade 3	1 (0.5)	1 (0.4)	2 (0.4)
Grade 4	0	0	0
Arthralgia - N1	215	264	479
Any	4 (1.9)	4 (1.5)	8 (1.7)
Grade 1	2 (0.9)	0	2 (0.4)
Grade 2	1 (0.5)	3 (1.1)	4 (0.8)
Grade 3	1 (0.5)	1 (0.4)	2 (0.4)
Grade 4	0	0	0
Nausea/Vomiting - N1	215	264	479
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=215) n (%)	mRNA-1273 (N=264) n (%)	Total (N=479) n (%)
Chills - N1	215	264	479
Any	0	1 (0.4)	1 (0.2)
Grade 1	0	0	0
Grade 2	0	1 (0.4)	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 14.3.1.6.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Solicited Adverse Reactions - N1	14591	14548	29139
Any Solicited Adverse Reactions	1399 (9.6)	1785 (12.3)	3184 (10.9)
95% CI	9.1, 10.1	11.7, 12.8	10.6, 11.3
Grade 1	586 (4.0)	596 (4.1)	1182 (4.1)
Grade 2	642 (4.4)	828 (5.7)	1470 (5.0)
Grade 3	171 (1.2)	360 (2.5)	531 (1.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	14590	14548	29138
Any Solicited Local Adverse Reactions	193 (1.3)	561 (3.9)	754 (2.6)
95% CI	1.1, 1.5	3.5, 4.2	2.4, 2.8
Grade 1	146 (1.0)	302 (2.1)	448 (1.5)
Grade 2	36 (0.2)	175 (1.2)	211 (0.7)
Grade 3	11 (<0.1)	84 (0.6)	95 (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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Pain - N1	14590	14548	29138
Any	100 (0.7)	218 (1.5)	318 (1.1)
Grade 1	74 (0.5)	91 (0.6)	165 (0.6)
Grade 2	19 (0.1)	95 (0.7)	114 (0.4)
Grade 3	7 (<0.1)	32 (0.2)	39 (0.1)
Grade 4	0	0	0
Erythema (Redness) - N1	14590	14548	29138
Any	12 (<0.1)	76 (0.5)	88 (0.3)
Grade 1	10 (<0.1)	18 (0.1)	28 (<0.1)
Grade 2	1 (<0.1)	27 (0.2)	28 (<0.1)
Grade 3	1 (<0.1)	31 (0.2)	32 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	14590	14548	29138
Any	17 (0.1)	68 (0.5)	85 (0.3)
Grade 1	13 (<0.1)	29 (0.2)	42 (0.1)
Grade 2	2 (<0.1)	25 (0.2)	27 (<0.1)
Grade 3	2 (<0.1)	14 (<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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Lymphadenopathy - N1 [1]	14590	14548	29138
Any	87 (0.6)	292 (2.0)	379 (1.3)
Grade 1	68 (0.5)	215 (1.5)	283 (1.0)
Grade 2	17 (0.1)	60 (0.4)	77 (0.3)
Grade 3	2 (<0.1)	17 (0.1)	19 (<0.1)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	14591	14548	29139
Any Solicited Systemic Adverse Reactions	1290 (8.8)	1444 (9.9)	2734 (9.4)
95% CI	8.4, 9.3	9.4, 10.4	9.1, 9.7
Grade 1	504 (3.5)	406 (2.8)	910 (3.1)
Grade 2	625 (4.3)	742 (5.1)	1367 (4.7)
Grade 3	161 (1.1)	295 (2.0)	456 (1.6)
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Fever - N1	14591	14548	29139
Any	3 (<0.1)	5 (<0.1)	8 (<0.1)
Grade 1	3 (<0.1)	1 (<0.1)	4 (<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	14590	14548	29138
Any	542 (3.7)	632 (4.3)	1174 (4.0)
Grade 1	269 (1.8)	235 (1.6)	504 (1.7)
Grade 2	204 (1.4)	311 (2.1)	515 (1.8)
Grade 3	69 (0.5)	86 (0.6)	155 (0.5)
Grade 4	0	0	0
Fatigue - N1	14590	14548	29138
Any	720 (4.9)	864 (5.9)	1584 (5.4)
Grade 1	221 (1.5)	186 (1.3)	407 (1.4)
Grade 2	413 (2.8)	485 (3.3)	898 (3.1)
Grade 3	86 (0.6)	193 (1.3)	279 (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 14.3.1.6.9
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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Myalgia - N1	14590	14548	29138
Any	396 (2.7)	403 (2.8)	799 (2.7)
Grade 1	150 (1.0)	106 (0.7)	256 (0.9)
Grade 2	199 (1.4)	212 (1.5)	411 (1.4)
Grade 3	47 (0.3)	85 (0.6)	132 (0.5)
Grade 4	0	0	0
Arthralgia - N1	14590	14548	29138
Any	452 (3.1)	442 (3.0)	894 (3.1)
Grade 1	192 (1.3)	132 (0.9)	324 (1.1)
Grade 2	223 (1.5)	241 (1.7)	464 (1.6)
Grade 3	37 (0.3)	69 (0.5)	106 (0.4)
Grade 4	0	0	0
Nausea/Vomiting - N1	14590	14548	29138
Any	105 (0.7)	115 (0.8)	220 (0.8)
Grade 1	54 (0.4)	43 (0.3)	97 (0.3)
Grade 2	49 (0.3)	64 (0.4)	113 (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=14591) n (%)	mRNA-1273 (N=14548) n (%)	Total (N=29139) n (%)
Chills - N1	14590	14548	29138
Any	86 (0.6)	82 (0.6)	168 (0.6)
Grade 1	44 (0.3)	22 (0.2)	66 (0.2)
Grade 2	37 (0.3)	49 (0.3)	86 (0.3)
Grade 3	5 (<0.1)	11 (<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: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Solicited Adverse Reactions - N1	337	343	680
Any Solicited Adverse Reactions	36 (10.7)	28 (8.2)	64 (9.4)
95% CI	7.6, 14.5	5.5, 11.6	7.3, 11.9
Grade 1	11 (3.3)	7 (2.0)	18 (2.6)
Grade 2	18 (5.3)	17 (5.0)	35 (5.1)
Grade 3	7 (2.1)	4 (1.2)	11 (1.6)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	337	343	680
Any Solicited Local Adverse Reactions	6 (1.8)	7 (2.0)	13 (1.9)
95% CI	0.7, 3.8	0.8, 4.2	1.0, 3.2
Grade 1	5 (1.5)	4 (1.2)	9 (1.3)
Grade 2	1 (0.3)	2 (0.6)	3 (0.4)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Pain - N1	337	343	680
Any	1 (0.3)	4 (1.2)	5 (0.7)
Grade 1	1 (0.3)	2 (0.6)	3 (0.4)
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	337	343	680
Any	0	2 (0.6)	2 (0.3)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	337	343	680
Any	0	3 (0.9)	3 (0.4)
Grade 1	0	3 (0.9)	3 (0.4)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Lymphadenopathy - N1 [1]	337	343	680
Any	6 (1.8)	4 (1.2)	10 (1.5)
Grade 1	5 (1.5)	2 (0.6)	7 (1.0)
Grade 2	1 (0.3)	2 (0.6)	3 (0.4)
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	337	343	680
Any Solicited Systemic Adverse Reactions	33 (9.8)	23 (6.7)	56 (8.2)
95% CI	6.8, 13.5	4.3, 9.9	6.3, 10.6
Grade 1	8 (2.4)	4 (1.2)	12 (1.8)
Grade 2	18 (5.3)	15 (4.4)	33 (4.9)
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Fever - N1	336	343	679
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	337	343	680
Any	14 (4.2)	16 (4.7)	30 (4.4)
Grade 1	3 (0.9)	5 (1.5)	8 (1.2)
Grade 2	8 (2.4)	8 (2.3)	16 (2.4)
Grade 3	3 (0.9)	3 (0.9)	6 (0.9)
Grade 4	0	0	0
Fatigue - N1	337	343	680
Any	21 (6.2)	12 (3.5)	33 (4.9)
Grade 1	4 (1.2)	2 (0.6)	6 (0.9)
Grade 2	14 (4.2)	9 (2.6)	23 (3.4)
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=337) n	(%)	mRNA-1273 (N=343) n	(%)	Total (N=680) n	(%)
Myalgia - N1	337		343		680	
Any	16	(4.7)	10	(2.9)	26	(3.8)
Grade 1	4	(1.2)	3	(0.9)	7	(1.0)
Grade 2	11	(3.3)	7	(2.0)	18	(2.6)
Grade 3	1	(0.3)	0		1	(0.1)
Grade 4	0		0		0	
Arthralgia - N1	337		343		680	
Any	14	(4.2)	6	(1.7)	20	(2.9)
Grade 1	5	(1.5)	0		5	(0.7)
Grade 2	8	(2.4)	6	(1.7)	14	(2.1)
Grade 3	1	(0.3)	0		1	(0.1)
Grade 4	0		0		0	
Nausea/Vomiting - N1	337		343		680	
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Chills - N1	337	343	680
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Solicited Adverse Reactions - N1	235	288	523
Any Solicited Adverse Reactions	28 (11.9)	38 (13.2)	66 (12.6)
95% CI	8.1, 16.8	9.5, 17.7	9.9, 15.8
Grade 1	18 (7.7)	10 (3.5)	28 (5.4)
Grade 2	6 (2.6)	21 (7.3)	27 (5.2)
Grade 3	4 (1.7)	7 (2.4)	11 (2.1)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	235	288	523
Any Solicited Local Adverse Reactions	5 (2.1)	11 (3.8)	16 (3.1)
95% CI	0.7, 4.9	1.9, 6.7	1.8, 4.9
Grade 1	4 (1.7)	6 (2.1)	10 (1.9)
Grade 2	0	4 (1.4)	4 (0.8)
Grade 3	1 (0.4)	1 (0.3)	2 (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 14.3.1.6.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Pain - N1	235	288	523
Any	2 (0.9)	5 (1.7)	7 (1.3)
Grade 1	1 (0.4)	1 (0.3)	2 (0.4)
Grade 2	0	4 (1.4)	4 (0.8)
Grade 3	1 (0.4)	0	1 (0.2)
Grade 4	0	0	0
Erythema (Redness) - N1	235	288	523
Any	1 (0.4)	1 (0.3)	2 (0.4)
Grade 1	1 (0.4)	0	1 (0.2)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	235	288	523
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Lymphadenopathy - N1 [1]	235	288	523
Any	2 (0.9)	5 (1.7)	7 (1.3)
Grade 1	2 (0.9)	5 (1.7)	7 (1.3)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	235	288	523
Any Solicited Systemic Adverse Reactions	25 (10.6)	31 (10.8)	56 (10.7)
95% CI	7.0, 15.3	7.4, 14.9	8.2, 13.7
Grade 1	15 (6.4)	5 (1.7)	20 (3.8)
Grade 2	6 (2.6)	20 (6.9)	26 (5.0)
Grade 3	4 (1.7)	6 (2.1)	10 (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 14.3.1.6.9
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=235) n	(%)	mRNA-1273 (N=288) n	(%)	Total (N=523) n	(%)
Fever - N1	235		287		522	
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	235		288		523	
Any	12	(5.1)	13	(4.5)	25	(4.8)
Grade 1	6	(2.6)	4	(1.4)	10	(1.9)
Grade 2	4	(1.7)	7	(2.4)	11	(2.1)
Grade 3	2	(0.9)	2	(0.7)	4	(0.8)
Grade 4	0		0		0	
Fatigue - N1	235		288		523	
Any	14	(6.0)	18	(6.3)	32	(6.1)
Grade 1	10	(4.3)	2	(0.7)	12	(2.3)
Grade 2	1	(0.4)	12	(4.2)	13	(2.5)
Grade 3	3	(1.3)	4	(1.4)	7	(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 14.3.1.6.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Myalgia - N1	235	288	523
Any	9 (3.8)	10 (3.5)	19 (3.6)
Grade 1	4 (1.7)	2 (0.7)	6 (1.1)
Grade 2	3 (1.3)	5 (1.7)	8 (1.5)
Grade 3	2 (0.9)	3 (1.0)	5 (1.0)
Grade 4	0	0	0
Arthralgia - N1	235	288	523
Any	10 (4.3)	6 (2.1)	16 (3.1)
Grade 1	4 (1.7)	0	4 (0.8)
Grade 2	4 (1.7)	4 (1.4)	8 (1.5)
Grade 3	2 (0.9)	2 (0.7)	4 (0.8)
Grade 4	0	0	0
Nausea/Vomiting - N1	235	288	523
Any	1 (0.4)	2 (0.7)	3 (0.6)
Grade 1	1 (0.4)	2 (0.7)	3 (0.6)
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Chills - N1	235	288	523
Any	0	1 (0.3)	1 (0.2)
Grade 1	0	0	0
Grade 2	0	1 (0.3)	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 14.3.1.7.6
Summary of Unsolicited TEAE by Age Group in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	2920 (25.6)	2968 (26.0)	5888 (25.8)
Serious	86 (0.8)	76 (0.7)	162 (0.7)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Medically-Attended	1430 (12.5)	1225 (10.7)	2655 (11.6)
Leading to Discontinuation from Study Vaccine	72 (0.6)	44 (0.4)	116 (0.5)
Leading to Discontinuation from Participation in the Study	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	173 (1.5)	188 (1.6)	361 (1.6)
Unsolicited TEAEs Related to Study Vaccination			
All	537 (4.7)	947 (8.3)	1484 (6.5)
Serious	3 (<0.1)	4 (<0.1)	7 (<0.1)
Fatal	0	0	0
Medically-Attended	71 (0.6)	112 (1.0)	183 (0.8)
Leading to Discontinuation from Study Vaccine	10 (<0.1)	14 (0.1)	24 (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	968 (25.8)	1090 (28.9)	2058 (27.4)
Serious	67 (1.8)	71 (1.9)	138 (1.8)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Medically-Attended	528 (14.1)	520 (13.8)	1048 (13.9)
Leading to Discontinuation from Study Vaccine	21 (0.6)	15 (0.4)	36 (0.5)
Leading to Discontinuation from Participation in the Study	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	94 (2.5)	112 (3.0)	206 (2.7)
Unsolicited TEAEs Related to Study Vaccination			
All	165 (4.4)	309 (8.2)	474 (6.3)
Serious	2 (<0.1)	3 (<0.1)	5 (<0.1)
Fatal	0	0	0
Medically-Attended	17 (0.5)	31 (0.8)	48 (0.6)
Leading to Discontinuation from Study Vaccine	6 (0.2)	4 (0.1)	10 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	9 (0.2)	24 (0.6)	33 (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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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3179 (21.8)	3520 (24.2)	6699 (23.0)
Serious	86 (0.6)	91 (0.6)	177 (0.6)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Medically-Attended	1430 (9.8)	1331 (9.1)	2761 (9.5)
Leading to Discontinuation from Study Vaccine	75 (0.5)	41 (0.3)	116 (0.4)
Leading to Discontinuation from Participation in the Study	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	195 (1.3)	230 (1.6)	425 (1.5)
Unsolicited TEAEs Related to Study Vaccination			
All	664 (4.5)	1216 (8.4)	1880 (6.4)
Serious	4 (<0.1)	6 (<0.1)	10 (<0.1)
Fatal	0	0	0
Medically-Attended	78 (0.5)	140 (1.0)	218 (0.7)
Leading to Discontinuation from Study Vaccine	15 (0.1)	17 (0.1)	32 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	27 (0.2)	71 (0.5)	98 (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 14.3.1.7.7
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	63 (18.7)	58 (16.9)	121 (17.8)
Serious	3 (0.9)	0	3 (0.4)
Fatal	0	0	0
Medically-Attended	23 (6.8)	22 (6.4)	45 (6.6)
Leading to Discontinuation from Study Vaccine	5 (1.5)	6 (1.7)	11 (1.6)
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	1 (0.3)	1 (0.1)
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 03DEC2020 06:59

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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	35 (14.9)	54 (18.8)	89 (17.0)
Serious	0	2 (0.7)	2 (0.4)
Fatal	0	0	0
Medically-Attended	12 (5.1)	19 (6.6)	31 (5.9)
Leading to Discontinuation from Study Vaccine	0	3 (1.0)	3 (0.6)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.4)	3 (1.0)	4 (0.8)
Unsolicited TEAEs Related to Study Vaccination			
All	8 (3.4)	10 (3.5)	18 (3.4)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	0	0
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	0	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 14.3.1.7.9
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

	Placebo (N=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3765 (25.8)	3930 (27.0)	7695 (26.4)
Serious	147 (1.0)	145 (1.0)	292 (1.0)
Fatal	6 (<0.1)	4 (<0.1)	10 (<0.1)
Medically-Attended	1906 (13.1)	1695 (11.6)	3601 (12.4)
Leading to Discontinuation from Study Vaccine	87 (0.6)	50 (0.3)	137 (0.5)
Leading to Discontinuation from Participation in the Study	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	259 (1.8)	294 (2.0)	553 (1.9)
Unsolicited TEAEs Related to Study Vaccination			
All	680 (4.7)	1228 (8.4)	1908 (6.5)
Serious	5 (<0.1)	7 (<0.1)	12 (<0.1)
Fatal	0	0	0
Medically-Attended	83 (0.6)	143 (1.0)	226 (0.8)
Leading to Discontinuation from Study Vaccine	16 (0.1)	17 (0.1)	33 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	29 (0.2)	73 (0.5)	102 (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 03DEC2020 06:59

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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	78 (23.1)	68 (19.8)	146 (21.5)
Serious	5 (1.5)	0	5 (0.7)
Fatal	0	0	0
Medically-Attended	31 (9.2)	27 (7.9)	58 (8.5)
Leading to Discontinuation from Study Vaccine	5 (1.5)	6 (1.7)	11 (1.6)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	7 (2.1)	3 (0.9)	10 (1.5)
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	1 (0.3)	1 (0.1)
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	45 (19.1)	60 (20.8)	105 (20.1)
Serious	1 (0.4)	2 (0.7)	3 (0.6)
Fatal	0	0	0
Medically-Attended	21 (8.9)	23 (8.0)	44 (8.4)
Leading to Discontinuation from Study Vaccine	1 (0.4)	3 (1.0)	4 (0.8)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.4)	3 (1.0)	4 (0.8)
Unsolicited TEAEs Related to Study Vaccination			
All	8 (3.4)	11 (3.8)	19 (3.6)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	0	0
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	0	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 14.3.1.7.10
Summary of Unsolicited Non-Serious TEAE up to 28 Days After Any Injection
Safety Set

	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3234 (21.3)	3589 (23.6)	6823 (22.5)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	1415 (9.3)	1316 (8.7)	2731 (9.0)
Leading to Discontinuation from Study Vaccine	64 (0.4)	40 (0.3)	104 (0.3)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	160 (1.1)	198 (1.3)	358 (1.2)
Unsolicited TEAEs Related to Study Vaccination			
All	684 (4.5)	1238 (8.2)	1922 (6.3)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	80 (0.5)	135 (0.9)	215 (0.7)
Leading to Discontinuation from Study Vaccine	13 (<0.1)	17 (0.1)	30 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	27 (0.2)	70 (0.5)	97 (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 14.3.1.7.11
Summary of Unsolicited Non-Serious TEAE in Overall Stage
Safety Set

	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3815 (25.2)	3992 (26.3)	7807 (25.7)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	1871 (12.3)	1658 (10.9)	3529 (11.6)
Leading to Discontinuation from Study Vaccine	75 (0.5)	46 (0.3)	121 (0.4)
Leading to Discontinuation from Participation in the Study	1 (<0.1)	0	1 (<0.1)
Severe	204 (1.3)	240 (1.6)	444 (1.5)
Unsolicited TEAEs Related to Study Vaccination			
All	700 (4.6)	1252 (8.2)	1952 (6.4)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	85 (0.6)	138 (0.9)	223 (0.7)
Leading to Discontinuation from Study Vaccine	13 (<0.1)	17 (0.1)	30 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	29 (0.2)	71 (0.5)	100 (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 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3888 (25.6)	4058 (26.7)	7946 (26.2)
Number of Unsolicited Adverse Events	7754	8136	15890
Infections and infestations	1125 (7.4)	835 (5.5)	1960 (6.5)
Urinary tract infection	127 (0.8)	107 (0.7)	234 (0.8)
Upper respiratory tract infection	109 (0.7)	95 (0.6)	204 (0.7)
Sinusitis	53 (0.3)	67 (0.4)	120 (0.4)
Viral infection	56 (0.4)	46 (0.3)	102 (0.3)
COVID-19	312 (2.1)	38 (0.3)	350 (1.2)
Rhinovirus infection	26 (0.2)	27 (0.2)	53 (0.2)
Herpes zoster	17 (0.1)	23 (0.2)	40 (0.1)
Pharyngitis	30 (0.2)	22 (0.1)	52 (0.2)
Ear infection	15 (<0.1)	21 (0.1)	36 (0.1)
Suspected COVID-19	27 (0.2)	21 (0.1)	48 (0.2)
Cellulitis	18 (0.1)	20 (0.1)	38 (0.1)
Pharyngitis streptococcal	22 (0.1)	20 (0.1)	42 (0.1)
Tooth infection	21 (0.1)	20 (0.1)	41 (0.1)
Gastroenteritis	21 (0.1)	19 (0.1)	40 (0.1)
Tooth abscess	23 (0.2)	18 (0.1)	41 (0.1)
Conjunctivitis	11 (<0.1)	15 (<0.1)	26 (<0.1)
Diverticulitis	10 (<0.1)	12 (<0.1)	22 (<0.1)
Bronchitis	10 (<0.1)	11 (<0.1)	21 (<0.1)
Oral herpes	7 (<0.1)	11 (<0.1)	18 (<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 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Viral upper respiratory tract infection	16 (0.1)	11 (<0.1)	27 (<0.1)
Gingivitis	6 (<0.1)	10 (<0.1)	16 (<0.1)
Hordeolum	14 (<0.1)	10 (<0.1)	24 (<0.1)
Localised infection	9 (<0.1)	10 (<0.1)	19 (<0.1)
Acute sinusitis	6 (<0.1)	9 (<0.1)	15 (<0.1)
Respiratory tract infection	6 (<0.1)	9 (<0.1)	15 (<0.1)
Folliculitis	7 (<0.1)	8 (<0.1)	15 (<0.1)
Fungal infection	9 (<0.1)	8 (<0.1)	17 (<0.1)
Otitis externa	11 (<0.1)	8 (<0.1)	19 (<0.1)
Otitis media	11 (<0.1)	8 (<0.1)	19 (<0.1)
Pneumonia	12 (<0.1)	8 (<0.1)	20 (<0.1)
Enterovirus infection	1 (<0.1)	7 (<0.1)	8 (<0.1)
Herpes simplex	3 (<0.1)	7 (<0.1)	10 (<0.1)
Onychomycosis	1 (<0.1)	7 (<0.1)	8 (<0.1)
Bacterial vaginosis	6 (<0.1)	6 (<0.1)	12 (<0.1)
Paronychia	4 (<0.1)	6 (<0.1)	10 (<0.1)
Skin infection	5 (<0.1)	6 (<0.1)	11 (<0.1)
Asymptomatic COVID-19	9 (<0.1)	5 (<0.1)	14 (<0.1)
Rhinitis	8 (<0.1)	5 (<0.1)	13 (<0.1)
Vulvovaginal candidiasis	6 (<0.1)	5 (<0.1)	11 (<0.1)
Vulvovaginal mycotic infection	15 (<0.1)	5 (<0.1)	20 (<0.1)
Cystitis	7 (<0.1)	4 (<0.1)	11 (<0.1)
Gonorrhoea	2 (<0.1)	4 (<0.1)	6 (<0.1)
Laryngitis	2 (<0.1)	4 (<0.1)	6 (<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 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
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)
Clostridium difficile infection	0	3 (<0.1)	3 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)	4 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Impetigo	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	12 (<0.1)	3 (<0.1)	15 (<0.1)
Postoperative wound infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Respiratory tract infection viral	9 (<0.1)	3 (<0.1)	12 (<0.1)
Wound infection	3 (<0.1)	3 (<0.1)	6 (<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	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gastroenteritis viral	11 (<0.1)	2 (<0.1)	13 (<0.1)
Infected bite	1 (<0.1)	2 (<0.1)	3 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oral candidiasis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Otitis media acute	4 (<0.1)	2 (<0.1)	6 (<0.1)
Sepsis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Sinusitis bacterial	3 (<0.1)	2 (<0.1)	5 (<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 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
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	4 (<0.1)	2 (<0.1)	6 (<0.1)
Tonsillitis	9 (<0.1)	2 (<0.1)	11 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abscess	1 (<0.1)	1 (<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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Candida infection	4 (<0.1)	1 (<0.1)	5 (<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	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)
Eye infection	3 (<0.1)	1 (<0.1)	4 (<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 cyst	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Infected dermal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site infection	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)
Nail infection	0	1 (<0.1)	1 (<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)
Pertussis	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)
Pulpitis dental	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pyelonephritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash pustular	0	1 (<0.1)	1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Salpingitis	0	1 (<0.1)	1 (<0.1)
Sexually transmitted disease	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Sialoadenitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Streptococcal infection	0	1 (<0.1)	1 (<0.1)
Tinea infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urosepsis	0	1 (<0.1)	1 (<0.1)
Uterine infection	0	1 (<0.1)	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Adenovirus infection	1 (<0.1)	0	1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0	1 (<0.1)
Balanitis candida	1 (<0.1)	0	1 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Breast abscess	2 (<0.1)	0	2 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0	2 (<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 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)
Gastrointestinal viral infection	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Genital herpes simplex	1 (<0.1)	0	1 (<0.1)
Herpes virus infection	1 (<0.1)	0	1 (<0.1)
Infected skin ulcer	1 (<0.1)	0	1 (<0.1)
Influenza	3 (<0.1)	0	3 (<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)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Septic shock	1 (<0.1)	0	1 (<0.1)
Skin bacterial infection	2 (<0.1)	0	2 (<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)
Trichomoniasis	1 (<0.1)	0	1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Viral sinusitis	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	49 (0.3)	63 (0.4)	112 (0.4)
Basal cell carcinoma	14 (<0.1)	9 (<0.1)	23 (<0.1)
Squamous cell carcinoma	7 (<0.1)	5 (<0.1)	12 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)	6 (<0.1)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Prostate cancer	4 (<0.1)	3 (<0.1)	7 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Uterine leiomyoma	0	2 (<0.1)	2 (<0.1)
Angiolipoma	0	1 (<0.1)	1 (<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 cancer in situ	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)
Colorectal cancer	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intraductal proliferative breast lesion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Lip squamous cell carcinoma	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 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)
Papillary thyroid cancer	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)
Prostate cancer stage I	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Renal cell carcinoma	0	1 (<0.1)	1 (<0.1)
Renal neoplasm	0	1 (<0.1)	1 (<0.1)
Skin cancer	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Benign breast neoplasm	1 (<0.1)	0	1 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
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)
Hepatic cancer	1 (<0.1)	0	1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0	1 (<0.1)
Metastases to bone	1 (<0.1)	0	1 (<0.1)
Penile cancer	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0	1 (<0.1)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	102 (0.7)	167 (1.1)	269 (0.9)
Lymphadenopathy	82 (0.5)	138 (0.9)	220 (0.7)
Anaemia	4 (<0.1)	11 (<0.1)	15 (<0.1)
Lymphadenitis	3 (<0.1)	10 (<0.1)	13 (<0.1)
Lymph node pain	5 (<0.1)	3 (<0.1)	8 (<0.1)
Thrombocytopenia	0	3 (<0.1)	3 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	7 (<0.1)	1 (<0.1)	8 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Splenomegaly	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Blood and lymphatic system disorders (Cont.)			
Increased tendency to bruise	1 (<0.1)	0	1 (<0.1)
Immune system disorders	53 (0.3)	35 (0.2)	88 (0.3)
Seasonal allergy	36 (0.2)	21 (0.1)	57 (0.2)
Hypersensitivity	4 (<0.1)	5 (<0.1)	9 (<0.1)
Drug hypersensitivity	4 (<0.1)	4 (<0.1)	8 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anaphylactic reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Immune system disorder	0	1 (<0.1)	1 (<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 metals	2 (<0.1)	0	2 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Serum sickness	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	10 (<0.1)	16 (0.1)	26 (<0.1)
Hypothyroidism	6 (<0.1)	9 (<0.1)	15 (<0.1)
Thyroid mass	0	2 (<0.1)	2 (<0.1)
Goitre	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperparathyroidism	0	1 (<0.1)	1 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Thyroid cyst	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Endocrine disorders (Cont.)			
Thyroid disorder	0	1 (<0.1)	1 (<0.1)
Thyroiditis	0	1 (<0.1)	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	110 (0.7)	97 (0.6)	207 (0.7)
Hyperlipidaemia	18 (0.1)	18 (0.1)	36 (0.1)
Type 2 diabetes mellitus	3 (<0.1)	14 (<0.1)	17 (<0.1)
Decreased appetite	9 (<0.1)	10 (<0.1)	19 (<0.1)
Hypercholesterolaemia	17 (0.1)	10 (<0.1)	27 (<0.1)
Dehydration	11 (<0.1)	8 (<0.1)	19 (<0.1)
Vitamin D deficiency	11 (<0.1)	8 (<0.1)	19 (<0.1)
Gout	9 (<0.1)	5 (<0.1)	14 (<0.1)
Diabetes mellitus	5 (<0.1)	4 (<0.1)	9 (<0.1)
Hyperglycaemia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Hyponatraemia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Abnormal loss of weight	2 (<0.1)	2 (<0.1)	4 (<0.1)
Glucose tolerance impaired	4 (<0.1)	2 (<0.1)	6 (<0.1)
Hypokalaemia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Insulin resistance	0	2 (<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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Metabolism and nutrition disorders (Cont.)			
Food intolerance	0	1 (<0.1)	1 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypoglycaemia	2 (<0.1)	1 (<0.1)	3 (<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	4 (<0.1)	0	4 (<0.1)
Electrolyte imbalance	1 (<0.1)	0	1 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hyperuricaemia	1 (<0.1)	0	1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Increased appetite	1 (<0.1)	0	1 (<0.1)
Metabolic acidosis	1 (<0.1)	0	1 (<0.1)
Obesity	1 (<0.1)	0	1 (<0.1)
Polydipsia	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	94 (0.6)	120 (0.8)	214 (0.7)
Anxiety	30 (0.2)	37 (0.2)	67 (0.2)
Depression	23 (0.2)	28 (0.2)	51 (0.2)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Psychiatric disorders (Cont.)			
Insomnia	16 (0.1)	20 (0.1)	36 (0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	6 (<0.1)	15 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<0.1)
Sleep disorder	0	5 (<0.1)	5 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)	4 (<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)
Claustrophobia	0	1 (<0.1)	1 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Depressed mood	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	3 (<0.1)	1 (<0.1)	4 (<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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) 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)
Suicidal ideation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Confusional state	2 (<0.1)	0	2 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Dissociative disorder	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)
Nervous system disorders	741 (4.9)	763 (5.0)	1504 (5.0)
Headache	539 (3.6)	512 (3.4)	1051 (3.5)
Dizziness	64 (0.4)	72 (0.5)	136 (0.4)
Paraesthesia	26 (0.2)	29 (0.2)	55 (0.2)
Presyncope	14 (<0.1)	14 (<0.1)	28 (<0.1)
Sciatica	10 (<0.1)	14 (<0.1)	24 (<0.1)
Sinus headache	6 (<0.1)	14 (<0.1)	20 (<0.1)
Syncope	26 (0.2)	14 (<0.1)	40 (0.1)
Migraine	22 (0.1)	13 (<0.1)	35 (0.1)
Ageusia	17 (0.1)	12 (<0.1)	29 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
Dysgeusia	6 (<0.1)	12 (<0.1)	18 (<0.1)
Hypoaesthesia	8 (<0.1)	12 (<0.1)	20 (<0.1)
Anosmia	11 (<0.1)	11 (<0.1)	22 (<0.1)
Tension headache	4 (<0.1)	8 (<0.1)	12 (<0.1)
Cervical radiculopathy	0	6 (<0.1)	6 (<0.1)
Hyperaesthesia	0	6 (<0.1)	6 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	4 (<0.1)	8 (<0.1)
Cerebrovascular accident	1 (<0.1)	4 (<0.1)	5 (<0.1)
Disturbance in attention	1 (<0.1)	4 (<0.1)	5 (<0.1)
Burning sensation	0	3 (<0.1)	3 (<0.1)
Facial paralysis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mental impairment	0	3 (<0.1)	3 (<0.1)
Nerve compression	2 (<0.1)	3 (<0.1)	5 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Dizziness postural	0	2 (<0.1)	2 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Lethargy	0	2 (<0.1)	2 (<0.1)
Neuropathy peripheral	2 (<0.1)	2 (<0.1)	4 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)	2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)	3 (<0.1)
Transient ischaemic attack	0	2 (<0.1)	2 (<0.1)
Amnesia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Aura	0	1 (<0.1)	1 (<0.1)
Autonomic nervous system imbalance	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) 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)
Cerebral small vessel ischaemic disease	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)
Head discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Neuralgia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Parosmia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Piriformis syndrome	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)	1 (<0.1)
Post-traumatic headache	2 (<0.1)	1 (<0.1)	3 (<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)
Subarachnoid haemorrhage	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
Taste disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
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)
Aphasia	1 (<0.1)	0	1 (<0.1)
Arachnoid cyst	1 (<0.1)	0	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dementia	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Dyskinesia	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)
Multiple sclerosis	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)
Thoracic radiculopathy	1 (<0.1)	0	1 (<0.1)
Eye disorders	60 (0.4)	64 (0.4)	124 (0.4)
Eye pruritus	5 (<0.1)	8 (<0.1)	13 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Eye disorders (Cont.)			
Eye irritation	0	5 (<0.1)	5 (<0.1)
Vision blurred	6 (<0.1)	4 (<0.1)	10 (<0.1)
Blepharitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	3 (<0.1)	4 (<0.1)
Eye pain	2 (<0.1)	3 (<0.1)	5 (<0.1)
Retinal detachment	2 (<0.1)	3 (<0.1)	5 (<0.1)
Cataract	1 (<0.1)	2 (<0.1)	3 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)	4 (<0.1)
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	6 (<0.1)	2 (<0.1)	8 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)	3 (<0.1)
Visual impairment	2 (<0.1)	2 (<0.1)	4 (<0.1)
Vitreous floaters	2 (<0.1)	2 (<0.1)	4 (<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)
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Dry eye	6 (<0.1)	1 (<0.1)	7 (<0.1)
Eye discharge	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye disorder	0	1 (<0.1)	1 (<0.1)
Eye haemorrhage	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Eye disorders (Cont.)			
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)
Ocular hyperaemia	6 (<0.1)	1 (<0.1)	7 (<0.1)
Orbital haematoma	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Presbyopia	0	1 (<0.1)	1 (<0.1)
Scleritis	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)
Ocular rosacea	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 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Eye disorders (Cont.)			
Retinal haemorrhage	1 (<0.1)	0	1 (<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)
Vitreous detachment	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	86 (0.6)	68 (0.4)	154 (0.5)
Vertigo	19 (0.1)	24 (0.2)	43 (0.1)
Ear pain	25 (0.2)	13 (<0.1)	38 (0.1)
Tinnitus	11 (<0.1)	9 (<0.1)	20 (<0.1)
Vertigo positional	2 (<0.1)	6 (<0.1)	8 (<0.1)
Cerumen impaction	3 (<0.1)	3 (<0.1)	6 (<0.1)
Ear discomfort	7 (<0.1)	3 (<0.1)	10 (<0.1)
Ear canal erythema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Middle ear effusion	3 (<0.1)	2 (<0.1)	5 (<0.1)
Motion sickness	0	2 (<0.1)	2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<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)
Meniere's disease	0	1 (<0.1)	1 (<0.1)
Deafness	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Ear and labyrinth disorders (Cont.)			
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Ear pruritus	2 (<0.1)	0	2 (<0.1)
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	6 (<0.1)	0	6 (<0.1)
Cardiac disorders	86 (0.6)	82 (0.5)	168 (0.6)
Tachycardia	13 (<0.1)	16 (0.1)	29 (<0.1)
Atrial fibrillation	11 (<0.1)	14 (<0.1)	25 (<0.1)
Bradycardia	22 (0.1)	13 (<0.1)	35 (0.1)
Palpitations	7 (<0.1)	8 (<0.1)	15 (<0.1)
Angina pectoris	2 (<0.1)	6 (<0.1)	8 (<0.1)
Coronary artery disease	4 (<0.1)	5 (<0.1)	9 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Cardiac failure congestive	5 (<0.1)	4 (<0.1)	9 (<0.1)
Arrhythmia	5 (<0.1)	3 (<0.1)	8 (<0.1)
Cardiac failure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Sinus tachycardia	0	3 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	2 (<0.1)	2 (<0.1)
Acute myocardial infarction	4 (<0.1)	2 (<0.1)	6 (<0.1)
Acute left ventricular 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)
Coronary artery thrombosis	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Cardiac disorders (Cont.)			
Mitral valve incompetence	0	1 (<0.1)	1 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Supraventricular extrasystoles	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	2 (<0.1)	0	2 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)
Extrasystoles	1 (<0.1)	0	1 (<0.1)
Sinus arrest	1 (<0.1)	0	1 (<0.1)
Sinus bradycardia	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	196 (1.3)	201 (1.3)	397 (1.3)
Hypertension	153 (1.0)	150 (1.0)	303 (1.0)
Hot flush	6 (<0.1)	12 (<0.1)	18 (<0.1)
Flushing	3 (<0.1)	7 (<0.1)	10 (<0.1)
Deep vein thrombosis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haematoma	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hypertensive urgency	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hypotension	6 (<0.1)	4 (<0.1)	10 (<0.1)
Orthostatic hypotension	0	4 (<0.1)	4 (<0.1)
Systolic hypertension	4 (<0.1)	4 (<0.1)	8 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Vascular disorders (Cont.)			
Peripheral coldness	0	2 (<0.1)	2 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Arteriosclerosis	0	1 (<0.1)	1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)	1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertensive emergency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pallor	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)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Blood pressure inadequately controlled	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)
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)
Varicose vein	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Respiratory, thoracic and mediastinal disorders	721 (4.8)	654 (4.3)	1375 (4.5)
Cough	200 (1.3)	210 (1.4)	410 (1.4)
Oropharyngeal pain	249 (1.6)	197 (1.3)	446 (1.5)
Nasal congestion	187 (1.2)	179 (1.2)	366 (1.2)
Rhinorrhoea	179 (1.2)	177 (1.2)	356 (1.2)
Dyspnoea	53 (0.3)	65 (0.4)	118 (0.4)
Tachypnoea	37 (0.2)	37 (0.2)	74 (0.2)
Sinus congestion	32 (0.2)	23 (0.2)	55 (0.2)
Throat irritation	14 (<0.1)	18 (0.1)	32 (0.1)
Epistaxis	10 (<0.1)	16 (0.1)	26 (<0.1)
Upper-airway cough syndrome	13 (<0.1)	15 (<0.1)	28 (<0.1)
Asthma	14 (<0.1)	14 (<0.1)	28 (<0.1)
Respiratory tract congestion	11 (<0.1)	14 (<0.1)	25 (<0.1)
Sneezing	11 (<0.1)	12 (<0.1)	23 (<0.1)
Rhinitis allergic	13 (<0.1)	10 (<0.1)	23 (<0.1)
Chronic obstructive pulmonary disease	11 (<0.1)	7 (<0.1)	18 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	6 (<0.1)	9 (<0.1)
Dysphonia	9 (<0.1)	5 (<0.1)	14 (<0.1)
Pharyngeal erythema	5 (<0.1)	5 (<0.1)	10 (<0.1)
Productive cough	7 (<0.1)	5 (<0.1)	12 (<0.1)
Pulmonary embolism	5 (<0.1)	5 (<0.1)	10 (<0.1)
Dry throat	3 (<0.1)	4 (<0.1)	7 (<0.1)
Respiratory disorder	6 (<0.1)	4 (<0.1)	10 (<0.1)
Sinus pain	5 (<0.1)	4 (<0.1)	9 (<0.1)
Wheezing	2 (<0.1)	4 (<0.1)	6 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Dyspnoea exertional	2 (<0.1)	3 (<0.1)	5 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Allergic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bronchiectasis	0	2 (<0.1)	2 (<0.1)
Hypoxia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory symptom	2 (<0.1)	2 (<0.1)	4 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)	1 (<0.1)
Emphysema	2 (<0.1)	1 (<0.1)	3 (<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)
Nasal septum deviation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rhonchi	0	1 (<0.1)	1 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)	1 (<0.1)
Sputum increased	0	1 (<0.1)	1 (<0.1)
Tonsillolith	5 (<0.1)	1 (<0.1)	6 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Haemoptysis	2 (<0.1)	0	2 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Nasal disorder	1 (<0.1)	0	1 (<0.1)
Nasal ulcer	1 (<0.1)	0	1 (<0.1)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Painful respiration	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Pleural effusion	4 (<0.1)	0	4 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pneumothorax	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Rales	1 (<0.1)	0	1 (<0.1)
Rhinalgia	1 (<0.1)	0	1 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Throat tightness	2 (<0.1)	0	2 (<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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders	520 (3.4)	562 (3.7)	1082 (3.6)
Diarrhoea	191 (1.3)	215 (1.4)	406 (1.3)
Nausea	153 (1.0)	146 (1.0)	299 (1.0)
Vomiting	45 (0.3)	51 (0.3)	96 (0.3)
Gastrooesophageal reflux disease	18 (0.1)	41 (0.3)	59 (0.2)
Toothache	29 (0.2)	33 (0.2)	62 (0.2)
Abdominal pain	25 (0.2)	24 (0.2)	49 (0.2)
Constipation	15 (<0.1)	15 (<0.1)	30 (<0.1)
Dental caries	9 (<0.1)	14 (<0.1)	23 (<0.1)
Abdominal pain upper	18 (0.1)	13 (<0.1)	31 (0.1)
Dyspepsia	17 (0.1)	10 (<0.1)	27 (<0.1)
Food poisoning	10 (<0.1)	10 (<0.1)	20 (<0.1)
Abdominal pain lower	7 (<0.1)	8 (<0.1)	15 (<0.1)
Colitis	4 (<0.1)	6 (<0.1)	10 (<0.1)
Abdominal discomfort	10 (<0.1)	5 (<0.1)	15 (<0.1)
Gastric ulcer	2 (<0.1)	5 (<0.1)	7 (<0.1)
Haemorrhoids	2 (<0.1)	5 (<0.1)	7 (<0.1)
Haematochezia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hiatus hernia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Inguinal hernia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	3 (<0.1)	5 (<0.1)
Oesophagitis	0	3 (<0.1)	3 (<0.1)
Stomatitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Umbilical hernia	2 (<0.1)	3 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
Abdominal distension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Diverticulum	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)	5 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)	2 (<0.1)
Large intestine polyp	4 (<0.1)	2 (<0.1)	6 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)
Melaena	0	2 (<0.1)	2 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oral mucosal blistering	0	2 (<0.1)	2 (<0.1)
Pancreatitis	0	2 (<0.1)	2 (<0.1)
Paraesthesia oral	4 (<0.1)	2 (<0.1)	6 (<0.1)
Proctalgia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swollen tongue	0	2 (<0.1)	2 (<0.1)
Tongue discolouration	0	2 (<0.1)	2 (<0.1)
Tooth impacted	3 (<0.1)	2 (<0.1)	5 (<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 intestinal	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Faeces soft	0	1 (<0.1)	1 (<0.1)
Gastritis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastrointestinal disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intestinal perforation	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 pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Peptic ulcer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periodontal disease	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rectal prolapse	0	1 (<0.1)	1 (<0.1)
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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tongue disorder	0	1 (<0.1)	1 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Abdominal tenderness	1 (<0.1)	0	1 (<0.1)
Anorectal discomfort	1 (<0.1)	0	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysphagia	3 (<0.1)	0	3 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric perforation	1 (<0.1)	0	1 (<0.1)
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastrointestinal motility disorder	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)
Gingival swelling	1 (<0.1)	0	1 (<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)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0	2 (<0.1)
Oral cavity fistula	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 mucosal erythema	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
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)
Hepatobiliary disorders	3 (<0.1)	15 (<0.1)	18 (<0.1)
Cholelithiasis	1 (<0.1)	6 (<0.1)	7 (<0.1)
Cholecystitis	0	4 (<0.1)	4 (<0.1)
Hepatic mass	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 steatosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic cyst	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	228 (1.5)	282 (1.9)	510 (1.7)
Rash	34 (0.2)	45 (0.3)	79 (0.3)
Urticaria	23 (0.2)	27 (0.2)	50 (0.2)
Pruritus	21 (0.1)	24 (0.2)	45 (0.1)
Dermatitis contact	29 (0.2)	21 (0.1)	50 (0.2)
Erythema	6 (<0.1)	16 (0.1)	22 (<0.1)
Hyperhidrosis	14 (<0.1)	14 (<0.1)	28 (<0.1)
Rash maculo-papular	2 (<0.1)	11 (<0.1)	13 (<0.1)
Night sweats	8 (<0.1)	10 (<0.1)	18 (<0.1)
Rash papular	3 (<0.1)	9 (<0.1)	12 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis	8 (<0.1)	8 (<0.1)	16 (<0.1)
Acne	7 (<0.1)	7 (<0.1)	14 (<0.1)
Alopecia	3 (<0.1)	7 (<0.1)	10 (<0.1)
Rash erythematous	2 (<0.1)	6 (<0.1)	8 (<0.1)
Rash macular	4 (<0.1)	6 (<0.1)	10 (<0.1)
Rash pruritic	4 (<0.1)	6 (<0.1)	10 (<0.1)
Skin lesion	5 (<0.1)	6 (<0.1)	11 (<0.1)
Actinic keratosis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Ecchymosis	8 (<0.1)	5 (<0.1)	13 (<0.1)
Rosacea	2 (<0.1)	5 (<0.1)	7 (<0.1)
Dermatitis atopic	7 (<0.1)	4 (<0.1)	11 (<0.1)
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Psoriasis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Blister	2 (<0.1)	3 (<0.1)	5 (<0.1)
Eczema	4 (<0.1)	3 (<0.1)	7 (<0.1)
Rash vesicular	0	3 (<0.1)	3 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)	8 (<0.1)
Dermatitis allergic	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Hidradenitis	0	2 (<0.1)	2 (<0.1)
Macule	0	2 (<0.1)	2 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Angioedema	3 (<0.1)	1 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Blood blister	0	1 (<0.1)	1 (<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)
Ingrowing nail	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	1 (<0.1)
Mechanical urticaria	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)	1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)	2 (<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 ulcer	0	1 (<0.1)	1 (<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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
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)
Miliaria	1 (<0.1)	0	1 (<0.1)
Myxoid cyst	1 (<0.1)	0	1 (<0.1)
Rash follicular	1 (<0.1)	0	1 (<0.1)
Scab	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	704 (4.6)	740 (4.9)	1444 (4.8)
Myalgia	197 (1.3)	225 (1.5)	422 (1.4)
Arthralgia	193 (1.3)	214 (1.4)	407 (1.3)
Back pain	121 (0.8)	93 (0.6)	214 (0.7)
Pain in extremity	78 (0.5)	67 (0.4)	145 (0.5)
Neck pain	34 (0.2)	42 (0.3)	76 (0.3)
Musculoskeletal pain	32 (0.2)	35 (0.2)	67 (0.2)
Muscle spasms	19 (0.1)	33 (0.2)	52 (0.2)
Tendonitis	10 (<0.1)	15 (<0.1)	25 (<0.1)
Musculoskeletal stiffness	13 (<0.1)	14 (<0.1)	27 (<0.1)
Musculoskeletal chest pain	14 (<0.1)	13 (<0.1)	27 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Arthritis	3 (<0.1)	11 (<0.1)	14 (<0.1)
Bursitis	5 (<0.1)	11 (<0.1)	16 (<0.1)
Osteoarthritis	21 (0.1)	11 (<0.1)	32 (0.1)
Rotator cuff syndrome	8 (<0.1)	7 (<0.1)	15 (<0.1)
Groin pain	1 (<0.1)	6 (<0.1)	7 (<0.1)
Joint range of motion decreased	2 (<0.1)	6 (<0.1)	8 (<0.1)
Joint swelling	7 (<0.1)	6 (<0.1)	13 (<0.1)
Muscle tightness	1 (<0.1)	6 (<0.1)	7 (<0.1)
Flank pain	1 (<0.1)	5 (<0.1)	6 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Muscular weakness	4 (<0.1)	5 (<0.1)	9 (<0.1)
Osteoporosis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bone pain	0	4 (<0.1)	4 (<0.1)
Costochondritis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Limb discomfort	3 (<0.1)	4 (<0.1)	7 (<0.1)
Osteopenia	0	4 (<0.1)	4 (<0.1)
Pain in jaw	4 (<0.1)	4 (<0.1)	8 (<0.1)
Axillary mass	3 (<0.1)	3 (<0.1)	6 (<0.1)
Neck mass	0	3 (<0.1)	3 (<0.1)
Spinal osteoarthritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Spinal stenosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Trigger finger	1 (<0.1)	3 (<0.1)	4 (<0.1)
Exostosis	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Fibromyalgia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Joint stiffness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Limb mass	3 (<0.1)	2 (<0.1)	5 (<0.1)
Muscle twitching	3 (<0.1)	2 (<0.1)	5 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Spinal pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bone lesion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	1 (<0.1)	2 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Osteonecrosis	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)	2 (<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)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Tenosynovitis stenosans	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Torticollis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)	2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Foot deformity	2 (<0.1)	0	2 (<0.1)
Intervertebral disc disorder	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)
Musculoskeletal disorder	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteochondrosis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0	1 (<0.1)
Synovial cyst	2 (<0.1)	0	2 (<0.1)
Synovitis	1 (<0.1)	0	1 (<0.1)
Systemic lupus erythematosus	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	51 (0.3)	53 (0.3)	104 (0.3)
Nephrolithiasis	24 (0.2)	17 (0.1)	41 (0.1)
Dysuria	4 (<0.1)	7 (<0.1)	11 (<0.1)
Chronic kidney disease	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pollakiuria	2 (<0.1)	3 (<0.1)	5 (<0.1)
Acute kidney injury	4 (<0.1)	2 (<0.1)	6 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Renal and urinary disorders (Cont.)			
Haematuria	9 (<0.1)	2 (<0.1)	11 (<0.1)
Polyuria	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)	3 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bladder diverticulum	0	1 (<0.1)	1 (<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)
Hypertonic bladder	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)
Renal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal failure	0	1 (<0.1)	1 (<0.1)
Renal pain	0	1 (<0.1)	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Chromaturia	2 (<0.1)	0	2 (<0.1)
Micturition urgency	2 (<0.1)	0	2 (<0.1)
Renal colic	2 (<0.1)	0	2 (<0.1)
Renal mass	1 (<0.1)	0	1 (<0.1)
Urge incontinence	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pregnancy	0	3 (<0.1)	3 (<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	45 (0.3)	59 (0.4)	104 (0.3)
Benign prostatic hyperplasia	7 (<0.1)	7 (<0.1)	14 (<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	3 (<0.1)	3 (<0.1)
Breast pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Ovarian cyst	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostatitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Uterine haemorrhage	0	2 (<0.1)	2 (<0.1)
Uterine polyp	0	2 (<0.1)	2 (<0.1)
Vaginal haemorrhage	0	2 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Adnexa uteri pain	0	1 (<0.1)	1 (<0.1)
Adnexal torsion	0	1 (<0.1)	1 (<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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Reproductive system and breast disorders (Cont.)			
Breast fibrosis	0	1 (<0.1)	1 (<0.1)
Breast hyperplasia	0	1 (<0.1)	1 (<0.1)
Breast mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Cervical dysplasia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ejaculation failure	0	1 (<0.1)	1 (<0.1)
Fibrocystic breast disease	0	1 (<0.1)	1 (<0.1)
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Menopausal symptoms	2 (<0.1)	1 (<0.1)	3 (<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 mass	0	1 (<0.1)	1 (<0.1)
Perineal rash	0	1 (<0.1)	1 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)	1 (<0.1)
Testicular pain	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)
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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Reproductive system and breast disorders (Cont.)			
Haematospermia	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)
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	2 (<0.1)	0	2 (<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)
Vulvovaginal discomfort	1 (<0.1)	0	1 (<0.1)
Congenital, familial and genetic disorders	2 (<0.1)	3 (<0.1)	5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)	2 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	2 (<0.1)	0	2 (<0.1)
General disorders and administration site conditions	719 (4.7)	1081 (7.1)	1800 (5.9)
Fatigue	392 (2.6)	416 (2.7)	808 (2.7)
Injection site pain	57 (0.4)	156 (1.0)	213 (0.7)
Injection site erythema	20 (0.1)	127 (0.8)	147 (0.5)
Pyrexia	70 (0.5)	101 (0.7)	171 (0.6)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Chills	87 (0.6)	100 (0.7)	187 (0.6)
Pain	78 (0.5)	84 (0.6)	162 (0.5)
Injection site swelling	16 (0.1)	83 (0.5)	99 (0.3)
Injection site pruritus	12 (<0.1)	76 (0.5)	88 (0.3)
Injection site rash	1 (<0.1)	37 (0.2)	38 (0.1)
Injection site induration	7 (<0.1)	30 (0.2)	37 (0.1)
Axillary pain	13 (<0.1)	25 (0.2)	38 (0.1)
Injection site macule	2 (<0.1)	21 (0.1)	23 (<0.1)
Chest discomfort	18 (0.1)	19 (0.1)	37 (0.1)
Chest pain	9 (<0.1)	18 (0.1)	27 (<0.1)
Injection site lymphadenopathy	4 (<0.1)	17 (0.1)	21 (<0.1)
Injection site urticaria	0	15 (<0.1)	15 (<0.1)
Injection site bruising	19 (0.1)	12 (<0.1)	31 (0.1)
Malaise	13 (<0.1)	12 (<0.1)	25 (<0.1)
Swelling	1 (<0.1)	12 (<0.1)	13 (<0.1)
Injection site warmth	1 (<0.1)	8 (<0.1)	9 (<0.1)
Peripheral swelling	11 (<0.1)	8 (<0.1)	19 (<0.1)
Oedema peripheral	7 (<0.1)	7 (<0.1)	14 (<0.1)
Injection site haemorrhage	2 (<0.1)	6 (<0.1)	8 (<0.1)
Vaccination site lymphadenopathy	0	6 (<0.1)	6 (<0.1)
Feeling hot	4 (<0.1)	5 (<0.1)	9 (<0.1)
Injection site irritation	0	4 (<0.1)	4 (<0.1)
Injection site reaction	0	4 (<0.1)	4 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Non-cardiac chest pain	5 (<0.1)	4 (<0.1)	9 (<0.1)
Swelling face	2 (<0.1)	4 (<0.1)	6 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)
Feeling abnormal	4 (<0.1)	3 (<0.1)	7 (<0.1)
Injection site haematoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site mass	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vaccination site erythema	0	3 (<0.1)	3 (<0.1)
Vaccination site swelling	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asthenia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)	2 (<0.1)
Hernia	0	2 (<0.1)	2 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	2 (<0.1)
Injection site papule	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site paraesthesia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Injection site scab	0	2 (<0.1)	2 (<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	4 (<0.1)	1 (<0.1)	5 (<0.1)
Early satiety	0	1 (<0.1)	1 (<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)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Granuloma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hangover	1 (<0.1)	1 (<0.1)	2 (<0.1)
Inflammation	0	1 (<0.1)	1 (<0.1)
Influenza like illness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Reactogenicity event	2 (<0.1)	1 (<0.1)	3 (<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 pain	4 (<0.1)	1 (<0.1)	5 (<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)
Drug intolerance	1 (<0.1)	0	1 (<0.1)
Gait disturbance	2 (<0.1)	0	2 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Impaired healing	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Instillation site vesicles	1 (<0.1)	0	1 (<0.1)
Medical device site inflammation	1 (<0.1)	0	1 (<0.1)
Mucosal hypertrophy	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)
Sluggishness	1 (<0.1)	0	1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0	1 (<0.1)
Thirst	1 (<0.1)	0	1 (<0.1)
Unevaluable event	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)
Vessel puncture site pain	1 (<0.1)	0	1 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	100 (0.7)	115 (0.8)	215 (0.7)
Blood pressure increased	38 (0.3)	32 (0.2)	70 (0.2)
Blood pressure systolic increased	19 (0.1)	19 (0.1)	38 (0.1)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Investigations (Cont.)			
Blood pressure diastolic increased	8 (<0.1)	11 (<0.1)	19 (<0.1)
Body temperature increased	2 (<0.1)	4 (<0.1)	6 (<0.1)
Heart rate increased	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hepatic enzyme increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Transaminases increased	0	4 (<0.1)	4 (<0.1)
Blood glucose increased	3 (<0.1)	3 (<0.1)	6 (<0.1)
Glycosylated haemoglobin increased	3 (<0.1)	3 (<0.1)	6 (<0.1)
Blood cholesterol increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Heart rate irregular	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Human rhinovirus test positive	0	2 (<0.1)	2 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	2 (<0.1)	3 (<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 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 parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Blood testosterone decreased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood uric acid increased	0	1 (<0.1)	1 (<0.1)
Blood urine present	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Investigations (Cont.)			
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	3 (<0.1)	1 (<0.1)	4 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Haemoglobin decreased	0	1 (<0.1)	1 (<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	0	1 (<0.1)	1 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Transaminases	0	1 (<0.1)	1 (<0.1)
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)
Viral test positive	2 (<0.1)	1 (<0.1)	3 (<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 endometrium	1 (<0.1)	0	1 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood prolactin increased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
Breath sounds abnormal	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Investigations (Cont.)			
C-reactive protein increased	2 (<0.1)	0	2 (<0.1)
Colonoscopy	1 (<0.1)	0	1 (<0.1)
International normalised ratio increased	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	378 (2.5)	326 (2.1)	704 (2.3)
Muscle strain	33 (0.2)	37 (0.2)	70 (0.2)
Ligament sprain	30 (0.2)	29 (0.2)	59 (0.2)
Skin laceration	34 (0.2)	24 (0.2)	58 (0.2)
Arthropod bite	27 (0.2)	23 (0.2)	50 (0.2)
Contusion	28 (0.2)	19 (0.1)	47 (0.2)
Tooth fracture	15 (<0.1)	17 (0.1)	32 (0.1)
Fall	20 (0.1)	16 (0.1)	36 (0.1)
Procedural pain	26 (0.2)	15 (<0.1)	41 (0.1)
Foot fracture	14 (<0.1)	14 (<0.1)	28 (<0.1)
Limb injury	10 (<0.1)	13 (<0.1)	23 (<0.1)
Skin abrasion	24 (0.2)	9 (<0.1)	33 (0.1)
Animal bite	8 (<0.1)	8 (<0.1)	16 (<0.1)
Road traffic accident	8 (<0.1)	8 (<0.1)	16 (<0.1)
Arthropod sting	16 (0.1)	7 (<0.1)	23 (<0.1)
Concussion	4 (<0.1)	7 (<0.1)	11 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Joint injury	7 (<0.1)	6 (<0.1)	13 (<0.1)
Meniscus injury	3 (<0.1)	6 (<0.1)	9 (<0.1)
Hand fracture	1 (<0.1)	5 (<0.1)	6 (<0.1)
Head injury	1 (<0.1)	5 (<0.1)	6 (<0.1)
Thermal burn	1 (<0.1)	5 (<0.1)	6 (<0.1)
Post-traumatic pain	5 (<0.1)	4 (<0.1)	9 (<0.1)
Rib fracture	2 (<0.1)	4 (<0.1)	6 (<0.1)
Wrist fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Corneal abrasion	3 (<0.1)	3 (<0.1)	6 (<0.1)
Epicondylitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Tendon rupture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Ankle fracture	6 (<0.1)	2 (<0.1)	8 (<0.1)
Back injury	4 (<0.1)	2 (<0.1)	6 (<0.1)
Bone contusion	4 (<0.1)	2 (<0.1)	6 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)	3 (<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	1 (<0.1)	2 (<0.1)	3 (<0.1)
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Humerus fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ligament injury	0	2 (<0.1)	2 (<0.1)
Ligament rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)

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MedDRA version 23.0.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Muscle rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Subdural haematoma	0	2 (<0.1)	2 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vaccination complication	4 (<0.1)	2 (<0.1)	6 (<0.1)
Wound	4 (<0.1)	2 (<0.1)	6 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<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)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)	1 (<0.1)
Exposure to SARS-CoV-2	3 (<0.1)	1 (<0.1)	4 (<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)
Incision site pain	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)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Joint dislocation	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)
Muscle hernia	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 procedural swelling	0	1 (<0.1)	1 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal column injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal compression fracture	0	1 (<0.1)	1 (<0.1)
Stab wound	0	1 (<0.1)	1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)	6 (<0.1)

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MedDRA version 23.0.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Traumatic fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Uterine rupture	0	1 (<0.1)	1 (<0.1)
Buttock injury	1 (<0.1)	0	1 (<0.1)
Ear injury	1 (<0.1)	0	1 (<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)
Gun shot wound	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	2 (<0.1)	0	2 (<0.1)
Pulmonary contusion	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Repetitive strain injury	1 (<0.1)	0	1 (<0.1)
Skeletal injury	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Sunburn	3 (<0.1)	0	3 (<0.1)
Superficial injury of eye	2 (<0.1)	0	2 (<0.1)
Trunk injury	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)
Vascular access site pain	1 (<0.1)	0	1 (<0.1)
Vascular access site swelling	1 (<0.1)	0	1 (<0.1)
Venomous sting	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	18 (0.1)	18 (0.1)	36 (0.1)
Endodontic procedure	4 (<0.1)	2 (<0.1)	6 (<0.1)
Skin neoplasm excision	0	2 (<0.1)	2 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cataract operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curetting of chalazion	0	1 (<0.1)	1 (<0.1)
Dental operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Influenza immunisation	0	1 (<0.1)	1 (<0.1)
Knee arthroplasty	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 14.3.1.8.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Surgical and medical procedures (Cont.)			
Pancreatic stent placement	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)
Tendon sheath incision	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Tooth extraction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Transfusion	0	1 (<0.1)	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Foot operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Jaw operation	1 (<0.1)	0	1 (<0.1)
Spinal fusion surgery	1 (<0.1)	0	1 (<0.1)
Tooth repair	3 (<0.1)	0	3 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)	3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)	7 (<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)
Device physical property issue	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 14.3.1.8.6
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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2920 (25.6)	2968 (26.0)	5888 (25.8)
Number of Unsolicited Adverse Events	5876	5951	11827
Infections and infestations	901 (7.9)	631 (5.5)	1532 (6.7)
Upper respiratory tract infection	100 (0.9)	77 (0.7)	177 (0.8)
Urinary tract infection	85 (0.7)	72 (0.6)	157 (0.7)
Sinusitis	44 (0.4)	53 (0.5)	97 (0.4)
Viral infection	47 (0.4)	37 (0.3)	84 (0.4)
COVID-19	273 (2.4)	28 (0.2)	301 (1.3)
Rhinovirus infection	24 (0.2)	22 (0.2)	46 (0.2)
Pharyngitis streptococcal	20 (0.2)	20 (0.2)	40 (0.2)
Pharyngitis	29 (0.3)	19 (0.2)	48 (0.2)
Suspected COVID-19	27 (0.2)	18 (0.2)	45 (0.2)
Ear infection	11 (<0.1)	17 (0.1)	28 (0.1)
Herpes zoster	13 (0.1)	15 (0.1)	28 (0.1)
Tooth infection	15 (0.1)	15 (0.1)	30 (0.1)
Tooth abscess	13 (0.1)	14 (0.1)	27 (0.1)
Gastroenteritis	18 (0.2)	13 (0.1)	31 (0.1)
Conjunctivitis	8 (<0.1)	12 (0.1)	20 (<0.1)
Cellulitis	12 (0.1)	11 (<0.1)	23 (0.1)
Bronchitis	9 (<0.1)	10 (<0.1)	19 (<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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Infections and infestations (Cont.)			
Viral upper respiratory tract infection	14 (0.1)	10 (<0.1)	24 (0.1)
Oral herpes	6 (<0.1)	9 (<0.1)	15 (<0.1)
Otitis media	10 (<0.1)	8 (<0.1)	18 (<0.1)
Respiratory tract infection	5 (<0.1)	8 (<0.1)	13 (<0.1)
Folliculitis	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hordeolum	9 (<0.1)	7 (<0.1)	16 (<0.1)
Acute sinusitis	4 (<0.1)	6 (<0.1)	10 (<0.1)
Bacterial vaginosis	6 (<0.1)	6 (<0.1)	12 (<0.1)
Diverticulitis	6 (<0.1)	6 (<0.1)	12 (<0.1)
Fungal infection	7 (<0.1)	6 (<0.1)	13 (<0.1)
Otitis externa	8 (<0.1)	6 (<0.1)	14 (<0.1)
Asymptomatic COVID-19	8 (<0.1)	5 (<0.1)	13 (<0.1)
Localised infection	6 (<0.1)	5 (<0.1)	11 (<0.1)
Skin infection	2 (<0.1)	5 (<0.1)	7 (<0.1)
Vulvovaginal mycotic infection	13 (0.1)	5 (<0.1)	18 (<0.1)
Enterovirus infection	1 (<0.1)	4 (<0.1)	5 (<0.1)
Gingivitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Gonorrhoea	2 (<0.1)	4 (<0.1)	6 (<0.1)
Herpes simplex	3 (<0.1)	4 (<0.1)	7 (<0.1)
Onychomycosis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Paronychia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Pneumonia	5 (<0.1)	4 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Infections and infestations (Cont.)			
Vulvovaginal candidiasis	5 (<0.1)	4 (<0.1)	9 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)	4 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)	5 (<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)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Cystitis	5 (<0.1)	2 (<0.1)	7 (<0.1)
Gastroenteritis viral	11 (<0.1)	2 (<0.1)	13 (<0.1)
Impetigo	1 (<0.1)	2 (<0.1)	3 (<0.1)
Infected bite	1 (<0.1)	2 (<0.1)	3 (<0.1)
Kidney infection	0	2 (<0.1)	2 (<0.1)
Nasopharyngitis	9 (<0.1)	2 (<0.1)	11 (<0.1)
Oral candidiasis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Respiratory tract infection viral	8 (<0.1)	2 (<0.1)	10 (<0.1)
Sinusitis bacterial	3 (<0.1)	2 (<0.1)	5 (<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	9 (<0.1)	2 (<0.1)	11 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Infections and infestations (Cont.)			
Viral rhinitis	0	2 (<0.1)	2 (<0.1)
Wound infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abscess	1 (<0.1)	1 (<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)
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	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected cyst	1 (<0.1)	1 (<0.1)	2 (<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)
Nail 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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Infections and infestations (Cont.)			
Osteomyelitis	0	1 (<0.1)	1 (<0.1)
Otitis media acute	3 (<0.1)	1 (<0.1)	4 (<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)
Pertussis	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)
Pulpitis dental	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pyelonephritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash pustular	0	1 (<0.1)	1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Salpingitis	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	0	1 (<0.1)	1 (<0.1)
Tinea pedis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urinary tract infection bacterial	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Infections and infestations (Cont.)			
Uterine infection	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Adenovirus infection	1 (<0.1)	0	1 (<0.1)
Appendicitis	1 (<0.1)	0	1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0	1 (<0.1)
Breast abscess	2 (<0.1)	0	2 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0	2 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Eye infection bacterial	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)
Infected dermal cyst	1 (<0.1)	0	1 (<0.1)
Influenza	3 (<0.1)	0	3 (<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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Infections and infestations (Cont.)			
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 bacterial infection	2 (<0.1)	0	2 (<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)
Tinea versicolour	1 (<0.1)	0	1 (<0.1)
Trichomoniasis	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)	18 (0.2)	33 (0.3)	51 (0.2)
Squamous cell carcinoma	0	4 (<0.1)	4 (<0.1)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Basal cell carcinoma	4 (<0.1)	2 (<0.1)	6 (<0.1)
Uterine leiomyoma	0	2 (<0.1)	2 (<0.1)
Breast cancer in situ	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Breast neoplasm	0	1 (<0.1)	1 (<0.1)
Colorectal cancer	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Invasive lobular breast carcinoma	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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)	1 (<0.1)
Papillary thyroid cancer	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)
Prostate cancer stage I	0	1 (<0.1)	1 (<0.1)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Renal cell carcinoma	0	1 (<0.1)	1 (<0.1)
Renal neoplasm	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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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Benign breast neoplasm	1 (<0.1)	0	1 (<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)
Hepatic cancer	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)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	89 (0.8)	139 (1.2)	228 (1.0)
Lymphadenopathy	72 (0.6)	113 (1.0)	185 (0.8)
Anaemia	3 (<0.1)	10 (<0.1)	13 (<0.1)
Lymphadenitis	2 (<0.1)	10 (<0.1)	12 (<0.1)
Lymph node pain	4 (<0.1)	3 (<0.1)	7 (<0.1)
Thrombocytopenia	0	3 (<0.1)	3 (<0.1)
Iron deficiency anaemia	7 (<0.1)	1 (<0.1)	8 (<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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Immune system disorders	39 (0.3)	28 (0.2)	67 (0.3)
Seasonal allergy	25 (0.2)	19 (0.2)	44 (0.2)
Hypersensitivity	4 (<0.1)	3 (<0.1)	7 (<0.1)
Drug hypersensitivity	3 (<0.1)	2 (<0.1)	5 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anaphylactic reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Immune system disorder	0	1 (<0.1)	1 (<0.1)
Allergy to metals	1 (<0.1)	0	1 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Serum sickness	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	6 (<0.1)	12 (0.1)	18 (<0.1)
Hypothyroidism	3 (<0.1)	8 (<0.1)	11 (<0.1)
Thyroid mass	0	2 (<0.1)	2 (<0.1)
Hyperparathyroidism	0	1 (<0.1)	1 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Thyroid disorder	0	1 (<0.1)	1 (<0.1)
Goitre	1 (<0.1)	0	1 (<0.1)
Hypogonadism	1 (<0.1)	0	1 (<0.1)
Oestrogen deficiency	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Metabolism and nutrition disorders	77 (0.7)	60 (0.5)	137 (0.6)
Type 2 diabetes mellitus	2 (<0.1)	11 (<0.1)	13 (<0.1)
Hyperlipidaemia	13 (0.1)	9 (<0.1)	22 (<0.1)
Decreased appetite	8 (<0.1)	8 (<0.1)	16 (<0.1)
Vitamin D deficiency	11 (<0.1)	6 (<0.1)	17 (<0.1)
Hypercholesterolaemia	14 (0.1)	5 (<0.1)	19 (<0.1)
Dehydration	8 (<0.1)	3 (<0.1)	11 (<0.1)
Diabetes mellitus	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hyperglycaemia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Abnormal loss of weight	0	2 (<0.1)	2 (<0.1)
Glucose tolerance impaired	4 (<0.1)	2 (<0.1)	6 (<0.1)
Food intolerance	0	1 (<0.1)	1 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Gout	5 (<0.1)	1 (<0.1)	6 (<0.1)
Hypocalcaemia	0	1 (<0.1)	1 (<0.1)
Hypoglycaemia	0	1 (<0.1)	1 (<0.1)
Hypokalaemia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hyponatraemia	1 (<0.1)	1 (<0.1)	2 (<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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Metabolism and nutrition disorders (Cont.)			
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	3 (<0.1)	0	3 (<0.1)
Electrolyte imbalance	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)
Metabolic acidosis	1 (<0.1)	0	1 (<0.1)
Obesity	1 (<0.1)	0	1 (<0.1)
Polydipsia	1 (<0.1)	0	1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	83 (0.7)	95 (0.8)	178 (0.8)
Anxiety	27 (0.2)	29 (0.3)	56 (0.2)
Depression	23 (0.2)	25 (0.2)	48 (0.2)
Insomnia	12 (0.1)	16 (0.1)	28 (0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	6 (<0.1)	15 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Psychiatric disorders (Cont.)			
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Claustrophobia	0	1 (<0.1)	1 (<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	3 (<0.1)	1 (<0.1)	4 (<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	1 (<0.1)	0	1 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Dissociative disorder	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)
Nightmare	1 (<0.1)	0	1 (<0.1)
Persistent depressive 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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Psychiatric disorders (Cont.)			
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	594 (5.2)	601 (5.3)	1195 (5.2)
Headache	446 (3.9)	407 (3.6)	853 (3.7)
Dizziness	43 (0.4)	55 (0.5)	98 (0.4)
Paraesthesia	24 (0.2)	24 (0.2)	48 (0.2)
Presyncope	11 (<0.1)	14 (0.1)	25 (0.1)
Syncope	20 (0.2)	12 (0.1)	32 (0.1)
Ageusia	14 (0.1)	11 (<0.1)	25 (0.1)
Migraine	19 (0.2)	11 (<0.1)	30 (0.1)
Anosmia	10 (<0.1)	10 (<0.1)	20 (<0.1)
Dysgeusia	3 (<0.1)	10 (<0.1)	13 (<0.1)
Sciatica	6 (<0.1)	10 (<0.1)	16 (<0.1)
Hypoaesthesia	6 (<0.1)	9 (<0.1)	15 (<0.1)
Sinus headache	5 (<0.1)	8 (<0.1)	13 (<0.1)
Tension headache	4 (<0.1)	6 (<0.1)	10 (<0.1)
Hyperaesthesia	0	4 (<0.1)	4 (<0.1)
Burning sensation	0	3 (<0.1)	3 (<0.1)
Carpal tunnel syndrome	3 (<0.1)	3 (<0.1)	6 (<0.1)
Disturbance in attention	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Nervous system disorders (Cont.)			
Mental impairment	0	3 (<0.1)	3 (<0.1)
Nerve compression	1 (<0.1)	3 (<0.1)	4 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cerebrovascular accident	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cervical radiculopathy	0	2 (<0.1)	2 (<0.1)
Lethargy	0	2 (<0.1)	2 (<0.1)
Neuropathy peripheral	1 (<0.1)	2 (<0.1)	3 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)	3 (<0.1)
Aura	0	1 (<0.1)	1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cerebral small vessel ischaemic disease	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)
Facial paralysis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Memory impairment	0	1 (<0.1)	1 (<0.1)
Migraine with aura	1 (<0.1)	1 (<0.1)	2 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement 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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Nervous system disorders (Cont.)			
Neuralgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Parosmia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	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)
Subarachnoid haemorrhage	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)
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)
Aphasia	1 (<0.1)	0	1 (<0.1)
Arachnoid cyst	1 (<0.1)	0	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dementia	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	2 (<0.1)	0	2 (<0.1)
Dyskinesia	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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Nervous system disorders (Cont.)			
Hyposmia	1 (<0.1)	0	1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	0	2 (<0.1)
Multiple sclerosis	1 (<0.1)	0	1 (<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)
Thoracic radiculopathy	1 (<0.1)	0	1 (<0.1)
Eye disorders	35 (0.3)	40 (0.4)	75 (0.3)
Eye pruritus	4 (<0.1)	5 (<0.1)	9 (<0.1)
Vision blurred	4 (<0.1)	4 (<0.1)	8 (<0.1)
Conjunctival haemorrhage	0	3 (<0.1)	3 (<0.1)
Eye irritation	0	3 (<0.1)	3 (<0.1)
Blepharitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lacrimation increased	5 (<0.1)	2 (<0.1)	7 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Blepharospasm	0	1 (<0.1)	1 (<0.1)
Blindness transient	0	1 (<0.1)	1 (<0.1)
Conjunctival hyperaemia	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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Eye disorders (Cont.)			
Eye haemorrhage	0	1 (<0.1)	1 (<0.1)
Eye inflammation	0	1 (<0.1)	1 (<0.1)
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)
Ocular hyperaemia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Orbital haematoma	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Presbyopia	0	1 (<0.1)	1 (<0.1)
Scleritis	0	1 (<0.1)	1 (<0.1)
Swelling of eyelid	1 (<0.1)	1 (<0.1)	2 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)	2 (<0.1)
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Cataract	1 (<0.1)	0	1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0	1 (<0.1)
Dry eye	3 (<0.1)	0	3 (<0.1)
Eye pain	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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Eye disorders (Cont.)			
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 haemorrhage	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)
Vitreous detachment	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	61 (0.5)	48 (0.4)	109 (0.5)
Vertigo	11 (<0.1)	16 (0.1)	27 (0.1)
Ear pain	20 (0.2)	11 (<0.1)	31 (0.1)
Tinnitus	8 (<0.1)	7 (<0.1)	15 (<0.1)
Ear discomfort	4 (<0.1)	3 (<0.1)	7 (<0.1)
Vertigo positional	2 (<0.1)	3 (<0.1)	5 (<0.1)
Cerumen impaction	2 (<0.1)	2 (<0.1)	4 (<0.1)
Ear canal erythema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Otorrhoea	0	2 (<0.1)	2 (<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	3 (<0.1)	1 (<0.1)	4 (<0.1)
Motion sickness	0	1 (<0.1)	1 (<0.1)
Deafness	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Ear and labyrinth disorders (Cont.)			
Ear congestion	2 (<0.1)	0	2 (<0.1)
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Ear pruritus	2 (<0.1)	0	2 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	0	4 (<0.1)
Cardiac disorders	52 (0.5)	42 (0.4)	94 (0.4)
Tachycardia	12 (0.1)	12 (0.1)	24 (0.1)
Bradycardia	15 (0.1)	11 (<0.1)	26 (0.1)
Palpitations	6 (<0.1)	5 (<0.1)	11 (<0.1)
Myocardial infarction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Angina pectoris	1 (<0.1)	2 (<0.1)	3 (<0.1)
Atrial fibrillation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac 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 myocardial infarction	1 (<0.1)	0	1 (<0.1)
Arrhythmia	3 (<0.1)	0	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Cardiac disorders (Cont.)			
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	2 (<0.1)	0	2 (<0.1)
Sinus arrest	1 (<0.1)	0	1 (<0.1)
Sinus bradycardia	1 (<0.1)	0	1 (<0.1)
Vascular disorders	126 (1.1)	129 (1.1)	255 (1.1)
Hypertension	99 (0.9)	105 (0.9)	204 (0.9)
Flushing	2 (<0.1)	5 (<0.1)	7 (<0.1)
Hot flush	3 (<0.1)	4 (<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)
Hypertensive urgency	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypotension	4 (<0.1)	2 (<0.1)	6 (<0.1)
Orthostatic hypotension	0	2 (<0.1)	2 (<0.1)
Peripheral coldness	0	2 (<0.1)	2 (<0.1)
Systolic hypertension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Pallor	0	1 (<0.1)	1 (<0.1)
Accelerated hypertension	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Vascular disorders (Cont.)			
Aortic aneurysm	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Blood pressure inadequately controlled	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)
Varicose vein	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	572 (5.0)	507 (4.4)	1079 (4.7)
Cough	170 (1.5)	173 (1.5)	343 (1.5)
Oropharyngeal pain	210 (1.8)	161 (1.4)	371 (1.6)
Nasal congestion	153 (1.3)	141 (1.2)	294 (1.3)
Rhinorrhoea	137 (1.2)	129 (1.1)	266 (1.2)
Dyspnoea	43 (0.4)	53 (0.5)	96 (0.4)
Tachypnoea	32 (0.3)	34 (0.3)	66 (0.3)
Sinus congestion	27 (0.2)	19 (0.2)	46 (0.2)
Throat irritation	11 (<0.1)	16 (0.1)	27 (0.1)
Epistaxis	4 (<0.1)	13 (0.1)	17 (<0.1)
Respiratory tract congestion	8 (<0.1)	10 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Upper-airway cough syndrome	10 (<0.1)	9 (<0.1)	19 (<0.1)
Asthma	11 (<0.1)	8 (<0.1)	19 (<0.1)
Rhinitis allergic	9 (<0.1)	8 (<0.1)	17 (<0.1)
Chronic obstructive pulmonary disease	5 (<0.1)	5 (<0.1)	10 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	5 (<0.1)	8 (<0.1)
Sneezing	9 (<0.1)	5 (<0.1)	14 (<0.1)
Productive cough	5 (<0.1)	4 (<0.1)	9 (<0.1)
Dry throat	2 (<0.1)	3 (<0.1)	5 (<0.1)
Pharyngeal erythema	2 (<0.1)	3 (<0.1)	5 (<0.1)
Pulmonary embolism	5 (<0.1)	3 (<0.1)	8 (<0.1)
Sinus pain	4 (<0.1)	3 (<0.1)	7 (<0.1)
Wheezing	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dysphonia	7 (<0.1)	2 (<0.1)	9 (<0.1)
Dyspnoea exertional	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hypoxia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Respiratory symptom	2 (<0.1)	2 (<0.1)	4 (<0.1)
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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Bronchiectasis	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)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Respiratory failure	0	1 (<0.1)	1 (<0.1)
Sputum increased	0	1 (<0.1)	1 (<0.1)
Tonsillolith	5 (<0.1)	1 (<0.1)	6 (<0.1)
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Haemoptysis	2 (<0.1)	0	2 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Nasal ulcer	1 (<0.1)	0	1 (<0.1)
Painful respiration	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Pleural effusion	2 (<0.1)	0	2 (<0.1)
Pneumonia aspiration	1 (<0.1)	0	1 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pneumothorax	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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary fibrosis	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Rales	1 (<0.1)	0	1 (<0.1)
Rhinalgia	1 (<0.1)	0	1 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Throat tightness	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	385 (3.4)	407 (3.6)	792 (3.5)
Diarrhoea	136 (1.2)	166 (1.5)	302 (1.3)
Nausea	126 (1.1)	107 (0.9)	233 (1.0)
Vomiting	35 (0.3)	36 (0.3)	71 (0.3)
Gastrooesophageal reflux disease	16 (0.1)	25 (0.2)	41 (0.2)
Toothache	23 (0.2)	24 (0.2)	47 (0.2)
Abdominal pain	23 (0.2)	17 (0.1)	40 (0.2)
Constipation	9 (<0.1)	12 (0.1)	21 (<0.1)
Dental caries	7 (<0.1)	10 (<0.1)	17 (<0.1)
Food poisoning	8 (<0.1)	9 (<0.1)	17 (<0.1)
Abdominal pain upper	15 (0.1)	8 (<0.1)	23 (0.1)
Abdominal pain lower	5 (<0.1)	6 (<0.1)	11 (<0.1)
Dyspepsia	13 (0.1)	5 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Gastrointestinal disorders (Cont.)			
Gastric ulcer	2 (<0.1)	5 (<0.1)	7 (<0.1)
Abdominal discomfort	6 (<0.1)	4 (<0.1)	10 (<0.1)
Haematochezia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aphthous ulcer	2 (<0.1)	3 (<0.1)	5 (<0.1)
Colitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hiatus hernia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Abdominal distension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Diverticulum	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	1 (<0.1)	2 (<0.1)	3 (<0.1)
Stomatitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Tongue discolouration	0	2 (<0.1)	2 (<0.1)
Tooth impacted	3 (<0.1)	2 (<0.1)	5 (<0.1)
Umbilical hernia	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)
Dry mouth	2 (<0.1)	1 (<0.1)	3 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Gastrointestinal disorders (Cont.)			
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)
Gastritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Inguinal hernia	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)
Large intestine polyp	0	1 (<0.1)	1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Melaena	0	1 (<0.1)	1 (<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)
Paraesthesia oral	3 (<0.1)	1 (<0.1)	4 (<0.1)
Peptic ulcer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periodontal disease	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal prolapse	0	1 (<0.1)	1 (<0.1)
Saliva altered	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Gastrointestinal disorders (Cont.)			
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)	1 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tongue disorder	0	1 (<0.1)	1 (<0.1)
Dysphagia	3 (<0.1)	0	3 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	2 (<0.1)	0	2 (<0.1)
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Gingival pain	1 (<0.1)	0	1 (<0.1)
Gingival swelling	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)
Noninfective gingivitis	2 (<0.1)	0	2 (<0.1)
Oral disorder	1 (<0.1)	0	1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0	1 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Regurgitation	1 (<0.1)	0	1 (<0.1)
Tongue coated	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Hepatobiliary disorders	3 (<0.1)	9 (<0.1)	12 (<0.1)
Cholelithiasis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Cholecystitis	0	3 (<0.1)	3 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Hepatic cyst	1 (<0.1)	0	1 (<0.1)
Hepatic steatosis	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	167 (1.5)	194 (1.7)	361 (1.6)
Rash	27 (0.2)	31 (0.3)	58 (0.3)
Urticaria	17 (0.1)	17 (0.1)	34 (0.1)
Dermatitis contact	18 (0.2)	16 (0.1)	34 (0.1)
Pruritus	12 (0.1)	16 (0.1)	28 (0.1)
Hyperhidrosis	12 (0.1)	10 (<0.1)	22 (<0.1)
Rash maculo-papular	2 (<0.1)	9 (<0.1)	11 (<0.1)
Night sweats	6 (<0.1)	8 (<0.1)	14 (<0.1)
Acne	7 (<0.1)	7 (<0.1)	14 (<0.1)
Alopecia	3 (<0.1)	7 (<0.1)	10 (<0.1)
Rash papular	3 (<0.1)	7 (<0.1)	10 (<0.1)
Dermatitis	7 (<0.1)	6 (<0.1)	13 (<0.1)
Erythema	3 (<0.1)	6 (<0.1)	9 (<0.1)
Ecchymosis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Rash erythematous	2 (<0.1)	5 (<0.1)	7 (<0.1)
Rash pruritic	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Blister	2 (<0.1)	3 (<0.1)	5 (<0.1)
Eczema	4 (<0.1)	3 (<0.1)	7 (<0.1)
Pityriasis rosea	0	3 (<0.1)	3 (<0.1)
Psoriasis	0	3 (<0.1)	3 (<0.1)
Rash vesicular	0	3 (<0.1)	3 (<0.1)
Rosacea	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin lesion	2 (<0.1)	3 (<0.1)	5 (<0.1)
Urticaria papular	4 (<0.1)	3 (<0.1)	7 (<0.1)
Dermatitis allergic	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Hidradenitis	0	2 (<0.1)	2 (<0.1)
Rash macular	1 (<0.1)	2 (<0.1)	3 (<0.1)
Actinic keratosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Angioedema	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood blister	0	1 (<0.1)	1 (<0.1)
Cold sweat	0	1 (<0.1)	1 (<0.1)
Dermal cyst	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dermatitis atopic	7 (<0.1)	1 (<0.1)	8 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)	2 (<0.1)
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Lichen planus	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Macule	0	1 (<0.1)	1 (<0.1)
Mechanical urticaria	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)	1 (<0.1)
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Skin ulcer	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)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Ingrowing nail	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)
Miliaria	1 (<0.1)	0	1 (<0.1)
Myxoid cyst	1 (<0.1)	0	1 (<0.1)
Rash follicular	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)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Musculoskeletal and connective tissue disorders	496 (4.3)	531 (4.7)	1027 (4.5)
Myalgia	156 (1.4)	169 (1.5)	325 (1.4)
Arthralgia	139 (1.2)	150 (1.3)	289 (1.3)
Back pain	82 (0.7)	66 (0.6)	148 (0.6)
Pain in extremity	53 (0.5)	48 (0.4)	101 (0.4)
Neck pain	24 (0.2)	31 (0.3)	55 (0.2)
Muscle spasms	12 (0.1)	25 (0.2)	37 (0.2)
Musculoskeletal pain	23 (0.2)	25 (0.2)	48 (0.2)
Tendonitis	5 (<0.1)	11 (<0.1)	16 (<0.1)
Musculoskeletal chest pain	11 (<0.1)	10 (<0.1)	21 (<0.1)
Osteoarthritis	9 (<0.1)	8 (<0.1)	17 (<0.1)
Bursitis	3 (<0.1)	6 (<0.1)	9 (<0.1)
Groin pain	0	6 (<0.1)	6 (<0.1)
Musculoskeletal stiffness	12 (0.1)	6 (<0.1)	18 (<0.1)
Arthritis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	5 (<0.1)	6 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)	6 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)	6 (<0.1)
Rotator cuff syndrome	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bone pain	0	4 (<0.1)	4 (<0.1)
Joint swelling	7 (<0.1)	4 (<0.1)	11 (<0.1)
Pain in jaw	3 (<0.1)	4 (<0.1)	7 (<0.1)
Axillary mass	3 (<0.1)	3 (<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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Costochondritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Flank pain	0	3 (<0.1)	3 (<0.1)
Limb discomfort	3 (<0.1)	3 (<0.1)	6 (<0.1)
Exostosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fibromyalgia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Limb mass	2 (<0.1)	2 (<0.1)	4 (<0.1)
Muscular weakness	3 (<0.1)	2 (<0.1)	5 (<0.1)
Neck mass	0	2 (<0.1)	2 (<0.1)
Osteopenia	0	2 (<0.1)	2 (<0.1)
Osteoporosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Spinal osteoarthritis	0	2 (<0.1)	2 (<0.1)
Spinal pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bone lesion	0	1 (<0.1)	1 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chondrocalcinosis pyrophosphate	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)
Joint stiffness	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Muscle twitching	3 (<0.1)	1 (<0.1)	4 (<0.1)
Osteonecrosis	0	1 (<0.1)	1 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Torticollis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Trigger finger	0	1 (<0.1)	1 (<0.1)
Undifferentiated connective tissue disease	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)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteochondrosis	1 (<0.1)	0	1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0	1 (<0.1)
Spinal stenosis	1 (<0.1)	0	1 (<0.1)
Synovial cyst	2 (<0.1)	0	2 (<0.1)
Synovitis	1 (<0.1)	0	1 (<0.1)
Systemic lupus erythematosus	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Renal and urinary disorders	29 (0.3)	28 (0.2)	57 (0.2)
Nephrolithiasis	17 (0.1)	9 (<0.1)	26 (0.1)
Dysuria	3 (<0.1)	6 (<0.1)	9 (<0.1)
Chronic kidney disease	0	2 (<0.1)	2 (<0.1)
Acute kidney injury	0	1 (<0.1)	1 (<0.1)
Bladder pain	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)
Hypertonic bladder	0	1 (<0.1)	1 (<0.1)
Nocturia	0	1 (<0.1)	1 (<0.1)
Polyuria	0	1 (<0.1)	1 (<0.1)
Renal failure	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)
Chromaturia	1 (<0.1)	0	1 (<0.1)
Haematuria	7 (<0.1)	0	7 (<0.1)
Micturition urgency	1 (<0.1)	0	1 (<0.1)
Pollakiuria	1 (<0.1)	0	1 (<0.1)
Renal colic	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.6
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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pregnancy	0	3 (<0.1)	3 (<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	40 (0.4)	43 (0.4)	83 (0.4)
Dysmenorrhoea	4 (<0.1)	4 (<0.1)	8 (<0.1)
Pelvic pain	0	4 (<0.1)	4 (<0.1)
Menorrhagia	0	3 (<0.1)	3 (<0.1)
Breast pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Erectile dysfunction	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostatitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Uterine haemorrhage	0	2 (<0.1)	2 (<0.1)
Uterine polyp	0	2 (<0.1)	2 (<0.1)
Vaginal haemorrhage	0	2 (<0.1)	2 (<0.1)
Adnexa uteri pain	0	1 (<0.1)	1 (<0.1)
Adnexal torsion	0	1 (<0.1)	1 (<0.1)
Benign prostatic hyperplasia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast disorder	0	1 (<0.1)	1 (<0.1)
Breast fibrosis	0	1 (<0.1)	1 (<0.1)
Breast hyperplasia	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Reproductive system and breast disorders (Cont.)			
Cervical dysplasia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ejaculation failure	0	1 (<0.1)	1 (<0.1)
Fibrocystic breast disease	0	1 (<0.1)	1 (<0.1)
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Menopausal symptoms	2 (<0.1)	1 (<0.1)	3 (<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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ovarian mass	0	1 (<0.1)	1 (<0.1)
Perineal rash	0	1 (<0.1)	1 (<0.1)
Testicular pain	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)
Breast mass	1 (<0.1)	0	1 (<0.1)
Cystocele	1 (<0.1)	0	1 (<0.1)
Endometriosis	1 (<0.1)	0	1 (<0.1)
Haematospermia	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Reproductive system and breast disorders (Cont.)			
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)
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)
Vulvovaginal discomfort	1 (<0.1)	0	1 (<0.1)
Congenital, familial and genetic disorders	2 (<0.1)	3 (<0.1)	5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)	2 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	2 (<0.1)	0	2 (<0.1)
General disorders and administration site conditions	543 (4.8)	806 (7.1)	1349 (5.9)
Fatigue	317 (2.8)	297 (2.6)	614 (2.7)
Injection site pain	41 (0.4)	121 (1.1)	162 (0.7)
Injection site erythema	11 (<0.1)	89 (0.8)	100 (0.4)
Pyrexia	57 (0.5)	76 (0.7)	133 (0.6)
Chills	68 (0.6)	74 (0.6)	142 (0.6)
Pain	61 (0.5)	67 (0.6)	128 (0.6)

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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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
General disorders and administration site conditions (Cont.)			
Injection site swelling	9 (<0.1)	66 (0.6)	75 (0.3)
Injection site pruritus	10 (<0.1)	55 (0.5)	65 (0.3)
Injection site rash	1 (<0.1)	28 (0.2)	29 (0.1)
Injection site induration	4 (<0.1)	25 (0.2)	29 (0.1)
Axillary pain	11 (<0.1)	23 (0.2)	34 (0.1)
Chest pain	6 (<0.1)	16 (0.1)	22 (<0.1)
Chest discomfort	14 (0.1)	15 (0.1)	29 (0.1)
Injection site lymphadenopathy	3 (<0.1)	15 (0.1)	18 (<0.1)
Injection site macule	2 (<0.1)	14 (0.1)	16 (<0.1)
Injection site urticaria	0	11 (<0.1)	11 (<0.1)
Malaise	8 (<0.1)	11 (<0.1)	19 (<0.1)
Injection site bruising	11 (<0.1)	9 (<0.1)	20 (<0.1)
Swelling	1 (<0.1)	9 (<0.1)	10 (<0.1)
Injection site warmth	1 (<0.1)	6 (<0.1)	7 (<0.1)
Vaccination site lymphadenopathy	0	5 (<0.1)	5 (<0.1)
Feeling hot	4 (<0.1)	4 (<0.1)	8 (<0.1)
Injection site haemorrhage	1 (<0.1)	4 (<0.1)	5 (<0.1)
Non-cardiac chest pain	4 (<0.1)	4 (<0.1)	8 (<0.1)
Oedema peripheral	2 (<0.1)	4 (<0.1)	6 (<0.1)
Peripheral swelling	6 (<0.1)	4 (<0.1)	10 (<0.1)
Swelling face	2 (<0.1)	4 (<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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
General disorders and administration site conditions (Cont.)			
Tenderness	0	4 (<0.1)	4 (<0.1)
Injection site haematoma	1 (<0.1)	3 (<0.1)	4 (<0.1)
Injection site irritation	0	3 (<0.1)	3 (<0.1)
Injection site reaction	0	3 (<0.1)	3 (<0.1)
Vaccination site erythema	0	3 (<0.1)	3 (<0.1)
Vaccination site swelling	0	3 (<0.1)	3 (<0.1)
Feeling abnormal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site mass	0	2 (<0.1)	2 (<0.1)
Injection site papule	1 (<0.1)	2 (<0.1)	3 (<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	3 (<0.1)	1 (<0.1)	4 (<0.1)
Early satiety	0	1 (<0.1)	1 (<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 cold	0	1 (<0.1)	1 (<0.1)
Granuloma	0	1 (<0.1)	1 (<0.1)
Hangover	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
General disorders and administration site conditions (Cont.)			
Hernia	0	1 (<0.1)	1 (<0.1)
Influenza like illness	1 (<0.1)	1 (<0.1)	2 (<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 paraesthesia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injection site scab	0	1 (<0.1)	1 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Mass	0	1 (<0.1)	1 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Reactogenicity event	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sensation of foreign body	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)
Discomfort	2 (<0.1)	0	2 (<0.1)
Gait disturbance	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)
Instillation site vesicles	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
General disorders and administration site conditions (Cont.)			
Medical device site inflammation	1 (<0.1)	0	1 (<0.1)
Mucosal hypertrophy	1 (<0.1)	0	1 (<0.1)
Polyp	1 (<0.1)	0	1 (<0.1)
Precancerous condition	2 (<0.1)	0	2 (<0.1)
Sluggishness	1 (<0.1)	0	1 (<0.1)
Unevaluable event	1 (<0.1)	0	1 (<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	2 (<0.1)	0	2 (<0.1)
Vessel puncture site pain	1 (<0.1)	0	1 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	73 (0.6)	73 (0.6)	146 (0.6)
Blood pressure increased	29 (0.3)	21 (0.2)	50 (0.2)
Blood pressure systolic increased	12 (0.1)	12 (0.1)	24 (0.1)
Blood pressure diastolic increased	6 (<0.1)	9 (<0.1)	15 (<0.1)
Body temperature increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Hepatic enzyme increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Transaminases increased	0	4 (<0.1)	4 (<0.1)
Heart rate increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Blood glucose increased	1 (<0.1)	2 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Investigations (Cont.)			
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Hormone level abnormal	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 potassium decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood testosterone decreased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood uric acid increased	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)
Glycosylated haemoglobin increased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Haemoglobin decreased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Human rhinovirus test positive	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	1 (<0.1)	1 (<0.1)	2 (<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)
Viral test positive	2 (<0.1)	1 (<0.1)	3 (<0.1)
White blood cell count increased	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Investigations (Cont.)			
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)
Biopsy endometrium	1 (<0.1)	0	1 (<0.1)
Blood prolactin increased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
Breath sounds abnormal	1 (<0.1)	0	1 (<0.1)
C-reactive protein increased	2 (<0.1)	0	2 (<0.1)
Cardiac murmur	2 (<0.1)	0	2 (<0.1)
Colonoscopy	1 (<0.1)	0	1 (<0.1)
International normalised ratio increased	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	261 (2.3)	213 (1.9)	474 (2.1)
Muscle strain	26 (0.2)	28 (0.2)	54 (0.2)
Ligament sprain	25 (0.2)	22 (0.2)	47 (0.2)
Skin laceration	27 (0.2)	15 (0.1)	42 (0.2)
Arthropod bite	21 (0.2)	13 (0.1)	34 (0.1)
Foot fracture	9 (<0.1)	11 (<0.1)	20 (<0.1)
Tooth fracture	9 (<0.1)	9 (<0.1)	18 (<0.1)
Limb injury	6 (<0.1)	8 (<0.1)	14 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Injury, poisoning and procedural complications (Cont.)			
Contusion	19 (0.2)	7 (<0.1)	26 (0.1)
Procedural pain	19 (0.2)	7 (<0.1)	26 (0.1)
Arthropod sting	8 (<0.1)	6 (<0.1)	14 (<0.1)
Concussion	3 (<0.1)	6 (<0.1)	9 (<0.1)
Skin abrasion	16 (0.1)	6 (<0.1)	22 (<0.1)
Animal bite	6 (<0.1)	5 (<0.1)	11 (<0.1)
Fall	11 (<0.1)	5 (<0.1)	16 (<0.1)
Joint injury	6 (<0.1)	5 (<0.1)	11 (<0.1)
Meniscus injury	1 (<0.1)	5 (<0.1)	6 (<0.1)
Head injury	0	4 (<0.1)	4 (<0.1)
Road traffic accident	4 (<0.1)	4 (<0.1)	8 (<0.1)
Thermal burn	1 (<0.1)	4 (<0.1)	5 (<0.1)
Hand fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Ankle fracture	5 (<0.1)	2 (<0.1)	7 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Clavicle fracture	0	2 (<0.1)	2 (<0.1)
Corneal abrasion	3 (<0.1)	2 (<0.1)	5 (<0.1)
Epicondylitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Ligament injury	0	2 (<0.1)	2 (<0.1)
Ligament rupture	1 (<0.1)	2 (<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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post-traumatic pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tendon injury	0	2 (<0.1)	2 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wound	3 (<0.1)	2 (<0.1)	5 (<0.1)
Wrist fracture	0	2 (<0.1)	2 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Back injury	4 (<0.1)	1 (<0.1)	5 (<0.1)
Bone contusion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bone fragmentation	0	1 (<0.1)	1 (<0.1)
Burns second degree	1 (<0.1)	1 (<0.1)	2 (<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)
Incision site pain	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)
Lip injury	0	1 (<0.1)	1 (<0.1)
Lumbar vertebral fracture	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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Injury, poisoning and procedural complications (Cont.)			
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Muscle hernia	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 procedural swelling	0	1 (<0.1)	1 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<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)
Spinal column injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stab wound	0	1 (<0.1)	1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)	6 (<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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Uterine rupture	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=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Injury, poisoning and procedural complications (Cont.)			
Vaccination complication	3 (<0.1)	1 (<0.1)	4 (<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)
Facial bones fracture	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)
Gun shot wound	1 (<0.1)	0	1 (<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)
Muscle injury	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0	2 (<0.1)
Procedural nausea	1 (<0.1)	0	1 (<0.1)
Scratch	1 (<0.1)	0	1 (<0.1)
Skeletal injury	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Sunburn	2 (<0.1)	0	2 (<0.1)
Superficial injury of eye	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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Injury, poisoning and procedural complications (Cont.)			
Traumatic fracture	1 (<0.1)	0	1 (<0.1)
Trunk injury	1 (<0.1)	0	1 (<0.1)
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Vascular access site pain	1 (<0.1)	0	1 (<0.1)
Vascular access site swelling	1 (<0.1)	0	1 (<0.1)
Venomous sting	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	12 (0.1)	8 (<0.1)	20 (<0.1)
Endodontic procedure	4 (<0.1)	2 (<0.1)	6 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Dental operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin neoplasm excision	0	1 (<0.1)	1 (<0.1)
Tendon sheath incision	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Tooth extraction	0	1 (<0.1)	1 (<0.1)
Cataract operation	1 (<0.1)	0	1 (<0.1)
Foot operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Jaw operation	1 (<0.1)	0	1 (<0.1)
Spinal fusion surgery	1 (<0.1)	0	1 (<0.1)
Tooth repair	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: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)
Social circumstances	2 (<0.1)	1 (<0.1)	3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)	2 (<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)

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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	968 (25.8)	1090 (28.9)	2058 (27.4)
Number of Unsolicited Adverse Events	1878	2185	4063
Infections and infestations	224 (6.0)	204 (5.4)	428 (5.7)
Urinary tract infection	42 (1.1)	35 (0.9)	77 (1.0)
Upper respiratory tract infection	9 (0.2)	18 (0.5)	27 (0.4)
Sinusitis	9 (0.2)	14 (0.4)	23 (0.3)
COVID-19	39 (1.0)	10 (0.3)	49 (0.7)
Cellulitis	6 (0.2)	9 (0.2)	15 (0.2)
Viral infection	9 (0.2)	9 (0.2)	18 (0.2)
Herpes zoster	4 (0.1)	8 (0.2)	12 (0.2)
Diverticulitis	4 (0.1)	6 (0.2)	10 (0.1)
Gastroenteritis	3 (<0.1)	6 (0.2)	9 (0.1)
Gingivitis	2 (<0.1)	6 (0.2)	8 (0.1)
Localised infection	3 (<0.1)	5 (0.1)	8 (0.1)
Rhinovirus infection	2 (<0.1)	5 (0.1)	7 (<0.1)
Tooth infection	6 (0.2)	5 (0.1)	11 (0.1)
Ear infection	4 (0.1)	4 (0.1)	8 (0.1)
Pneumonia	7 (0.2)	4 (0.1)	11 (0.1)
Tooth abscess	10 (0.3)	4 (0.1)	14 (0.2)
Acute sinusitis	2 (<0.1)	3 (<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 (%)
Infections and infestations (Cont.)			
Conjunctivitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Enterovirus infection	0	3 (<0.1)	3 (<0.1)
Herpes simplex	0	3 (<0.1)	3 (<0.1)
Hordeolum	5 (0.1)	3 (<0.1)	8 (0.1)
Laryngitis	0	3 (<0.1)	3 (<0.1)
Onychomycosis	0	3 (<0.1)	3 (<0.1)
Pharyngitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Suspected COVID-19	0	3 (<0.1)	3 (<0.1)
Appendicitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cystitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Fungal infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oral herpes	1 (<0.1)	2 (<0.1)	3 (<0.1)
Otitis externa	3 (<0.1)	2 (<0.1)	5 (<0.1)
Paronychia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Postoperative wound infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rhinitis	4 (0.1)	2 (<0.1)	6 (<0.1)
Sepsis	1 (<0.1)	2 (<0.1)	3 (<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)

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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.)			
Clostridium difficile colitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Clostridium difficile infection	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)
Impetigo	0	1 (<0.1)	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Injection site infection	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	3 (<0.1)	1 (<0.1)	4 (<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)
Pyelonephritis acute	0	1 (<0.1)	1 (<0.1)
Respiratory tract infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory tract infection viral	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Tinea infection	0	1 (<0.1)	1 (<0.1)
Tinea pedis	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 (%)
Infections and infestations (Cont.)			
Urosepsis	0	1 (<0.1)	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	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)
Wound infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	0	1 (<0.1)
Balanitis candida	1 (<0.1)	0	1 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Body tinea	2 (<0.1)	0	2 (<0.1)
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
Candida infection	3 (<0.1)	0	3 (<0.1)
Denture stomatitis	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)
Genital herpes simplex	1 (<0.1)	0	1 (<0.1)
Infected skin ulcer	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 media	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 (%)
Infections and infestations (Cont.)			
Pharyngitis streptococcal	2 (<0.1)	0	2 (<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	2 (<0.1)	0	2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	31 (0.8)	30 (0.8)	61 (0.8)
Basal cell carcinoma	10 (0.3)	7 (0.2)	17 (0.2)
Prostate cancer	3 (<0.1)	3 (<0.1)	6 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Malignant melanoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Squamous cell carcinoma of skin	1 (<0.1)	2 (<0.1)	3 (<0.1)
Angiolipoma	0	1 (<0.1)	1 (<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)

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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.)			
Lip squamous cell carcinoma	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)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Skin cancer	2 (<0.1)	1 (<0.1)	3 (<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)
Leiomyosarcoma metastatic	1 (<0.1)	0	1 (<0.1)
Metastases to bone	1 (<0.1)	0	1 (<0.1)
Penile cancer	1 (<0.1)	0	1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	13 (0.3)	28 (0.7)	41 (0.5)
Lymphadenopathy	10 (0.3)	25 (0.7)	35 (0.5)
Anaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood loss anaemia	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 (%)
Blood and lymphatic system disorders (Cont.)			
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	14 (0.4)	7 (0.2)	21 (0.3)
Drug hypersensitivity	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypersensitivity	0	2 (<0.1)	2 (<0.1)
Seasonal allergy	11 (0.3)	2 (<0.1)	13 (0.2)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to chemicals	1 (<0.1)	0	1 (<0.1)
Allergy to metals	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	4 (0.1)	4 (0.1)	8 (0.1)
Goitre	0	1 (<0.1)	1 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Hypothyroidism	3 (<0.1)	1 (<0.1)	4 (<0.1)
Thyroiditis	0	1 (<0.1)	1 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	33 (0.9)	37 (1.0)	70 (0.9)
Hyperlipidaemia	5 (0.1)	9 (0.2)	14 (0.2)
Dehydration	3 (<0.1)	5 (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: >=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)
Gout	4 (0.1)	4 (0.1)	8 (0.1)
Hyponatraemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Decreased appetite	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vitamin D deficiency	0	2 (<0.1)	2 (<0.1)
Diabetes mellitus	3 (<0.1)	1 (<0.1)	4 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypokalaemia	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	2 (<0.1)	0	2 (<0.1)
Dyslipidaemia	1 (<0.1)	0	1 (<0.1)
Hyperuricaemia	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	11 (0.3)	25 (0.7)	36 (0.5)
Anxiety	3 (<0.1)	8 (0.2)	11 (0.1)
Insomnia	4 (0.1)	4 (0.1)	8 (0.1)
Depression	0	3 (<0.1)	3 (<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)
Depressed mood	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)
Suicidal ideation	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	147 (3.9)	162 (4.3)	309 (4.1)
Headache	93 (2.5)	105 (2.8)	198 (2.6)
Dizziness	21 (0.6)	17 (0.5)	38 (0.5)
Sinus headache	1 (<0.1)	6 (0.2)	7 (<0.1)
Paraesthesia	2 (<0.1)	5 (0.1)	7 (<0.1)
Cervical radiculopathy	0	4 (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 (%)
Nervous system disorders (Cont.)			
Sciatica	4 (0.1)	4 (0.1)	8 (0.1)
Hypoaesthesia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Cerebrovascular accident	0	2 (<0.1)	2 (<0.1)
Dysgeusia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Facial paralysis	0	2 (<0.1)	2 (<0.1)
Hyperaesthesia	0	2 (<0.1)	2 (<0.1)
Migraine	3 (<0.1)	2 (<0.1)	5 (<0.1)
Syncope	6 (0.2)	2 (<0.1)	8 (0.1)
Tension headache	0	2 (<0.1)	2 (<0.1)
Ageusia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Amnesia	2 (<0.1)	1 (<0.1)	3 (<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	1 (<0.1)	1 (<0.1)	2 (<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)
Hyposmia	0	1 (<0.1)	1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Piriformis 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: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)			
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)
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)
Neuralgia	2 (<0.1)	0	2 (<0.1)
Neuropathy peripheral	1 (<0.1)	0	1 (<0.1)
Post-traumatic headache	2 (<0.1)	0	2 (<0.1)
Presyncope	3 (<0.1)	0	3 (<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	25 (0.7)	24 (0.6)	49 (0.7)
Eye pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Eye pruritus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cataract	0	2 (<0.1)	2 (<0.1)
Eye irritation	0	2 (<0.1)	2 (<0.1)
Glaucoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Accommodation 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: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Eye disorders (Cont.)			
Blepharitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry eye	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eye disorder	0	1 (<0.1)	1 (<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)
Retinal detachment	1 (<0.1)	1 (<0.1)	2 (<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)
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)
Lacrimation increased	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)
Ocular rosacea	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	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 (%)
Eye disorders (Cont.)			
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	2 (<0.1)	0	2 (<0.1)
Ear and labyrinth disorders	25 (0.7)	20 (0.5)	45 (0.6)
Vertigo	8 (0.2)	8 (0.2)	16 (0.2)
Vertigo positional	0	3 (<0.1)	3 (<0.1)
Ear pain	5 (0.1)	2 (<0.1)	7 (<0.1)
Tinnitus	3 (<0.1)	2 (<0.1)	5 (<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)
Meniere's disease	0	1 (<0.1)	1 (<0.1)
Middle ear effusion	0	1 (<0.1)	1 (<0.1)
Motion sickness	0	1 (<0.1)	1 (<0.1)
Ear discomfort	3 (<0.1)	0	3 (<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)

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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	34 (0.9)	40 (1.1)	74 (1.0)
Atrial fibrillation	8 (0.2)	12 (0.3)	20 (0.3)
Angina pectoris	1 (<0.1)	4 (0.1)	5 (<0.1)
Coronary artery disease	4 (0.1)	4 (0.1)	8 (0.1)
Tachycardia	1 (<0.1)	4 (0.1)	5 (<0.1)
Arrhythmia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Palpitations	1 (<0.1)	3 (<0.1)	4 (<0.1)
Acute coronary syndrome	0	2 (<0.1)	2 (<0.1)
Acute myocardial infarction	3 (<0.1)	2 (<0.1)	5 (<0.1)
Bradycardia	7 (0.2)	2 (<0.1)	9 (0.1)
Cardiac failure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cardiac failure congestive	3 (<0.1)	2 (<0.1)	5 (<0.1)
Myocardial infarction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus tachycardia	0	2 (<0.1)	2 (<0.1)
Cardio-respiratory arrest	0	1 (<0.1)	1 (<0.1)
Cardiomyopathy	0	1 (<0.1)	1 (<0.1)
Coronary artery thrombosis	0	1 (<0.1)	1 (<0.1)
Mitral valve incompetence	0	1 (<0.1)	1 (<0.1)
Pericarditis	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	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)

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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.)			
Extrasystoles	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	70 (1.9)	72 (1.9)	142 (1.9)
Hypertension	54 (1.4)	45 (1.2)	99 (1.3)
Hot flush	3 (<0.1)	8 (0.2)	11 (0.1)
Deep vein thrombosis	0	2 (<0.1)	2 (<0.1)
Flushing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Haematoma	0	2 (<0.1)	2 (<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)
Systolic hypertension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Aortic aneurysm	3 (<0.1)	1 (<0.1)	4 (<0.1)
Arteriosclerosis	0	1 (<0.1)	1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)	1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertensive emergency	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)
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Peripheral vascular 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: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Vascular disorders (Cont.)			
Phlebitis	1 (<0.1)	0	1 (<0.1)
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	149 (4.0)	147 (3.9)	296 (3.9)
Rhinorrhoea	42 (1.1)	48 (1.3)	90 (1.2)
Nasal congestion	34 (0.9)	38 (1.0)	72 (1.0)
Cough	30 (0.8)	37 (1.0)	67 (0.9)
Oropharyngeal pain	39 (1.0)	36 (1.0)	75 (1.0)
Dyspnoea	10 (0.3)	12 (0.3)	22 (0.3)
Sneezing	2 (<0.1)	7 (0.2)	9 (0.1)
Asthma	3 (<0.1)	6 (0.2)	9 (0.1)
Upper-airway cough syndrome	3 (<0.1)	6 (0.2)	9 (0.1)
Respiratory tract congestion	3 (<0.1)	4 (0.1)	7 (<0.1)
Sinus congestion	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)
Tachypnoea	5 (0.1)	3 (<0.1)	8 (0.1)
Chronic obstructive pulmonary disease	6 (0.2)	2 (<0.1)	8 (0.1)
Pharyngeal erythema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Pulmonary embolism	0	2 (<0.1)	2 (<0.1)
Respiratory disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Rhinitis allergic	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.)			
Throat irritation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Acute respiratory failure	0	1 (<0.1)	1 (<0.1)
Allergic sinusitis	0	1 (<0.1)	1 (<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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Nasal septum deviation	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 failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rhonchi	0	1 (<0.1)	1 (<0.1)
Sinus pain	1 (<0.1)	1 (<0.1)	2 (<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)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	0	1 (<0.1)
Pleural effusion	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.)			
Pleuritic pain	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Throat tightness	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	135 (3.6)	155 (4.1)	290 (3.9)
Diarrhoea	55 (1.5)	49 (1.3)	104 (1.4)
Nausea	27 (0.7)	39 (1.0)	66 (0.9)
Gastrooesophageal reflux disease	2 (<0.1)	16 (0.4)	18 (0.2)
Vomiting	10 (0.3)	15 (0.4)	25 (0.3)
Toothache	6 (0.2)	9 (0.2)	15 (0.2)
Abdominal pain	2 (<0.1)	7 (0.2)	9 (0.1)
Abdominal pain upper	3 (<0.1)	5 (0.1)	8 (0.1)
Dyspepsia	4 (0.1)	5 (0.1)	9 (0.1)
Dental caries	2 (<0.1)	4 (0.1)	6 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Constipation	6 (0.2)	3 (<0.1)	9 (0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Abdominal pain lower	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gastrointestinal haemorrhage	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 (%)
Gastrointestinal disorders (Cont.)			
Hypoaesthesia oral	0	2 (<0.1)	2 (<0.1)
Oral mucosal blistering	0	2 (<0.1)	2 (<0.1)
Abdominal discomfort	4 (0.1)	1 (<0.1)	5 (<0.1)
Diverticular perforation	0	1 (<0.1)	1 (<0.1)
Diverticulum intestinal	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)
Flatulence	0	1 (<0.1)	1 (<0.1)
Food poisoning	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastrointestinal pain	0	1 (<0.1)	1 (<0.1)
Haemorrhoids	0	1 (<0.1)	1 (<0.1)
Hiatus hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	1 (<0.1)
Intestinal perforation	0	1 (<0.1)	1 (<0.1)
Large intestine polyp	4 (0.1)	1 (<0.1)	5 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Melaena	0	1 (<0.1)	1 (<0.1)
Oesophageal pain	0	1 (<0.1)	1 (<0.1)
Oesophagitis	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	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: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)			
Rectal haemorrhage	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)
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)
Umbilical hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Abdominal tenderness	1 (<0.1)	0	1 (<0.1)
Anorectal discomfort	1 (<0.1)	0	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)
Gastric perforation	1 (<0.1)	0	1 (<0.1)
Gastritis	2 (<0.1)	0	2 (<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)
Oral cavity fistula	1 (<0.1)	0	1 (<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)

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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 (%)
Hepatobiliary disorders	0	6 (0.2)	6 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Cholecystitis	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Cholelithiasis	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Hepatic steatosis	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	61 (1.6)	88 (2.3)	149 (2.0)
Rash	7 (0.2)	14 (0.4)	21 (0.3)
Erythema	3 (<0.1)	10 (0.3)	13 (0.2)
Urticaria	6 (0.2)	10 (0.3)	16 (0.2)
Pruritus	9 (0.2)	8 (0.2)	17 (0.2)
Dermatitis contact	11 (0.3)	5 (0.1)	16 (0.2)
Actinic keratosis	0	4 (0.1)	4 (<0.1)
Hyperhidrosis	2 (<0.1)	4 (0.1)	6 (<0.1)
Rash macular	3 (<0.1)	4 (0.1)	7 (<0.1)
Dermatitis atopic	0	3 (<0.1)	3 (<0.1)
Skin lesion	3 (<0.1)	3 (<0.1)	6 (<0.1)
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 maculo-papular	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 (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash papular	0	2 (<0.1)	2 (<0.1)
Rash pruritic	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ingrowing nail	0	1 (<0.1)	1 (<0.1)
Lichen sclerosus	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)
Precancerous skin lesion	0	1 (<0.1)	1 (<0.1)
Psoriasis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash erythematous	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)
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)
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)
Ecchymosis	4 (0.1)	0	4 (<0.1)
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Scab	1 (<0.1)	0	1 (<0.1)
Seborrhoeic dermatitis	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.)			
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Urticaria papular	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	208 (5.5)	209 (5.5)	417 (5.5)
Arthralgia	54 (1.4)	64 (1.7)	118 (1.6)
Myalgia	41 (1.1)	56 (1.5)	97 (1.3)
Back pain	39 (1.0)	27 (0.7)	66 (0.9)
Pain in extremity	25 (0.7)	19 (0.5)	44 (0.6)
Neck pain	10 (0.3)	11 (0.3)	21 (0.3)
Musculoskeletal pain	9 (0.2)	10 (0.3)	19 (0.3)
Muscle spasms	7 (0.2)	8 (0.2)	15 (0.2)
Musculoskeletal stiffness	1 (<0.1)	8 (0.2)	9 (0.1)
Arthritis	0	6 (0.2)	6 (<0.1)
Bursitis	2 (<0.1)	5 (0.1)	7 (<0.1)
Tendonitis	5 (0.1)	4 (0.1)	9 (0.1)
Muscular weakness	1 (<0.1)	3 (<0.1)	4 (<0.1)
Musculoskeletal chest pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Osteoarthritis	12 (0.3)	3 (<0.1)	15 (0.2)
Osteoporosis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Spinal stenosis	0	3 (<0.1)	3 (<0.1)
Flank pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Joint swelling	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.)			
Osteopenia	0	2 (<0.1)	2 (<0.1)
Rotator cuff syndrome	5 (0.1)	2 (<0.1)	7 (<0.1)
Trigger finger	1 (<0.1)	2 (<0.1)	3 (<0.1)
Costochondritis	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)
Muscle twitching	0	1 (<0.1)	1 (<0.1)
Neck mass	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Spondylitis	0	1 (<0.1)	1 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Tenosynovitis stenosans	0	1 (<0.1)	1 (<0.1)
Bone lesion	1 (<0.1)	0	1 (<0.1)
Exostosis	1 (<0.1)	0	1 (<0.1)
Fibromyalgia	1 (<0.1)	0	1 (<0.1)
Foot deformity	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 (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Groin pain	1 (<0.1)	0	1 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	0	3 (<0.1)
Limb mass	1 (<0.1)	0	1 (<0.1)
Lumbar spinal stenosis	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)
Renal and urinary disorders	22 (0.6)	25 (0.7)	47 (0.6)
Nephrolithiasis	7 (0.2)	8 (0.2)	15 (0.2)
Pollakiuria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Chronic kidney disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Haematuria	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute kidney injury	4 (0.1)	1 (<0.1)	5 (<0.1)
Bladder diverticulum	0	1 (<0.1)	1 (<0.1)
Bladder prolapse	0	1 (<0.1)	1 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
Dysuria	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)
Polyuria	0	1 (<0.1)	1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urinary hesitation	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 (%)
Renal and urinary disorders (Cont.)			
Urinary incontinence	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urinary retention	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	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)
Reproductive system and breast disorders	5 (0.1)	16 (0.4)	21 (0.3)
Benign prostatic hyperplasia	2 (<0.1)	6 (0.2)	8 (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)
Postmenopausal haemorrhage	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)	1 (<0.1)
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Prostatitis	2 (<0.1)	0	2 (<0.1)
Prostatomegaly	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 (%)
General disorders and administration site conditions	176 (4.7)	275 (7.3)	451 (6.0)
Fatigue	75 (2.0)	119 (3.2)	194 (2.6)
Injection site erythema	9 (0.2)	38 (1.0)	47 (0.6)
Injection site pain	16 (0.4)	35 (0.9)	51 (0.7)
Chills	19 (0.5)	26 (0.7)	45 (0.6)
Pyrexia	13 (0.3)	25 (0.7)	38 (0.5)
Injection site pruritus	2 (<0.1)	21 (0.6)	23 (0.3)
Injection site swelling	7 (0.2)	17 (0.5)	24 (0.3)
Pain	17 (0.5)	17 (0.5)	34 (0.5)
Injection site rash	0	9 (0.2)	9 (0.1)
Injection site macule	0	7 (0.2)	7 (<0.1)
Injection site induration	3 (<0.1)	5 (0.1)	8 (0.1)
Chest discomfort	4 (0.1)	4 (0.1)	8 (0.1)
Injection site urticaria	0	4 (0.1)	4 (<0.1)
Peripheral swelling	5 (0.1)	4 (0.1)	9 (0.1)
Injection site bruising	8 (0.2)	3 (<0.1)	11 (0.1)
Oedema peripheral	5 (0.1)	3 (<0.1)	8 (0.1)
Swelling	0	3 (<0.1)	3 (<0.1)
Axillary pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Chest pain	3 (<0.1)	2 (<0.1)	5 (<0.1)
Injection site haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	2 (<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 (%)
General disorders and administration site conditions (Cont.)			
Injection site warmth	0	2 (<0.1)	2 (<0.1)
Asthenia	1 (<0.1)	1 (<0.1)	2 (<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)
Hernia	0	1 (<0.1)	1 (<0.1)
Inflammation	0	1 (<0.1)	1 (<0.1)
Injection site discolouration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site irritation	0	1 (<0.1)	1 (<0.1)
Injection site joint pain	0	1 (<0.1)	1 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)	2 (<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)
Malaise	5 (0.1)	1 (<0.1)	6 (<0.1)
Temperature intolerance	0	1 (<0.1)	1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Vaccination site pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst	1 (<0.1)	0	1 (<0.1)
Drug intolerance	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 (%)
General disorders and administration site conditions (Cont.)			
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)
Impaired healing	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site haematoma	1 (<0.1)	0	1 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Mass	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)
Systemic inflammatory response syndrome	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	27 (0.7)	42 (1.1)	69 (0.9)
Blood pressure increased	9 (0.2)	11 (0.3)	20 (0.3)
Blood pressure systolic increased	7 (0.2)	7 (0.2)	14 (0.2)
Blood pressure diastolic increased	2 (<0.1)	2 (<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 (%)
Investigations (Cont.)			
Glycosylated haemoglobin increased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Blood cholesterol increased	2 (<0.1)	1 (<0.1)	3 (<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	2 (<0.1)	1 (<0.1)	3 (<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 urine present	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)
Heart rate increased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	0	1 (<0.1)	1 (<0.1)
Hepatitis B antibody positive	0	1 (<0.1)	1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)	1 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Transaminases	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 iron decreased	2 (<0.1)	0	2 (<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 (%)
Investigations (Cont.)			
Body temperature increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	117 (3.1)	113 (3.0)	230 (3.1)
Contusion	9 (0.2)	12 (0.3)	21 (0.3)
Fall	9 (0.2)	11 (0.3)	20 (0.3)
Arthropod bite	6 (0.2)	10 (0.3)	16 (0.2)
Muscle strain	7 (0.2)	9 (0.2)	16 (0.2)
Skin laceration	7 (0.2)	9 (0.2)	16 (0.2)
Procedural pain	7 (0.2)	8 (0.2)	15 (0.2)
Tooth fracture	6 (0.2)	8 (0.2)	14 (0.2)
Ligament sprain	5 (0.1)	7 (0.2)	12 (0.2)
Limb injury	4 (0.1)	5 (0.1)	9 (0.1)
Road traffic accident	4 (0.1)	4 (0.1)	8 (0.1)
Animal bite	2 (<0.1)	3 (<0.1)	5 (<0.1)
Foot fracture	5 (0.1)	3 (<0.1)	8 (0.1)
Rib fracture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Skin abrasion	8 (0.2)	3 (<0.1)	11 (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)

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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 (%)
Injury, poisoning and procedural complications (Cont.)			
Post-traumatic pain	3 (<0.1)	2 (<0.1)	5 (<0.1)
Subdural haematoma	0	2 (<0.1)	2 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<0.1)
Arthropod sting	8 (0.2)	1 (<0.1)	9 (0.1)
Back injury	0	1 (<0.1)	1 (<0.1)
Bone contusion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Burns first degree	0	1 (<0.1)	1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Corneal abrasion	0	1 (<0.1)	1 (<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)
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)

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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 (%)
Injury, poisoning and procedural complications (Cont.)			
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)
Spinal compression fracture	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 fracture	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Vaccination complication	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ankle fracture	1 (<0.1)	0	1 (<0.1)
Buttock injury	1 (<0.1)	0	1 (<0.1)
Clavicle fracture	1 (<0.1)	0	1 (<0.1)
Ear injury	1 (<0.1)	0	1 (<0.1)
Exposure to SARS-CoV-2	2 (<0.1)	0	2 (<0.1)
Eye injury	2 (<0.1)	0	2 (<0.1)
Foreign body	1 (<0.1)	0	1 (<0.1)
Foreign body in ear	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)

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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.)			
Periorbital haemorrhage	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)
Pulmonary contusion	1 (<0.1)	0	1 (<0.1)
Repetitive strain injury	1 (<0.1)	0	1 (<0.1)
Scar	1 (<0.1)	0	1 (<0.1)
Sunburn	1 (<0.1)	0	1 (<0.1)
Tendon injury	1 (<0.1)	0	1 (<0.1)
Thoracic vertebral fracture	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	6 (0.2)	10 (0.3)	16 (0.2)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cataract operation	0	1 (<0.1)	1 (<0.1)
Curetting of chalazion	0	1 (<0.1)	1 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Influenza immunisation	0	1 (<0.1)	1 (<0.1)
Knee arthroplasty	0	1 (<0.1)	1 (<0.1)
Pancreatic stent placement	0	1 (<0.1)	1 (<0.1)
Skin cyst excision	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 (%)
Surgical and medical procedures (Cont.)			
Skin neoplasm excision	0	1 (<0.1)	1 (<0.1)
Skin operation	0	1 (<0.1)	1 (<0.1)
Transfusion	0	1 (<0.1)	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Tooth extraction	3 (<0.1)	0	3 (<0.1)
Tooth repair	1 (<0.1)	0	1 (<0.1)
Product issues	3 (<0.1)	1 (<0.1)	4 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Device physical property issue	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 14.3.1.8.7
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3179 (21.8)	3520 (24.2)	6699 (23.0)
Number of Unsolicited Adverse Events	5909	6578	12487
Infections and infestations	719 (4.9)	584 (4.0)	1303 (4.5)
Urinary tract infection	100 (0.7)	82 (0.6)	182 (0.6)
Sinusitis	32 (0.2)	53 (0.4)	85 (0.3)
Upper respiratory tract infection	72 (0.5)	48 (0.3)	120 (0.4)
Viral infection	27 (0.2)	22 (0.2)	49 (0.2)
Rhinovirus infection	15 (0.1)	20 (0.1)	35 (0.1)
Tooth infection	13 (<0.1)	19 (0.1)	32 (0.1)
Herpes zoster	13 (<0.1)	18 (0.1)	31 (0.1)
Tooth abscess	22 (0.2)	18 (0.1)	40 (0.1)
Gastroenteritis	16 (0.1)	17 (0.1)	33 (0.1)
COVID-19	119 (0.8)	16 (0.1)	135 (0.5)
Ear infection	10 (<0.1)	16 (0.1)	26 (<0.1)
Pharyngitis	20 (0.1)	15 (0.1)	35 (0.1)
Cellulitis	12 (<0.1)	12 (<0.1)	24 (<0.1)
Conjunctivitis	8 (<0.1)	12 (<0.1)	20 (<0.1)
Pharyngitis streptococcal	17 (0.1)	12 (<0.1)	29 (<0.1)
Gingivitis	4 (<0.1)	10 (<0.1)	14 (<0.1)
Oral herpes	6 (<0.1)	10 (<0.1)	16 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Hordeolum	9 (<0.1)	8 (<0.1)	17 (<0.1)
Viral upper respiratory tract infection	11 (<0.1)	8 (<0.1)	19 (<0.1)
Diverticulitis	8 (<0.1)	7 (<0.1)	15 (<0.1)
Localised infection	8 (<0.1)	7 (<0.1)	15 (<0.1)
Otitis media	7 (<0.1)	7 (<0.1)	14 (<0.1)
Pneumonia	8 (<0.1)	7 (<0.1)	15 (<0.1)
Bacterial vaginosis	5 (<0.1)	6 (<0.1)	11 (<0.1)
Enterovirus infection	1 (<0.1)	6 (<0.1)	7 (<0.1)
Fungal infection	6 (<0.1)	6 (<0.1)	12 (<0.1)
Herpes simplex	3 (<0.1)	6 (<0.1)	9 (<0.1)
Acute sinusitis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Folliculitis	6 (<0.1)	5 (<0.1)	11 (<0.1)
Onychomycosis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Otitis externa	11 (<0.1)	5 (<0.1)	16 (<0.1)
Paronychia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)	9 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Vulvovaginal mycotic infection	13 (<0.1)	5 (<0.1)	18 (<0.1)
Bronchitis	6 (<0.1)	4 (<0.1)	10 (<0.1)
Skin infection	3 (<0.1)	4 (<0.1)	7 (<0.1)
Suspected COVID-19	10 (<0.1)	4 (<0.1)	14 (<0.1)
Abscess limb	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Asymptomatic COVID-19	2 (<0.1)	3 (<0.1)	5 (<0.1)
Clostridium difficile infection	0	3 (<0.1)	3 (<0.1)
Furuncle	0	3 (<0.1)	3 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Impetigo	0	3 (<0.1)	3 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Respiratory tract infection viral	6 (<0.1)	3 (<0.1)	9 (<0.1)
Rhinitis	8 (<0.1)	3 (<0.1)	11 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Subcutaneous abscess	1 (<0.1)	3 (<0.1)	4 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cystitis	6 (<0.1)	2 (<0.1)	8 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Laryngitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Nasopharyngitis	8 (<0.1)	2 (<0.1)	10 (<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)
Tinea pedis	4 (<0.1)	2 (<0.1)	6 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Tonsillitis	9 (<0.1)	2 (<0.1)	11 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abscess	0	1 (<0.1)	1 (<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	1 (<0.1)	1 (<0.1)	2 (<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)
Clostridium difficile colitis	0	1 (<0.1)	1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastroenteritis viral	8 (<0.1)	1 (<0.1)	9 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Injection site infection	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 14.3.1.8.7
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
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)
Lyme disease	0	1 (<0.1)	1 (<0.1)
Nail infection	0	1 (<0.1)	1 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)	2 (<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)
Pyelonephritis acute	0	1 (<0.1)	1 (<0.1)
Rash pustular	0	1 (<0.1)	1 (<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)
Upper respiratory tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urinary tract infection bacterial	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Urosepsis	0	1 (<0.1)	1 (<0.1)
Uterine infection	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bacterial vulvovaginitis	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)
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
COVID-19 pneumonia	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)
Fungal skin infection	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)
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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
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)
Postoperative wound 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 bacterial infection	2 (<0.1)	0	2 (<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 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)	38 (0.3)	48 (0.3)	86 (0.3)
Basal cell carcinoma	13 (<0.1)	7 (<0.1)	20 (<0.1)
Squamous cell carcinoma	6 (<0.1)	4 (<0.1)	10 (<0.1)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Lipoma	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Malignant melanoma	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)	5 (<0.1)
Uterine leiomyoma	0	2 (<0.1)	2 (<0.1)
Angiolipoma	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)
Colorectal cancer	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)	2 (<0.1)
Invasive lobular breast carcinoma	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 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 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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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Papillary thyroid cancer	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)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Skin cancer	1 (<0.1)	1 (<0.1)	2 (<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 metastatic	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)
Hepatic cancer	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)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Thyroid cancer	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Blood and lymphatic system disorders	85 (0.6)	152 (1.0)	237 (0.8)
Lymphadenopathy	70 (0.5)	127 (0.9)	197 (0.7)
Anaemia	1 (<0.1)	10 (<0.1)	11 (<0.1)
Lymphadenitis	3 (<0.1)	8 (<0.1)	11 (<0.1)
Lymph node pain	5 (<0.1)	3 (<0.1)	8 (<0.1)
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	5 (<0.1)	1 (<0.1)	6 (<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	43 (0.3)	27 (0.2)	70 (0.2)
Seasonal allergy	28 (0.2)	18 (0.1)	46 (0.2)
Hypersensitivity	3 (<0.1)	5 (<0.1)	8 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Drug hypersensitivity	4 (<0.1)	1 (<0.1)	5 (<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 metals	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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Immune system disorders (Cont.)			
Serum sickness	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	10 (<0.1)	7 (<0.1)	17 (<0.1)
Hypothyroidism	6 (<0.1)	6 (<0.1)	12 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Goitre	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	75 (0.5)	78 (0.5)	153 (0.5)
Hyperlipidaemia	12 (<0.1)	15 (0.1)	27 (<0.1)
Decreased appetite	7 (<0.1)	10 (<0.1)	17 (<0.1)
Type 2 diabetes mellitus	3 (<0.1)	10 (<0.1)	13 (<0.1)
Dehydration	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hypercholesterolaemia	12 (<0.1)	7 (<0.1)	19 (<0.1)
Vitamin D deficiency	9 (<0.1)	6 (<0.1)	15 (<0.1)
Diabetes mellitus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Gout	7 (<0.1)	3 (<0.1)	10 (<0.1)
Hyperglycaemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypertriglyceridaemia	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Metabolism and nutrition disorders (Cont.)			
Abnormal loss of weight	0	2 (<0.1)	2 (<0.1)
Glucose tolerance impaired	4 (<0.1)	2 (<0.1)	6 (<0.1)
Hyponatraemia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Food intolerance	0	1 (<0.1)	1 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypokalaemia	2 (<0.1)	1 (<0.1)	3 (<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	3 (<0.1)	0	3 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hyperkalaemia	1 (<0.1)	0	1 (<0.1)
Hyperuricaemia	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	2 (<0.1)	0	2 (<0.1)
Obesity	1 (<0.1)	0	1 (<0.1)
Polydipsia	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Psychiatric disorders	74 (0.5)	102 (0.7)	176 (0.6)
Anxiety	25 (0.2)	30 (0.2)	55 (0.2)
Depression	16 (0.1)	25 (0.2)	41 (0.1)
Insomnia	14 (<0.1)	17 (0.1)	31 (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	5 (<0.1)	4 (<0.1)	9 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)	4 (<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)
Claustrophobia	0	1 (<0.1)	1 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Depressed mood	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	2 (<0.1)	1 (<0.1)	3 (<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 14.3.1.8.7
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) 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)
Suicidal ideation	1 (<0.1)	1 (<0.1)	2 (<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)
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)
Nervous system disorders	592 (4.1)	663 (4.6)	1255 (4.3)
Headache	434 (3.0)	451 (3.1)	885 (3.0)
Dizziness	51 (0.3)	63 (0.4)	114 (0.4)
Paraesthesia	23 (0.2)	28 (0.2)	51 (0.2)
Sinus headache	6 (<0.1)	13 (<0.1)	19 (<0.1)
Dysgeusia	6 (<0.1)	12 (<0.1)	18 (<0.1)
Syncope	14 (<0.1)	12 (<0.1)	26 (<0.1)
Migraine	16 (0.1)	11 (<0.1)	27 (<0.1)
Sciatica	9 (<0.1)	11 (<0.1)	20 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
Hypoaesthesia	7 (<0.1)	10 (<0.1)	17 (<0.1)
Ageusia	7 (<0.1)	9 (<0.1)	16 (<0.1)
Tension headache	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hyperaesthesia	0	6 (<0.1)	6 (<0.1)
Presyncope	12 (<0.1)	6 (<0.1)	18 (<0.1)
Anosmia	6 (<0.1)	5 (<0.1)	11 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	4 (<0.1)	8 (<0.1)
Cervical radiculopathy	0	4 (<0.1)	4 (<0.1)
Disturbance in attention	1 (<0.1)	4 (<0.1)	5 (<0.1)
Cerebrovascular accident	0	3 (<0.1)	3 (<0.1)
Mental impairment	0	3 (<0.1)	3 (<0.1)
Burning sensation	0	2 (<0.1)	2 (<0.1)
Nerve compression	0	2 (<0.1)	2 (<0.1)
Neuropathy peripheral	0	2 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)	2 (<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)
Aura	0	1 (<0.1)	1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Balance disorder	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 14.3.1.8.7
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cerebral small vessel ischaemic disease	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)
Facial paralysis	1 (<0.1)	1 (<0.1)	2 (<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)
Neuralgia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Piriformis syndrome	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	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)
Subarachnoid haemorrhage	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Taste disorder	2 (<0.1)	1 (<0.1)	3 (<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)
Aphasia	1 (<0.1)	0	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dementia	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Dyskinesia	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)
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	52 (0.4)	50 (0.3)	102 (0.3)
Eye pruritus	5 (<0.1)	7 (<0.1)	12 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Eye disorders (Cont.)			
Eye irritation	0	5 (<0.1)	5 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	3 (<0.1)	4 (<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)
Retinal detachment	2 (<0.1)	2 (<0.1)	4 (<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	2 (<0.1)	2 (<0.1)	4 (<0.1)
Vitreous floaters	2 (<0.1)	2 (<0.1)	4 (<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)
Cataract	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)
Dry eye	6 (<0.1)	1 (<0.1)	7 (<0.1)
Eye discharge	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye disorder	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Eye disorders (Cont.)			
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)
Ocular hyperaemia	6 (<0.1)	1 (<0.1)	7 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Scleritis	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)
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)
Ocular rosacea	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 haemorrhage	1 (<0.1)	0	1 (<0.1)
Strabismus	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Eye disorders (Cont.)			
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)
Vitreous detachment	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	66 (0.5)	57 (0.4)	123 (0.4)
Vertigo	16 (0.1)	16 (0.1)	32 (0.1)
Ear pain	16 (0.1)	13 (<0.1)	29 (<0.1)
Tinnitus	10 (<0.1)	9 (<0.1)	19 (<0.1)
Vertigo positional	1 (<0.1)	5 (<0.1)	6 (<0.1)
Cerumen impaction	2 (<0.1)	2 (<0.1)	4 (<0.1)
Ear canal erythema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ear discomfort	5 (<0.1)	2 (<0.1)	7 (<0.1)
Middle ear effusion	3 (<0.1)	2 (<0.1)	5 (<0.1)
Motion sickness	0	2 (<0.1)	2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<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)
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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Ear and labyrinth disorders (Cont.)			
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	0	4 (<0.1)
Cardiac disorders	62 (0.4)	57 (0.4)	119 (0.4)
Bradycardia	18 (0.1)	12 (<0.1)	30 (0.1)
Tachycardia	10 (<0.1)	12 (<0.1)	22 (<0.1)
Atrial fibrillation	8 (<0.1)	9 (<0.1)	17 (<0.1)
Palpitations	6 (<0.1)	5 (<0.1)	11 (<0.1)
Angina pectoris	2 (<0.1)	3 (<0.1)	5 (<0.1)
Cardiac failure congestive	3 (<0.1)	3 (<0.1)	6 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)	6 (<0.1)
Myocardial infarction	0	3 (<0.1)	3 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arrhythmia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sinus tachycardia	0	2 (<0.1)	2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	0	1 (<0.1)	1 (<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)
Coronary artery thrombosis	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Cardiac disorders (Cont.)			
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)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)
Extrasystoles	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	149 (1.0)	156 (1.1)	305 (1.0)
Hypertension	115 (0.8)	117 (0.8)	232 (0.8)
Hot flush	6 (<0.1)	12 (<0.1)	18 (<0.1)
Flushing	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hypertensive urgency	2 (<0.1)	4 (<0.1)	6 (<0.1)
Systolic hypertension	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hypotension	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematoma	3 (<0.1)	2 (<0.1)	5 (<0.1)
Orthostatic hypotension	0	2 (<0.1)	2 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Vascular disorders (Cont.)			
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)
Blood pressure inadequately controlled	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)
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)
Varicose vein	1 (<0.1)	0	1 (<0.1)
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	565 (3.9)	516 (3.5)	1081 (3.7)
Cough	155 (1.1)	161 (1.1)	316 (1.1)
Oropharyngeal pain	198 (1.4)	138 (0.9)	336 (1.2)
Nasal congestion	138 (0.9)	130 (0.9)	268 (0.9)
Rhinorrhoea	132 (0.9)	126 (0.9)	258 (0.9)
Dyspnoea	38 (0.3)	45 (0.3)	83 (0.3)
Tachypnoea	31 (0.2)	32 (0.2)	63 (0.2)
Sinus congestion	24 (0.2)	16 (0.1)	40 (0.1)
Throat irritation	13 (<0.1)	16 (0.1)	29 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Epistaxis	8 (<0.1)	13 (<0.1)	21 (<0.1)
Upper-airway cough syndrome	10 (<0.1)	12 (<0.1)	22 (<0.1)
Asthma	11 (<0.1)	11 (<0.1)	22 (<0.1)
Respiratory tract congestion	9 (<0.1)	9 (<0.1)	18 (<0.1)
Sneezing	9 (<0.1)	8 (<0.1)	17 (<0.1)
Rhinitis allergic	10 (<0.1)	7 (<0.1)	17 (<0.1)
Chronic obstructive pulmonary disease	10 (<0.1)	6 (<0.1)	16 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)	7 (<0.1)
Pharyngeal erythema	4 (<0.1)	4 (<0.1)	8 (<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	8 (<0.1)	3 (<0.1)	11 (<0.1)
Dyspnoea exertional	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)	6 (<0.1)
Sinus pain	4 (<0.1)	3 (<0.1)	7 (<0.1)
Wheezing	2 (<0.1)	3 (<0.1)	5 (<0.1)
Allergic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bronchiectasis	0	2 (<0.1)	2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Respiratory failure	0	2 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Acute respiratory failure	0	1 (<0.1)	1 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)	1 (<0.1)
Hypoxia	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)
Nasal septum deviation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Respiratory symptom	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)	1 (<0.1)
Sputum increased	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)
Emphysema	1 (<0.1)	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Painful respiration	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pleural effusion	4 (<0.1)	0	4 (<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 fibrosis	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Rales	1 (<0.1)	0	1 (<0.1)
Rhinalgia	1 (<0.1)	0	1 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Throat tightness	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	426 (2.9)	466 (3.2)	892 (3.1)
Diarrhoea	158 (1.1)	182 (1.3)	340 (1.2)
Nausea	123 (0.8)	116 (0.8)	239 (0.8)
Vomiting	36 (0.2)	42 (0.3)	78 (0.3)
Gastrooesophageal reflux disease	10 (<0.1)	31 (0.2)	41 (0.1)
Toothache	22 (0.2)	30 (0.2)	52 (0.2)
Abdominal pain	17 (0.1)	20 (0.1)	37 (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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Dental caries	8 (<0.1)	12 (<0.1)	20 (<0.1)
Constipation	11 (<0.1)	11 (<0.1)	22 (<0.1)
Food poisoning	8 (<0.1)	10 (<0.1)	18 (<0.1)
Abdominal pain upper	17 (0.1)	9 (<0.1)	26 (<0.1)
Dyspepsia	14 (<0.1)	9 (<0.1)	23 (<0.1)
Abdominal discomfort	8 (<0.1)	5 (<0.1)	13 (<0.1)
Abdominal pain lower	7 (<0.1)	5 (<0.1)	12 (<0.1)
Colitis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)	6 (<0.1)
Inguinal hernia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)	6 (<0.1)
Gastric ulcer	2 (<0.1)	3 (<0.1)	5 (<0.1)
Haematochezia	0	3 (<0.1)	3 (<0.1)
Hiatus hernia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	3 (<0.1)	5 (<0.1)
Abdominal distension	2 (<0.1)	2 (<0.1)	4 (<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)
Hypoaesthesia oral	0	2 (<0.1)	2 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mouth ulceration	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Paraesthesia oral	3 (<0.1)	2 (<0.1)	5 (<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)
Tongue discolouration	0	2 (<0.1)	2 (<0.1)
Umbilical hernia	2 (<0.1)	2 (<0.1)	4 (<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)
Diverticulum intestinal	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)
Gastrointestinal disorder	0	1 (<0.1)	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	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)
Large intestine polyp	3 (<0.1)	1 (<0.1)	4 (<0.1)
Oesophageal pain	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Peptic ulcer	0	1 (<0.1)	1 (<0.1)
Periodontal disease	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)
Rectal prolapse	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 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)
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 perforation	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 motility disorder	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
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)
Gingival swelling	1 (<0.1)	0	1 (<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)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0	2 (<0.1)
Oral cavity fistula	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 mucosal erythema	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)
Hepatobiliary disorders	1 (<0.1)	12 (<0.1)	13 (<0.1)
Cholelithiasis	0	6 (<0.1)	6 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Hepatobiliary disorders (Cont.)			
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)
Hepatic steatosis	0	1 (<0.1)	1 (<0.1)
Hepatic cyst	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	186 (1.3)	253 (1.7)	439 (1.5)
Rash	27 (0.2)	42 (0.3)	69 (0.2)
Pruritus	18 (0.1)	22 (0.2)	40 (0.1)
Urticaria	18 (0.1)	22 (0.2)	40 (0.1)
Dermatitis contact	25 (0.2)	20 (0.1)	45 (0.2)
Erythema	5 (<0.1)	15 (0.1)	20 (<0.1)
Hyperhidrosis	14 (<0.1)	11 (<0.1)	25 (<0.1)
Rash maculo-papular	1 (<0.1)	11 (<0.1)	12 (<0.1)
Night sweats	6 (<0.1)	9 (<0.1)	15 (<0.1)
Rash papular	3 (<0.1)	9 (<0.1)	12 (<0.1)
Dermatitis	4 (<0.1)	8 (<0.1)	12 (<0.1)
Acne	5 (<0.1)	6 (<0.1)	11 (<0.1)
Alopecia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Actinic keratosis	0	5 (<0.1)	5 (<0.1)
Rash erythematous	2 (<0.1)	5 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash macular	3 (<0.1)	5 (<0.1)	8 (<0.1)
Rash pruritic	2 (<0.1)	5 (<0.1)	7 (<0.1)
Dermatitis atopic	5 (<0.1)	4 (<0.1)	9 (<0.1)
Ecchymosis	5 (<0.1)	4 (<0.1)	9 (<0.1)
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Psoriasis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Rosacea	2 (<0.1)	4 (<0.1)	6 (<0.1)
Skin lesion	4 (<0.1)	4 (<0.1)	8 (<0.1)
Blister	1 (<0.1)	3 (<0.1)	4 (<0.1)
Eczema	3 (<0.1)	3 (<0.1)	6 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)	8 (<0.1)
Dermatitis allergic	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Hidradenitis	0	2 (<0.1)	2 (<0.1)
Macule	0	2 (<0.1)	2 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Ingrowing nail	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	1 (<0.1)
Mechanical urticaria	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)	1 (<0.1)
Rash vesicular	0	1 (<0.1)	1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin ulcer	0	1 (<0.1)	1 (<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)
Rash follicular	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Scab	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	597 (4.1)	654 (4.5)	1251 (4.3)
Myalgia	164 (1.1)	202 (1.4)	366 (1.3)
Arthralgia	177 (1.2)	198 (1.4)	375 (1.3)
Back pain	105 (0.7)	78 (0.5)	183 (0.6)
Pain in extremity	71 (0.5)	59 (0.4)	130 (0.4)
Neck pain	27 (0.2)	37 (0.3)	64 (0.2)
Muscle spasms	15 (0.1)	31 (0.2)	46 (0.2)
Musculoskeletal pain	25 (0.2)	30 (0.2)	55 (0.2)
Tendonitis	10 (<0.1)	14 (<0.1)	24 (<0.1)
Musculoskeletal chest pain	12 (<0.1)	13 (<0.1)	25 (<0.1)
Musculoskeletal stiffness	12 (<0.1)	13 (<0.1)	25 (<0.1)
Arthritis	1 (<0.1)	8 (<0.1)	9 (<0.1)
Bursitis	4 (<0.1)	8 (<0.1)	12 (<0.1)
Osteoarthritis	13 (<0.1)	7 (<0.1)	20 (<0.1)
Rotator cuff syndrome	7 (<0.1)	7 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Groin pain	1 (<0.1)	6 (<0.1)	7 (<0.1)
Joint range of motion decreased	2 (<0.1)	6 (<0.1)	8 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)	6 (<0.1)
Muscular weakness	2 (<0.1)	5 (<0.1)	7 (<0.1)
Bone pain	0	4 (<0.1)	4 (<0.1)
Costochondritis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	4 (<0.1)	5 (<0.1)
Joint swelling	7 (<0.1)	4 (<0.1)	11 (<0.1)
Osteoporosis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pain in jaw	3 (<0.1)	4 (<0.1)	7 (<0.1)
Axillary mass	2 (<0.1)	3 (<0.1)	5 (<0.1)
Flank pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Limb discomfort	3 (<0.1)	3 (<0.1)	6 (<0.1)
Spinal osteoarthritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Spinal stenosis	0	3 (<0.1)	3 (<0.1)
Trigger finger	1 (<0.1)	3 (<0.1)	4 (<0.1)
Exostosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fibromyalgia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Joint stiffness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle twitching	2 (<0.1)	2 (<0.1)	4 (<0.1)
Neck mass	0	2 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteopenia	0	2 (<0.1)	2 (<0.1)
Plantar fasciitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Spinal pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bone lesion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bone swelling	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Limb mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)	2 (<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)
Undifferentiated connective tissue disease	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0	1 (<0.1)
Femoroacetabular impingement	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Foot deformity	2 (<0.1)	0	2 (<0.1)
Intervertebral disc disorder	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Synovial cyst	2 (<0.1)	0	2 (<0.1)
Synovitis	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	39 (0.3)	39 (0.3)	78 (0.3)
Nephrolithiasis	20 (0.1)	12 (<0.1)	32 (0.1)
Dysuria	3 (<0.1)	5 (<0.1)	8 (<0.1)
Pollakiuria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematuria	7 (<0.1)	2 (<0.1)	9 (<0.1)
Polyuria	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acute kidney injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bladder diverticulum	0	1 (<0.1)	1 (<0.1)
Bladder pain	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Renal and urinary disorders (Cont.)			
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)
Hypertonic bladder	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)
Renal cyst	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 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)
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)
Reproductive system and breast disorders	39 (0.3)	49 (0.3)	88 (0.3)
Benign prostatic hyperplasia	6 (<0.1)	5 (<0.1)	11 (<0.1)
Dysmenorrhoea	3 (<0.1)	4 (<0.1)	7 (<0.1)
Erectile dysfunction	2 (<0.1)	4 (<0.1)	6 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Reproductive system and breast disorders (Cont.)			
Pelvic pain	0	4 (<0.1)	4 (<0.1)
Menorrhagia	0	3 (<0.1)	3 (<0.1)
Breast pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostatitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Uterine haemorrhage	0	2 (<0.1)	2 (<0.1)
Vaginal haemorrhage	0	2 (<0.1)	2 (<0.1)
Adnexal torsion	0	1 (<0.1)	1 (<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 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)
Ejaculation failure	0	1 (<0.1)	1 (<0.1)
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Menopausal symptoms	1 (<0.1)	1 (<0.1)	2 (<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	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Reproductive system and breast disorders (Cont.)			
Ovarian mass	0	1 (<0.1)	1 (<0.1)
Perineal rash	0	1 (<0.1)	1 (<0.1)
Testicular pain	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)
Haematospermia	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)
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	2 (<0.1)	0	2 (<0.1)
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Uterine spasm	2 (<0.1)	0	2 (<0.1)
Vulvovaginal discomfort	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Congenital, familial and genetic disorders	2 (<0.1)	3 (<0.1)	5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)	2 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	2 (<0.1)	0	2 (<0.1)
General disorders and administration site conditions	606 (4.2)	972 (6.7)	1578 (5.4)
Fatigue	330 (2.3)	363 (2.5)	693 (2.4)
Injection site pain	52 (0.4)	144 (1.0)	196 (0.7)
Injection site erythema	19 (0.1)	123 (0.8)	142 (0.5)
Injection site swelling	14 (<0.1)	81 (0.6)	95 (0.3)
Chills	71 (0.5)	79 (0.5)	150 (0.5)
Pyrexia	44 (0.3)	78 (0.5)	122 (0.4)
Injection site pruritus	12 (<0.1)	75 (0.5)	87 (0.3)
Pain	50 (0.3)	56 (0.4)	106 (0.4)
Injection site rash	1 (<0.1)	37 (0.3)	38 (0.1)
Injection site induration	7 (<0.1)	29 (0.2)	36 (0.1)
Axillary pain	11 (<0.1)	25 (0.2)	36 (0.1)
Injection site macule	2 (<0.1)	21 (0.1)	23 (<0.1)
Injection site lymphadenopathy	4 (<0.1)	16 (0.1)	20 (<0.1)
Injection site urticaria	0	15 (0.1)	15 (<0.1)
Chest discomfort	12 (<0.1)	13 (<0.1)	25 (<0.1)
Chest pain	8 (<0.1)	13 (<0.1)	21 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Malaise	9 (<0.1)	12 (<0.1)	21 (<0.1)
Injection site bruising	18 (0.1)	11 (<0.1)	29 (<0.1)
Swelling	1 (<0.1)	10 (<0.1)	11 (<0.1)
Injection site warmth	1 (<0.1)	8 (<0.1)	9 (<0.1)
Injection site haemorrhage	2 (<0.1)	6 (<0.1)	8 (<0.1)
Peripheral swelling	10 (<0.1)	6 (<0.1)	16 (<0.1)
Oedema peripheral	4 (<0.1)	5 (<0.1)	9 (<0.1)
Vaccination site lymphadenopathy	0	5 (<0.1)	5 (<0.1)
Injection site irritation	0	4 (<0.1)	4 (<0.1)
Injection site reaction	0	4 (<0.1)	4 (<0.1)
Non-cardiac chest pain	4 (<0.1)	4 (<0.1)	8 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)
Feeling abnormal	3 (<0.1)	3 (<0.1)	6 (<0.1)
Feeling hot	4 (<0.1)	3 (<0.1)	7 (<0.1)
Injection site haematoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site mass	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vaccination site erythema	0	3 (<0.1)	3 (<0.1)
Vaccination site swelling	0	3 (<0.1)	3 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)	2 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Injection site papule	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site paraesthesia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Injection site scab	0	2 (<0.1)	2 (<0.1)
Swelling face	2 (<0.1)	2 (<0.1)	4 (<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	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)
Influenza like illness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Mass	0	1 (<0.1)	1 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Reactogenicity event	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sensation of foreign body	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Temperature intolerance	0	1 (<0.1)	1 (<0.1)
Vaccination site induration	0	1 (<0.1)	1 (<0.1)
Vaccination site pain	2 (<0.1)	1 (<0.1)	3 (<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	0	1 (<0.1)	1 (<0.1)
Discomfort	2 (<0.1)	0	2 (<0.1)
Gait disturbance	2 (<0.1)	0	2 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Impaired healing	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Instillation site vesicles	1 (<0.1)	0	1 (<0.1)
Medical device site inflammation	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)
Sluggishness	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) 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)
Vessel puncture site pain	1 (<0.1)	0	1 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	63 (0.4)	84 (0.6)	147 (0.5)
Blood pressure increased	24 (0.2)	22 (0.2)	46 (0.2)
Blood pressure systolic increased	10 (<0.1)	15 (0.1)	25 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	9 (<0.1)	11 (<0.1)
Body temperature increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Hepatic enzyme increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Heart rate increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Transaminases increased	0	3 (<0.1)	3 (<0.1)
Blood glucose increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Blood cholesterol increased	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Investigations (Cont.)			
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 parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Blood testosterone decreased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood uric acid increased	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Human rhinovirus test positive	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)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Thyroid function test abnormal	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Investigations (Cont.)			
Transaminases	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)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood prolactin increased	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)
Lipase increased	1 (<0.1)	0	1 (<0.1)
Prostatic specific antigen 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	312 (2.1)	275 (1.9)	587 (2.0)
Muscle strain	29 (0.2)	34 (0.2)	63 (0.2)
Ligament sprain	23 (0.2)	25 (0.2)	48 (0.2)
Skin laceration	28 (0.2)	23 (0.2)	51 (0.2)
Arthropod bite	26 (0.2)	21 (0.1)	47 (0.2)
Contusion	26 (0.2)	18 (0.1)	44 (0.2)
Fall	17 (0.1)	13 (<0.1)	30 (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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
Tooth fracture	14 (<0.1)	13 (<0.1)	27 (<0.1)
Limb injury	8 (<0.1)	12 (<0.1)	20 (<0.1)
Foot fracture	10 (<0.1)	11 (<0.1)	21 (<0.1)
Procedural pain	20 (0.1)	11 (<0.1)	31 (0.1)
Skin abrasion	21 (0.1)	9 (<0.1)	30 (0.1)
Arthropod sting	15 (0.1)	7 (<0.1)	22 (<0.1)
Road traffic accident	5 (<0.1)	6 (<0.1)	11 (<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)
Meniscus injury	3 (<0.1)	4 (<0.1)	7 (<0.1)
Rib fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Wrist fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Epicondylitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Post-traumatic pain	4 (<0.1)	3 (<0.1)	7 (<0.1)
Tendon rupture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Thermal burn	1 (<0.1)	3 (<0.1)	4 (<0.1)
Back injury	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bone contusion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cervical vertebral fracture	0	2 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) 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)
Joint injury	5 (<0.1)	2 (<0.1)	7 (<0.1)
Ligament injury	0	2 (<0.1)	2 (<0.1)
Ligament rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Upper limb fracture	0	2 (<0.1)	2 (<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)
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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
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)
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)
Muscle hernia	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	0	1 (<0.1)	1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post procedural swelling	0	1 (<0.1)	1 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Procedural headache	0	1 (<0.1)	1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Scar	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal compression fracture	0	1 (<0.1)	1 (<0.1)
Stab wound	0	1 (<0.1)	1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)	6 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Uterine rupture	0	1 (<0.1)	1 (<0.1)
Vaccination complication	2 (<0.1)	1 (<0.1)	3 (<0.1)
Wound	2 (<0.1)	1 (<0.1)	3 (<0.1)
Buttock injury	1 (<0.1)	0	1 (<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)
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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
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	2 (<0.1)	0	2 (<0.1)
Procedural nausea	1 (<0.1)	0	1 (<0.1)
Pulmonary contusion	1 (<0.1)	0	1 (<0.1)
Repetitive strain injury	1 (<0.1)	0	1 (<0.1)
Skeletal injury	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Sunburn	3 (<0.1)	0	3 (<0.1)
Superficial injury of eye	1 (<0.1)	0	1 (<0.1)
Trunk injury	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)	12 (<0.1)	24 (<0.1)
Endodontic procedure	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ankle arthroplasty	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Surgical and medical procedures (Cont.)			
Cataract operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curetting of chalazion	0	1 (<0.1)	1 (<0.1)
Dental operation	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)
Tendon sheath incision	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Tooth extraction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Foot 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 repair	3 (<0.1)	0	3 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)	3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)	7 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Device dislocation	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Product issues (Cont.)			
Embedded device	0	1 (<0.1)	1 (<0.1)
Device physical property issue	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.
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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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	63 (18.7)	58 (16.9)	121 (17.8)
Number of Unsolicited Adverse Events	118	120	238
Infections and infestations	11 (3.3)	17 (5.0)	28 (4.1)
COVID-19	5 (1.5)	7 (2.0)	12 (1.8)
Viral infection	2 (0.6)	3 (0.9)	5 (0.7)
Asymptomatic COVID-19	1 (0.3)	1 (0.3)	2 (0.3)
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)	1 (0.3)	3 (0.4)
Lymphadenopathy	2 (0.6)	1 (0.3)	3 (0.4)

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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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
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	1 (0.3)	0	1 (0.1)
Increased appetite	1 (0.3)	0	1 (0.1)
Metabolic acidosis	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	18 (5.3)	11 (3.2)	29 (4.3)
Headache	14 (4.2)	8 (2.3)	22 (3.2)
Dizziness	0	2 (0.6)	2 (0.3)
Ageusia	0	1 (0.3)	1 (0.1)
Hypoaesthesia	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)

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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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Nervous system disorders (Cont.)			
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)	1 (0.3)	2 (0.3)
Angina pectoris	0	1 (0.3)	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)	3 (0.9)	4 (0.6)
Hypertension	1 (0.3)	3 (0.9)	4 (0.6)
Respiratory, thoracic and mediastinal disorders	10 (3.0)	9 (2.6)	19 (2.8)
Nasal congestion	3 (0.9)	4 (1.2)	7 (1.0)
Rhinorrhoea	2 (0.6)	3 (0.9)	5 (0.7)

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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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
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)
Pharyngeal erythema	0	1 (0.3)	1 (0.1)
Productive cough	0	1 (0.3)	1 (0.1)
Respiratory tract congestion	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 (1.7)	11 (1.6)
Diarrhoea	0	3 (0.9)	3 (0.4)
Gastrooesophageal reflux disease	3 (0.9)	2 (0.6)	5 (0.7)
Gastric ulcer	0	1 (0.3)	1 (0.1)
Nausea	1 (0.3)	1 (0.3)	2 (0.3)
Oesophageal ulcer	0	1 (0.3)	1 (0.1)
Umbilical hernia	0	1 (0.3)	1 (0.1)
Abdominal pain	1 (0.3)	0	1 (0.1)
Dyspepsia	1 (0.3)	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: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Hepatobiliary disorders	1 (0.3)	0	1 (0.1)
Cholelithiasis	1 (0.3)	0	1 (0.1)
Skin and subcutaneous tissue disorders	6 (1.8)	6 (1.7)	12 (1.8)
Urticaria	1 (0.3)	2 (0.6)	3 (0.4)
Acne	0	1 (0.3)	1 (0.1)
Ecchymosis	0	1 (0.3)	1 (0.1)
Hyperhidrosis	0	1 (0.3)	1 (0.1)
Rash macular	0	1 (0.3)	1 (0.1)
Blister	1 (0.3)	0	1 (0.1)
Dermatitis contact	1 (0.3)	0	1 (0.1)
Erythema	1 (0.3)	0	1 (0.1)
Night sweats	1 (0.3)	0	1 (0.1)
Rash	1 (0.3)	0	1 (0.1)
Musculoskeletal and connective tissue disorders	17 (5.0)	11 (3.2)	28 (4.1)
Myalgia	3 (0.9)	4 (1.2)	7 (1.0)
Arthralgia	2 (0.6)	2 (0.6)	4 (0.6)
Back pain	4 (1.2)	2 (0.6)	6 (0.9)
Pain in extremity	0	2 (0.6)	2 (0.3)
Limb discomfort	0	1 (0.3)	1 (0.1)
Muscle spasms	0	1 (0.3)	1 (0.1)
Muscle tightness	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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Neck pain	3 (0.9)	1 (0.3)	4 (0.6)
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	4 (1.2)	0	4 (0.6)
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)
Renal and urinary disorders	3 (0.9)	1 (0.3)	4 (0.6)
Dysuria	0	1 (0.3)	1 (0.1)
Chromaturia	1 (0.3)	0	1 (0.1)
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	11 (3.3)	16 (4.7)	27 (4.0)
Fatigue	6 (1.8)	3 (0.9)	9 (1.3)
Injection site pain	1 (0.3)	3 (0.9)	4 (0.6)
Feeling hot	0	2 (0.6)	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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
General disorders and administration site conditions (Cont.)			
Injection site erythema	0	2 (0.6)	2 (0.3)
Chest pain	0	1 (0.3)	1 (0.1)
Chills	1 (0.3)	1 (0.3)	2 (0.3)
Hangover	0	1 (0.3)	1 (0.1)
Injection site bruising	1 (0.3)	1 (0.3)	2 (0.3)
Injection site induration	0	1 (0.3)	1 (0.1)
Injection site lymphadenopathy	0	1 (0.3)	1 (0.1)
Injection site swelling	0	1 (0.3)	1 (0.1)
Oedema peripheral	0	1 (0.3)	1 (0.1)
Pain	1 (0.3)	1 (0.3)	2 (0.3)
Pyrexia	0	1 (0.3)	1 (0.1)
Swelling face	0	1 (0.3)	1 (0.1)
Axillary pain	1 (0.3)	0	1 (0.1)
Non-cardiac chest pain	1 (0.3)	0	1 (0.1)
Investigations	3 (0.9)	3 (0.9)	6 (0.9)
Blood glucose increased	0	1 (0.3)	1 (0.1)
Blood pressure increased	0	1 (0.3)	1 (0.1)
Heart rate increased	0	1 (0.3)	1 (0.1)
Blood pressure systolic increased	1 (0.3)	0	1 (0.1)
Heart rate irregular	1 (0.3)	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 14.3.1.8.7
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Investigations (Cont.)			
International normalised ratio 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	0	1 (0.3)	1 (0.1)
Concussion	1 (0.3)	0	1 (0.1)
Contusion	1 (0.3)	0	1 (0.1)
Ligament sprain	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.
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: Missing

System Organ Class Preferred Term	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	35 (14.9)	54 (18.8)	89 (17.0)
Number of Unsolicited Adverse Events	58	100	158
Infections and infestations	4 (1.7)	10 (3.5)	14 (2.7)
COVID-19	1 (0.4)	1 (0.3)	2 (0.4)
Conjunctivitis	1 (0.4)	1 (0.3)	2 (0.4)
Folliculitis	0	1 (0.3)	1 (0.2)
Herpes simplex	0	1 (0.3)	1 (0.2)
Herpes zoster	0	1 (0.3)	1 (0.2)
Laryngitis	0	1 (0.3)	1 (0.2)
Lyme disease	0	1 (0.3)	1 (0.2)
Pharyngitis	0	1 (0.3)	1 (0.2)
Staphylococcal infection	0	1 (0.3)	1 (0.2)
Urinary tract infection	1 (0.4)	1 (0.3)	2 (0.4)
Breast abscess	1 (0.4)	0	1 (0.2)
Blood and lymphatic system disorders	2 (0.9)	1 (0.3)	3 (0.6)
Lymphadenopathy	2 (0.9)	1 (0.3)	3 (0.6)
Immune system disorders	0	1 (0.3)	1 (0.2)
Seasonal allergy	0	1 (0.3)	1 (0.2)

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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: Missing

System Organ Class Preferred Term	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Psychiatric disorders	0	1 (0.3)	1 (0.2)
Depression	0	1 (0.3)	1 (0.2)
Nervous system disorders	12 (5.1)	10 (3.5)	22 (4.2)
Headache	10 (4.3)	7 (2.4)	17 (3.3)
Anosmia	0	1 (0.3)	1 (0.2)
Dizziness	0	1 (0.3)	1 (0.2)
Dizziness postural	0	1 (0.3)	1 (0.2)
Essential tremor	0	1 (0.3)	1 (0.2)
Horner's syndrome	1 (0.4)	0	1 (0.2)
Nerve compression	1 (0.4)	0	1 (0.2)
Ear and labyrinth disorders	1 (0.4)	2 (0.7)	3 (0.6)
Meniere's disease	0	1 (0.3)	1 (0.2)
Vertigo	0	1 (0.3)	1 (0.2)
Vertigo positional	0	1 (0.3)	1 (0.2)
Ear discomfort	1 (0.4)	0	1 (0.2)
Cardiac disorders	0	1 (0.3)	1 (0.2)
Cardiac failure congestive	0	1 (0.3)	1 (0.2)
Vascular disorders	2 (0.9)	4 (1.4)	6 (1.1)
Hypertension	1 (0.4)	3 (1.0)	4 (0.8)

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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: Missing

System Organ Class Preferred Term	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Vascular disorders (Cont.)			
Haematoma	0	1 (0.3)	1 (0.2)
Hypotension	1 (0.4)	0	1 (0.2)
Respiratory, thoracic and mediastinal disorders	8 (3.4)	11 (3.8)	19 (3.6)
Oropharyngeal pain	2 (0.9)	7 (2.4)	9 (1.7)
Nasal congestion	3 (1.3)	4 (1.4)	7 (1.3)
Cough	0	2 (0.7)	2 (0.4)
Dry throat	0	1 (0.3)	1 (0.2)
Dysphonia	0	1 (0.3)	1 (0.2)
Dyspnoea	0	1 (0.3)	1 (0.2)
Respiratory tract congestion	0	1 (0.3)	1 (0.2)
Rhinorrhoea	2 (0.9)	1 (0.3)	3 (0.6)
Sneezing	0	1 (0.3)	1 (0.2)
Upper-airway cough syndrome	0	1 (0.3)	1 (0.2)
Oropharyngeal discomfort	1 (0.4)	0	1 (0.2)
Productive cough	1 (0.4)	0	1 (0.2)
Sinus congestion	1 (0.4)	0	1 (0.2)
Tachypnoea	1 (0.4)	0	1 (0.2)
Gastrointestinal disorders	9 (3.8)	6 (2.1)	15 (2.9)
Diarrhoea	4 (1.7)	4 (1.4)	8 (1.5)
Abdominal pain upper	0	1 (0.3)	1 (0.2)

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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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Gastrointestinal disorders (Cont.)			
Dyspepsia	0	1 (0.3)	1 (0.2)
Constipation	1 (0.4)	0	1 (0.2)
Inguinal hernia	1 (0.4)	0	1 (0.2)
Nausea	1 (0.4)	0	1 (0.2)
Paraesthesia oral	1 (0.4)	0	1 (0.2)
Toothache	1 (0.4)	0	1 (0.2)
Vomiting	2 (0.9)	0	2 (0.4)
Skin and subcutaneous tissue disorders	1 (0.4)	5 (1.7)	6 (1.1)
Erythema	0	1 (0.3)	1 (0.2)
Nail disorder	0	1 (0.3)	1 (0.2)
Pruritus	0	1 (0.3)	1 (0.2)
Rash erythematous	0	1 (0.3)	1 (0.2)
Urticaria	0	1 (0.3)	1 (0.2)
Rash	1 (0.4)	0	1 (0.2)
Musculoskeletal and connective tissue disorders	3 (1.3)	6 (2.1)	9 (1.7)
Back pain	0	2 (0.7)	2 (0.4)
Joint swelling	0	1 (0.3)	1 (0.2)
Musculoskeletal pain	0	1 (0.3)	1 (0.2)
Myalgia	0	1 (0.3)	1 (0.2)
Neck mass	0	1 (0.3)	1 (0.2)

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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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Arthralgia	2 (0.9)	0	2 (0.4)
Pain in jaw	1 (0.4)	0	1 (0.2)
Reproductive system and breast disorders	0	1 (0.3)	1 (0.2)
Adenomyosis	0	1 (0.3)	1 (0.2)
General disorders and administration site conditions	5 (2.1)	18 (6.3)	23 (4.4)
Fatigue	0	6 (2.1)	6 (1.1)
Injection site pain	1 (0.4)	4 (1.4)	5 (1.0)
Pain	0	3 (1.0)	3 (0.6)
Pyrexia	2 (0.9)	3 (1.0)	5 (1.0)
Chills	0	2 (0.7)	2 (0.4)
Injection site erythema	1 (0.4)	2 (0.7)	3 (0.6)
Hernia	0	1 (0.3)	1 (0.2)
Injection site pruritus	0	1 (0.3)	1 (0.2)
Injection site swelling	1 (0.4)	1 (0.3)	2 (0.4)
Vaccination site lymphadenopathy	0	1 (0.3)	1 (0.2)
Investigations	0	1 (0.3)	1 (0.2)
Blood pressure increased	0	1 (0.3)	1 (0.2)

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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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Injury, poisoning and procedural complications	3 (1.3)	2 (0.7)	5 (1.0)
Joint injury	0	1 (0.3)	1 (0.2)
Procedural pain	0	1 (0.3)	1 (0.2)
Corneal abrasion	1 (0.4)	0	1 (0.2)
Ligament sprain	1 (0.4)	0	1 (0.2)
Limb injury	1 (0.4)	0	1 (0.2)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3765 (25.8)	3930 (27.0)	7695 (26.4)
Number of Unsolicited Adverse Events	7530	7876	15406
Infections and infestations	1099 (7.5)	803 (5.5)	1902 (6.5)
Urinary tract infection	123 (0.8)	106 (0.7)	229 (0.8)
Upper respiratory tract infection	104 (0.7)	93 (0.6)	197 (0.7)
Sinusitis	53 (0.4)	66 (0.5)	119 (0.4)
Viral infection	53 (0.4)	43 (0.3)	96 (0.3)
COVID-19	303 (2.1)	30 (0.2)	333 (1.1)
Rhinovirus infection	26 (0.2)	27 (0.2)	53 (0.2)
Herpes zoster	17 (0.1)	22 (0.2)	39 (0.1)
Ear infection	15 (0.1)	21 (0.1)	36 (0.1)
Suspected COVID-19	27 (0.2)	21 (0.1)	48 (0.2)
Cellulitis	18 (0.1)	20 (0.1)	38 (0.1)
Pharyngitis	30 (0.2)	20 (0.1)	50 (0.2)
Tooth infection	21 (0.1)	20 (0.1)	41 (0.1)
Gastroenteritis	21 (0.1)	19 (0.1)	40 (0.1)
Pharyngitis streptococcal	21 (0.1)	19 (0.1)	40 (0.1)
Tooth abscess	23 (0.2)	18 (0.1)	41 (0.1)
Conjunctivitis	10 (<0.1)	14 (<0.1)	24 (<0.1)
Diverticulitis	10 (<0.1)	12 (<0.1)	22 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.9
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Bronchitis	10 (<0.1)	11 (<0.1)	21 (<0.1)
Oral herpes	7 (<0.1)	11 (<0.1)	18 (<0.1)
Viral upper respiratory tract infection	16 (0.1)	11 (<0.1)	27 (<0.1)
Gingivitis	6 (<0.1)	10 (<0.1)	16 (<0.1)
Hordeolum	14 (<0.1)	10 (<0.1)	24 (<0.1)
Localised infection	9 (<0.1)	10 (<0.1)	19 (<0.1)
Acute sinusitis	6 (<0.1)	9 (<0.1)	15 (<0.1)
Fungal infection	9 (<0.1)	8 (<0.1)	17 (<0.1)
Otitis media	11 (<0.1)	8 (<0.1)	19 (<0.1)
Pneumonia	12 (<0.1)	8 (<0.1)	20 (<0.1)
Respiratory tract infection	6 (<0.1)	8 (<0.1)	14 (<0.1)
Enterovirus infection	1 (<0.1)	7 (<0.1)	8 (<0.1)
Onychomycosis	1 (<0.1)	7 (<0.1)	8 (<0.1)
Otitis externa	11 (<0.1)	7 (<0.1)	18 (<0.1)
Bacterial vaginosis	6 (<0.1)	6 (<0.1)	12 (<0.1)
Folliculitis	7 (<0.1)	6 (<0.1)	13 (<0.1)
Herpes simplex	3 (<0.1)	6 (<0.1)	9 (<0.1)
Skin infection	5 (<0.1)	6 (<0.1)	11 (<0.1)
Paronychia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Rhinitis	8 (<0.1)	5 (<0.1)	13 (<0.1)
Vulvovaginal candidiasis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Vulvovaginal mycotic infection	14 (<0.1)	5 (<0.1)	19 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Asymptomatic COVID-19	7 (<0.1)	4 (<0.1)	11 (<0.1)
Gonorrhoea	2 (<0.1)	4 (<0.1)	6 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Clostridium difficile infection	0	3 (<0.1)	3 (<0.1)
Cystitis	7 (<0.1)	3 (<0.1)	10 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)	4 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Impetigo	1 (<0.1)	3 (<0.1)	4 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Laryngitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Nasopharyngitis	12 (<0.1)	3 (<0.1)	15 (<0.1)
Postoperative wound infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Respiratory tract infection viral	9 (<0.1)	3 (<0.1)	12 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Subcutaneous abscess	1 (<0.1)	3 (<0.1)	4 (<0.1)
Wound infection	3 (<0.1)	3 (<0.1)	6 (<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	1 (<0.1)	2 (<0.1)	3 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lyme disease	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 Preferred Term	Placebo (N=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Oral candidiasis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Otitis media acute	4 (<0.1)	2 (<0.1)	6 (<0.1)
Sepsis	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	4 (<0.1)	2 (<0.1)	6 (<0.1)
Tonsillitis	9 (<0.1)	2 (<0.1)	11 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abscess	1 (<0.1)	1 (<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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Candida infection	4 (<0.1)	1 (<0.1)	5 (<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	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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Eye infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastroenteritis viral	11 (<0.1)	1 (<0.1)	12 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Infected cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Infected dermal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site infection	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)
Nail infection	0	1 (<0.1)	1 (<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)
Pertussis	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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Postoperative abscess	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Pulpitis dental	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pyelonephritis	0	1 (<0.1)	1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)	1 (<0.1)
Rash pustular	0	1 (<0.1)	1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Salpingitis	0	1 (<0.1)	1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Sinusitis bacterial	3 (<0.1)	1 (<0.1)	4 (<0.1)
Streptococcal infection	0	1 (<0.1)	1 (<0.1)
Tinea infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urosepsis	0	1 (<0.1)	1 (<0.1)
Uterine infection	0	1 (<0.1)	1 (<0.1)
Adenovirus infection	1 (<0.1)	0	1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0	1 (<0.1)
Balanitis candida	1 (<0.1)	0	1 (<0.1)
Blastocystis infection	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Breast abscess	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0	2 (<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 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)
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)
Infected skin ulcer	1 (<0.1)	0	1 (<0.1)
Influenza	3 (<0.1)	0	3 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Pustule	1 (<0.1)	0	1 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Skin bacterial infection	2 (<0.1)	0	2 (<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)
Trichomoniasis	1 (<0.1)	0	1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Viral sinusitis	2 (<0.1)	0	2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	49 (0.3)	62 (0.4)	111 (0.4)
Basal cell carcinoma	14 (<0.1)	9 (<0.1)	23 (<0.1)
Squamous cell carcinoma	7 (<0.1)	5 (<0.1)	12 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)	6 (<0.1)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Prostate cancer	4 (<0.1)	3 (<0.1)	7 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	2 (<0.1)	4 (<0.1)
Uterine leiomyoma	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 Preferred Term	Placebo (N=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Angiolipoma	0	1 (<0.1)	1 (<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 cancer in situ	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)
Colorectal cancer	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intraductal proliferative breast lesion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Invasive lobular breast carcinoma	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 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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
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)
Papillary thyroid cancer	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)
Prostate cancer stage I	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Renal cell carcinoma	0	1 (<0.1)	1 (<0.1)
Renal neoplasm	0	1 (<0.1)	1 (<0.1)
Skin cancer	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Benign breast neoplasm	1 (<0.1)	0	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)
Colon cancer stage III	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Hepatic cancer	1 (<0.1)	0	1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0	1 (<0.1)
Metastases to bone	1 (<0.1)	0	1 (<0.1)
Penile cancer	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0	1 (<0.1)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	98 (0.7)	165 (1.1)	263 (0.9)
Lymphadenopathy	78 (0.5)	136 (0.9)	214 (0.7)
Anaemia	4 (<0.1)	11 (<0.1)	15 (<0.1)
Lymphadenitis	3 (<0.1)	10 (<0.1)	13 (<0.1)
Lymph node pain	5 (<0.1)	3 (<0.1)	8 (<0.1)
Thrombocytopenia	0	3 (<0.1)	3 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	7 (<0.1)	1 (<0.1)	8 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Immune system disorders	52 (0.4)	34 (0.2)	86 (0.3)
Seasonal allergy	35 (0.2)	20 (0.1)	55 (0.2)
Hypersensitivity	4 (<0.1)	5 (<0.1)	9 (<0.1)
Drug hypersensitivity	4 (<0.1)	4 (<0.1)	8 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anaphylactic reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Immune system disorder	0	1 (<0.1)	1 (<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 metals	2 (<0.1)	0	2 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Serum sickness	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	10 (<0.1)	16 (0.1)	26 (<0.1)
Hypothyroidism	6 (<0.1)	9 (<0.1)	15 (<0.1)
Thyroid mass	0	2 (<0.1)	2 (<0.1)
Goitre	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperparathyroidism	0	1 (<0.1)	1 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Thyroid disorder	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Endocrine disorders (Cont.)			
Thyroiditis	0	1 (<0.1)	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	104 (0.7)	94 (0.6)	198 (0.7)
Hyperlipidaemia	18 (0.1)	16 (0.1)	34 (0.1)
Type 2 diabetes mellitus	3 (<0.1)	13 (<0.1)	16 (<0.1)
Decreased appetite	9 (<0.1)	10 (<0.1)	19 (<0.1)
Hypercholesterolaemia	15 (0.1)	10 (<0.1)	25 (<0.1)
Dehydration	10 (<0.1)	8 (<0.1)	18 (<0.1)
Vitamin D deficiency	11 (<0.1)	7 (<0.1)	18 (<0.1)
Gout	9 (<0.1)	5 (<0.1)	14 (<0.1)
Diabetes mellitus	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hyperglycaemia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Hyponatraemia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Abnormal loss of weight	2 (<0.1)	2 (<0.1)	4 (<0.1)
Glucose tolerance impaired	4 (<0.1)	2 (<0.1)	6 (<0.1)
Hypokalaemia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Insulin resistance	0	2 (<0.1)	2 (<0.1)
Diabetes mellitus inadequate control	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Metabolism and nutrition disorders (Cont.)			
Diabetic ketoacidosis	0	1 (<0.1)	1 (<0.1)
Food intolerance	0	1 (<0.1)	1 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypocalcaemia	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	4 (<0.1)	0	4 (<0.1)
Electrolyte imbalance	1 (<0.1)	0	1 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hyperuricaemia	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	2 (<0.1)	0	2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Obesity	1 (<0.1)	0	1 (<0.1)
Polydipsia	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	94 (0.6)	116 (0.8)	210 (0.7)
Anxiety	30 (0.2)	36 (0.2)	66 (0.2)

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MedDRA version 23.0.
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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Psychiatric disorders (Cont.)			
Depression	23 (0.2)	26 (0.2)	49 (0.2)
Insomnia	16 (0.1)	20 (0.1)	36 (0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	6 (<0.1)	15 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<0.1)
Sleep disorder	0	5 (<0.1)	5 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)	4 (<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)
Claustrophobia	0	1 (<0.1)	1 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Depressed mood	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	3 (<0.1)	1 (<0.1)	4 (<0.1)
Panic attack	3 (<0.1)	1 (<0.1)	4 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Psychiatric disorders (Cont.)			
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)
Suicidal ideation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Confusional state	2 (<0.1)	0	2 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Dissociative disorder	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)
Nervous system disorders	709 (4.9)	738 (5.1)	1447 (5.0)
Headache	514 (3.5)	495 (3.4)	1009 (3.5)
Dizziness	64 (0.4)	69 (0.5)	133 (0.5)
Paraesthesia	25 (0.2)	29 (0.2)	54 (0.2)
Presyncope	14 (<0.1)	14 (<0.1)	28 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
Sinus headache	6 (<0.1)	14 (<0.1)	20 (<0.1)
Migraine	19 (0.1)	13 (<0.1)	32 (0.1)
Sciatica	10 (<0.1)	13 (<0.1)	23 (<0.1)
Syncope	26 (0.2)	13 (<0.1)	39 (0.1)
Dysgeusia	6 (<0.1)	12 (<0.1)	18 (<0.1)
Ageusia	17 (0.1)	11 (<0.1)	28 (<0.1)
Hypoaesthesia	8 (<0.1)	11 (<0.1)	19 (<0.1)
Anosmia	11 (<0.1)	10 (<0.1)	21 (<0.1)
Tension headache	4 (<0.1)	8 (<0.1)	12 (<0.1)
Cervical radiculopathy	0	6 (<0.1)	6 (<0.1)
Hyperaesthesia	0	6 (<0.1)	6 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	4 (<0.1)	8 (<0.1)
Cerebrovascular accident	1 (<0.1)	4 (<0.1)	5 (<0.1)
Disturbance in attention	1 (<0.1)	4 (<0.1)	5 (<0.1)
Burning sensation	0	3 (<0.1)	3 (<0.1)
Facial paralysis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mental impairment	0	3 (<0.1)	3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Lethargy	0	2 (<0.1)	2 (<0.1)
Nerve compression	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neuropathy peripheral	2 (<0.1)	2 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
Peripheral sensory neuropathy	0	2 (<0.1)	2 (<0.1)
Somnolence	0	2 (<0.1)	2 (<0.1)
Transient ischaemic attack	0	2 (<0.1)	2 (<0.1)
Amnesia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Aura	0	1 (<0.1)	1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Cerebral small vessel ischaemic disease	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)
Head discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Idiopathic intracranial hypertension	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Neuralgia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Parosmia	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
Piriformis syndrome	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)	1 (<0.1)
Post-traumatic headache	2 (<0.1)	1 (<0.1)	3 (<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)
Subarachnoid haemorrhage	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Taste disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
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)
Aphasia	1 (<0.1)	0	1 (<0.1)
Arachnoid cyst	1 (<0.1)	0	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dementia	1 (<0.1)	0	1 (<0.1)
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Dyskinesia	1 (<0.1)	0	1 (<0.1)
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Multiple sclerosis	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
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)
Thoracic radiculopathy	1 (<0.1)	0	1 (<0.1)
Eye disorders	60 (0.4)	63 (0.4)	123 (0.4)
Eye pruritus	5 (<0.1)	8 (<0.1)	13 (<0.1)
Eye irritation	0	5 (<0.1)	5 (<0.1)
Blepharitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	3 (<0.1)	4 (<0.1)
Eye pain	2 (<0.1)	3 (<0.1)	5 (<0.1)
Retinal detachment	2 (<0.1)	3 (<0.1)	5 (<0.1)
Vision blurred	6 (<0.1)	3 (<0.1)	9 (<0.1)
Cataract	1 (<0.1)	2 (<0.1)	3 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)	4 (<0.1)
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	6 (<0.1)	2 (<0.1)	8 (<0.1)
Swelling of eyelid	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Eye disorders (Cont.)			
Visual impairment	2 (<0.1)	2 (<0.1)	4 (<0.1)
Vitreous floaters	2 (<0.1)	2 (<0.1)	4 (<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)
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Dry eye	6 (<0.1)	1 (<0.1)	7 (<0.1)
Eye discharge	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye disorder	0	1 (<0.1)	1 (<0.1)
Eye haemorrhage	0	1 (<0.1)	1 (<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)
Ocular hyperaemia	6 (<0.1)	1 (<0.1)	7 (<0.1)
Orbital haematoma	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Presbyopia	0	1 (<0.1)	1 (<0.1)
Scleritis	0	1 (<0.1)	1 (<0.1)
Vitreous disorder	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) 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)
Ocular rosacea	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 haemorrhage	1 (<0.1)	0	1 (<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)
Vitreous detachment	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	80 (0.5)	64 (0.4)	144 (0.5)
Vertigo	18 (0.1)	22 (0.2)	40 (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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Ear and labyrinth disorders (Cont.)			
Ear pain	24 (0.2)	13 (<0.1)	37 (0.1)
Tinnitus	10 (<0.1)	9 (<0.1)	19 (<0.1)
Vertigo positional	2 (<0.1)	5 (<0.1)	7 (<0.1)
Ear discomfort	6 (<0.1)	3 (<0.1)	9 (<0.1)
Cerumen impaction	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ear canal erythema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Middle ear effusion	3 (<0.1)	2 (<0.1)	5 (<0.1)
Motion sickness	0	2 (<0.1)	2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<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)
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 hyperaemia	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	5 (<0.1)	0	5 (<0.1)
Cardiac disorders	85 (0.6)	80 (0.5)	165 (0.6)
Tachycardia	13 (<0.1)	16 (0.1)	29 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Cardiac disorders (Cont.)			
Atrial fibrillation	10 (<0.1)	14 (<0.1)	24 (<0.1)
Bradycardia	22 (0.2)	13 (<0.1)	35 (0.1)
Palpitations	7 (<0.1)	8 (<0.1)	15 (<0.1)
Angina pectoris	2 (<0.1)	5 (<0.1)	7 (<0.1)
Coronary artery disease	4 (<0.1)	5 (<0.1)	9 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Arrhythmia	5 (<0.1)	3 (<0.1)	8 (<0.1)
Cardiac failure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cardiac failure congestive	5 (<0.1)	3 (<0.1)	8 (<0.1)
Sinus tachycardia	0	3 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	2 (<0.1)	2 (<0.1)
Acute myocardial infarction	4 (<0.1)	2 (<0.1)	6 (<0.1)
Acute left ventricular failure	0	1 (<0.1)	1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Coronary artery thrombosis	0	1 (<0.1)	1 (<0.1)
Mitral valve incompetence	0	1 (<0.1)	1 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Supraventricular extrasystoles	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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Cardiac disorders (Cont.)			
Atrial tachycardia	2 (<0.1)	0	2 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)
Extrasystoles	1 (<0.1)	0	1 (<0.1)
Sinus arrest	1 (<0.1)	0	1 (<0.1)
Sinus bradycardia	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	192 (1.3)	194 (1.3)	386 (1.3)
Hypertension	150 (1.0)	144 (1.0)	294 (1.0)
Hot flush	6 (<0.1)	12 (<0.1)	18 (<0.1)
Flushing	3 (<0.1)	7 (<0.1)	10 (<0.1)
Deep vein thrombosis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hypertensive urgency	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hypotension	5 (<0.1)	4 (<0.1)	9 (<0.1)
Orthostatic hypotension	0	4 (<0.1)	4 (<0.1)
Systolic hypertension	4 (<0.1)	4 (<0.1)	8 (<0.1)
Haematoma	4 (<0.1)	3 (<0.1)	7 (<0.1)
Peripheral coldness	0	2 (<0.1)	2 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Arteriosclerosis	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Vascular disorders (Cont.)			
Axillary vein thrombosis	0	1 (<0.1)	1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertensive emergency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pallor	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)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Blood pressure inadequately controlled	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)
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)
Varicose vein	1 (<0.1)	0	1 (<0.1)
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	698 (4.8)	632 (4.3)	1330 (4.6)
Cough	198 (1.4)	206 (1.4)	404 (1.4)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Oropharyngeal pain	244 (1.7)	188 (1.3)	432 (1.5)
Rhinorrhoea	174 (1.2)	172 (1.2)	346 (1.2)
Nasal congestion	180 (1.2)	171 (1.2)	351 (1.2)
Dyspnoea	53 (0.4)	63 (0.4)	116 (0.4)
Tachypnoea	35 (0.2)	37 (0.3)	72 (0.2)
Sinus congestion	30 (0.2)	22 (0.2)	52 (0.2)
Throat irritation	14 (<0.1)	17 (0.1)	31 (0.1)
Epistaxis	9 (<0.1)	15 (0.1)	24 (<0.1)
Asthma	14 (<0.1)	14 (<0.1)	28 (<0.1)
Upper-airway cough syndrome	13 (<0.1)	14 (<0.1)	27 (<0.1)
Respiratory tract congestion	10 (<0.1)	12 (<0.1)	22 (<0.1)
Sneezing	11 (<0.1)	11 (<0.1)	22 (<0.1)
Rhinitis allergic	13 (<0.1)	10 (<0.1)	23 (<0.1)
Chronic obstructive pulmonary disease	11 (<0.1)	7 (<0.1)	18 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	6 (<0.1)	9 (<0.1)
Pulmonary embolism	5 (<0.1)	5 (<0.1)	10 (<0.1)
Dysphonia	9 (<0.1)	4 (<0.1)	13 (<0.1)
Pharyngeal erythema	5 (<0.1)	4 (<0.1)	9 (<0.1)
Productive cough	6 (<0.1)	4 (<0.1)	10 (<0.1)
Respiratory disorder	6 (<0.1)	4 (<0.1)	10 (<0.1)
Sinus pain	5 (<0.1)	4 (<0.1)	9 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Wheezing	2 (<0.1)	4 (<0.1)	6 (<0.1)
Dry throat	3 (<0.1)	3 (<0.1)	6 (<0.1)
Dyspnoea exertional	2 (<0.1)	3 (<0.1)	5 (<0.1)
Acute respiratory failure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Allergic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bronchiectasis	0	2 (<0.1)	2 (<0.1)
Hypoxia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory symptom	2 (<0.1)	2 (<0.1)	4 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	1 (<0.1)	1 (<0.1)
Emphysema	2 (<0.1)	1 (<0.1)	3 (<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)
Nasal septum deviation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Pneumonia aspiration	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Rhonchi	0	1 (<0.1)	1 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)	1 (<0.1)
Sputum increased	0	1 (<0.1)	1 (<0.1)
Tonsillolith	5 (<0.1)	1 (<0.1)	6 (<0.1)
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Haemoptysis	1 (<0.1)	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Nasal disorder	1 (<0.1)	0	1 (<0.1)
Nasal ulcer	1 (<0.1)	0	1 (<0.1)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Painful respiration	1 (<0.1)	0	1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Pleural effusion	4 (<0.1)	0	4 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pneumothorax	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Rales	1 (<0.1)	0	1 (<0.1)
Rhinalgia	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Throat tightness	2 (<0.1)	0	2 (<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	506 (3.5)	545 (3.7)	1051 (3.6)
Diarrhoea	186 (1.3)	204 (1.4)	390 (1.3)
Nausea	151 (1.0)	142 (1.0)	293 (1.0)
Vomiting	43 (0.3)	51 (0.4)	94 (0.3)
Gastrooesophageal reflux disease	15 (0.1)	39 (0.3)	54 (0.2)
Toothache	28 (0.2)	33 (0.2)	61 (0.2)
Abdominal pain	24 (0.2)	24 (0.2)	48 (0.2)
Constipation	14 (<0.1)	15 (0.1)	29 (<0.1)
Dental caries	9 (<0.1)	14 (<0.1)	23 (<0.1)
Abdominal pain upper	18 (0.1)	12 (<0.1)	30 (0.1)
Food poisoning	10 (<0.1)	10 (<0.1)	20 (<0.1)
Dyspepsia	16 (0.1)	9 (<0.1)	25 (<0.1)
Abdominal pain lower	7 (<0.1)	8 (<0.1)	15 (<0.1)
Colitis	4 (<0.1)	6 (<0.1)	10 (<0.1)
Abdominal discomfort	10 (<0.1)	5 (<0.1)	15 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Haemorrhoids	2 (<0.1)	5 (<0.1)	7 (<0.1)
Gastric ulcer	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haematochezia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hiatus hernia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Inguinal hernia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	3 (<0.1)	5 (<0.1)
Oesophagitis	0	3 (<0.1)	3 (<0.1)
Abdominal distension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Diverticulum	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)	5 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)	2 (<0.1)
Large intestine polyp	4 (<0.1)	2 (<0.1)	6 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)
Melaena	0	2 (<0.1)	2 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oral mucosal blistering	0	2 (<0.1)	2 (<0.1)
Pancreatitis	0	2 (<0.1)	2 (<0.1)

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MedDRA version 23.0.
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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Paraesthesia oral	3 (<0.1)	2 (<0.1)	5 (<0.1)
Proctalgia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Stomatitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Swollen tongue	0	2 (<0.1)	2 (<0.1)
Tongue discolouration	0	2 (<0.1)	2 (<0.1)
Tooth impacted	3 (<0.1)	2 (<0.1)	5 (<0.1)
Umbilical hernia	2 (<0.1)	2 (<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 intestinal	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)
Faeces soft	0	1 (<0.1)	1 (<0.1)
Gastritis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastrointestinal disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intestinal perforation	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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Oesophageal pain	0	1 (<0.1)	1 (<0.1)
Oral pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Peptic ulcer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periodontal disease	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rectal prolapse	0	1 (<0.1)	1 (<0.1)
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 discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Abdominal tenderness	1 (<0.1)	0	1 (<0.1)
Anorectal discomfort	1 (<0.1)	0	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Dysphagia	3 (<0.1)	0	3 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric perforation	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastrointestinal motility disorder	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)
Gingival swelling	1 (<0.1)	0	1 (<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)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0	2 (<0.1)
Oral cavity fistula	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 mucosal erythema	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)
Hepatobiliary disorders	2 (<0.1)	15 (0.1)	17 (<0.1)
Cholelithiasis	0	6 (<0.1)	6 (<0.1)
Cholecystitis	0	4 (<0.1)	4 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Hepatobiliary disorders (Cont.)			
Hepatic mass	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 steatosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic cyst	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	220 (1.5)	271 (1.9)	491 (1.7)
Rash	32 (0.2)	45 (0.3)	77 (0.3)
Urticaria	22 (0.2)	24 (0.2)	46 (0.2)
Pruritus	21 (0.1)	23 (0.2)	44 (0.2)
Dermatitis contact	28 (0.2)	21 (0.1)	49 (0.2)
Erythema	5 (<0.1)	15 (0.1)	20 (<0.1)
Hyperhidrosis	14 (<0.1)	13 (<0.1)	27 (<0.1)
Rash maculo-papular	2 (<0.1)	11 (<0.1)	13 (<0.1)
Night sweats	7 (<0.1)	10 (<0.1)	17 (<0.1)
Rash papular	3 (<0.1)	9 (<0.1)	12 (<0.1)
Dermatitis	7 (<0.1)	8 (<0.1)	15 (<0.1)
Alopecia	3 (<0.1)	7 (<0.1)	10 (<0.1)
Acne	7 (<0.1)	6 (<0.1)	13 (<0.1)
Rash pruritic	4 (<0.1)	6 (<0.1)	10 (<0.1)
Skin lesion	5 (<0.1)	6 (<0.1)	11 (<0.1)
Actinic keratosis	1 (<0.1)	5 (<0.1)	6 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash erythematous	2 (<0.1)	5 (<0.1)	7 (<0.1)
Rash macular	4 (<0.1)	5 (<0.1)	9 (<0.1)
Rosacea	2 (<0.1)	5 (<0.1)	7 (<0.1)
Dermatitis atopic	7 (<0.1)	4 (<0.1)	11 (<0.1)
Ecchymosis	8 (<0.1)	4 (<0.1)	12 (<0.1)
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Psoriasis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Blister	1 (<0.1)	3 (<0.1)	4 (<0.1)
Eczema	4 (<0.1)	3 (<0.1)	7 (<0.1)
Rash vesicular	0	3 (<0.1)	3 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)	8 (<0.1)
Dermatitis allergic	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Hidradenitis	0	2 (<0.1)	2 (<0.1)
Macule	0	2 (<0.1)	2 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Angioedema	3 (<0.1)	1 (<0.1)	4 (<0.1)
Blood blister	0	1 (<0.1)	1 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lichen planus	0	1 (<0.1)	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	1 (<0.1)
Mechanical urticaria	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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)	1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)	2 (<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 ulcer	0	1 (<0.1)	1 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Miliaria	1 (<0.1)	0	1 (<0.1)
Myxoid cyst	1 (<0.1)	0	1 (<0.1)
Rash follicular	1 (<0.1)	0	1 (<0.1)
Scab	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	681 (4.7)	720 (4.9)	1401 (4.8)
Myalgia	194 (1.3)	219 (1.5)	413 (1.4)
Arthralgia	189 (1.3)	212 (1.5)	401 (1.4)
Back pain	117 (0.8)	89 (0.6)	206 (0.7)
Pain in extremity	78 (0.5)	64 (0.4)	142 (0.5)
Neck pain	31 (0.2)	41 (0.3)	72 (0.2)
Musculoskeletal pain	28 (0.2)	34 (0.2)	62 (0.2)
Muscle spasms	18 (0.1)	32 (0.2)	50 (0.2)
Tendonitis	10 (<0.1)	15 (0.1)	25 (<0.1)
Musculoskeletal stiffness	12 (<0.1)	14 (<0.1)	26 (<0.1)
Musculoskeletal chest pain	14 (<0.1)	13 (<0.1)	27 (<0.1)
Arthritis	1 (<0.1)	11 (<0.1)	12 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteoarthritis	20 (0.1)	11 (<0.1)	31 (0.1)
Bursitis	5 (<0.1)	10 (<0.1)	15 (<0.1)
Rotator cuff syndrome	8 (<0.1)	7 (<0.1)	15 (<0.1)
Groin pain	1 (<0.1)	6 (<0.1)	7 (<0.1)
Joint range of motion decreased	2 (<0.1)	6 (<0.1)	8 (<0.1)
Flank pain	1 (<0.1)	5 (<0.1)	6 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Joint swelling	7 (<0.1)	5 (<0.1)	12 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)	6 (<0.1)
Muscular weakness	4 (<0.1)	5 (<0.1)	9 (<0.1)
Osteoporosis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bone pain	0	4 (<0.1)	4 (<0.1)
Costochondritis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Osteopenia	0	4 (<0.1)	4 (<0.1)
Pain in jaw	3 (<0.1)	4 (<0.1)	7 (<0.1)
Axillary mass	2 (<0.1)	3 (<0.1)	5 (<0.1)
Limb discomfort	3 (<0.1)	3 (<0.1)	6 (<0.1)
Spinal osteoarthritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Spinal stenosis	0	3 (<0.1)	3 (<0.1)
Trigger finger	1 (<0.1)	3 (<0.1)	4 (<0.1)
Exostosis	2 (<0.1)	2 (<0.1)	4 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Fibromyalgia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Joint stiffness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Limb mass	3 (<0.1)	2 (<0.1)	5 (<0.1)
Muscle twitching	2 (<0.1)	2 (<0.1)	4 (<0.1)
Neck mass	0	2 (<0.1)	2 (<0.1)
Plantar fasciitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Spinal pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bone lesion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	1 (<0.1)	2 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Osteonecrosis	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spondylitis	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Tenosynovitis stenosans	0	1 (<0.1)	1 (<0.1)
Torticollis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)	2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Foot deformity	2 (<0.1)	0	2 (<0.1)
Intervertebral disc disorder	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)
Musculoskeletal disorder	1 (<0.1)	0	1 (<0.1)
Myositis	1 (<0.1)	0	1 (<0.1)
Osteochondrosis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0	1 (<0.1)
Synovial cyst	2 (<0.1)	0	2 (<0.1)
Synovitis	1 (<0.1)	0	1 (<0.1)
Systemic lupus erythematosus	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Renal and urinary disorders	47 (0.3)	52 (0.4)	99 (0.3)
Nephrolithiasis	23 (0.2)	17 (0.1)	40 (0.1)
Dysuria	3 (<0.1)	6 (<0.1)	9 (<0.1)
Chronic kidney disease	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pollakiuria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Acute kidney injury	4 (<0.1)	2 (<0.1)	6 (<0.1)
Haematuria	9 (<0.1)	2 (<0.1)	11 (<0.1)
Polyuria	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)	3 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bladder diverticulum	0	1 (<0.1)	1 (<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)
Hypertonic bladder	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)
Renal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal failure	0	1 (<0.1)	1 (<0.1)
Renal 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 14.3.1.8.9
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Renal and urinary disorders (Cont.)			
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Chromaturia	1 (<0.1)	0	1 (<0.1)
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)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pregnancy	0	3 (<0.1)	3 (<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	44 (0.3)	57 (0.4)	101 (0.3)
Benign prostatic hyperplasia	7 (<0.1)	7 (<0.1)	14 (<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	3 (<0.1)	3 (<0.1)
Breast pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Ovarian cyst	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostatitis	4 (<0.1)	2 (<0.1)	6 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Reproductive system and breast disorders (Cont.)			
Uterine haemorrhage	0	2 (<0.1)	2 (<0.1)
Uterine polyp	0	2 (<0.1)	2 (<0.1)
Vaginal haemorrhage	0	2 (<0.1)	2 (<0.1)
Adnexa uteri pain	0	1 (<0.1)	1 (<0.1)
Adnexal torsion	0	1 (<0.1)	1 (<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 fibrosis	0	1 (<0.1)	1 (<0.1)
Breast hyperplasia	0	1 (<0.1)	1 (<0.1)
Breast mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Cervical dysplasia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ejaculation failure	0	1 (<0.1)	1 (<0.1)
Fibrocystic breast disease	0	1 (<0.1)	1 (<0.1)
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Menopausal symptoms	2 (<0.1)	1 (<0.1)	3 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Reproductive system and breast disorders (Cont.)			
Ovarian mass	0	1 (<0.1)	1 (<0.1)
Perineal rash	0	1 (<0.1)	1 (<0.1)
Testicular pain	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)
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)
Haematospermia	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)
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	2 (<0.1)	0	2 (<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)
Vulvovaginal discomfort	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Congenital, familial and genetic disorders	2 (<0.1)	3 (<0.1)	5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)	2 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	2 (<0.1)	0	2 (<0.1)
General disorders and administration site conditions	702 (4.8)	1044 (7.2)	1746 (6.0)
Fatigue	386 (2.6)	406 (2.8)	792 (2.7)
Injection site pain	55 (0.4)	149 (1.0)	204 (0.7)
Injection site erythema	19 (0.1)	123 (0.8)	142 (0.5)
Chills	86 (0.6)	96 (0.7)	182 (0.6)
Pyrexia	68 (0.5)	96 (0.7)	164 (0.6)
Injection site swelling	14 (<0.1)	81 (0.6)	95 (0.3)
Pain	77 (0.5)	80 (0.5)	157 (0.5)
Injection site pruritus	12 (<0.1)	75 (0.5)	87 (0.3)
Injection site rash	1 (<0.1)	37 (0.3)	38 (0.1)
Injection site induration	7 (<0.1)	29 (0.2)	36 (0.1)
Axillary pain	12 (<0.1)	25 (0.2)	37 (0.1)
Injection site macule	2 (<0.1)	21 (0.1)	23 (<0.1)
Chest discomfort	18 (0.1)	18 (0.1)	36 (0.1)
Chest pain	9 (<0.1)	17 (0.1)	26 (<0.1)
Injection site lymphadenopathy	4 (<0.1)	16 (0.1)	20 (<0.1)
Injection site urticaria	0	15 (0.1)	15 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Malaise	13 (<0.1)	12 (<0.1)	25 (<0.1)
Swelling	1 (<0.1)	12 (<0.1)	13 (<0.1)
Injection site bruising	18 (0.1)	11 (<0.1)	29 (<0.1)
Injection site warmth	1 (<0.1)	8 (<0.1)	9 (<0.1)
Peripheral swelling	11 (<0.1)	8 (<0.1)	19 (<0.1)
Injection site haemorrhage	2 (<0.1)	6 (<0.1)	8 (<0.1)
Oedema peripheral	7 (<0.1)	6 (<0.1)	13 (<0.1)
Vaccination site lymphadenopathy	0	5 (<0.1)	5 (<0.1)
Injection site irritation	0	4 (<0.1)	4 (<0.1)
Injection site reaction	0	4 (<0.1)	4 (<0.1)
Non-cardiac chest pain	4 (<0.1)	4 (<0.1)	8 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)
Feeling abnormal	4 (<0.1)	3 (<0.1)	7 (<0.1)
Feeling hot	4 (<0.1)	3 (<0.1)	7 (<0.1)
Injection site haematoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site mass	1 (<0.1)	3 (<0.1)	4 (<0.1)
Swelling face	2 (<0.1)	3 (<0.1)	5 (<0.1)
Vaccination site erythema	0	3 (<0.1)	3 (<0.1)
Vaccination site swelling	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asthenia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Exercise tolerance decreased	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 Preferred Term	Placebo (N=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Induration	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	2 (<0.1)
Injection site papule	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site paraesthesia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Injection site scab	0	2 (<0.1)	2 (<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	4 (<0.1)	1 (<0.1)	5 (<0.1)
Early satiety	0	1 (<0.1)	1 (<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)
Hernia	0	1 (<0.1)	1 (<0.1)
Inflammation	0	1 (<0.1)	1 (<0.1)
Influenza like illness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nodule	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 14.3.1.8.9
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Reactogenicity event	2 (<0.1)	1 (<0.1)	3 (<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 pain	4 (<0.1)	1 (<0.1)	5 (<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)
Drug intolerance	1 (<0.1)	0	1 (<0.1)
Gait disturbance	2 (<0.1)	0	2 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Impaired healing	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Instillation site vesicles	1 (<0.1)	0	1 (<0.1)
Medical device site inflammation	1 (<0.1)	0	1 (<0.1)
Mucosal hypertrophy	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
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)
Sluggishness	1 (<0.1)	0	1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0	1 (<0.1)
Thirst	1 (<0.1)	0	1 (<0.1)
Unevaluable event	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)
Vessel puncture site pain	1 (<0.1)	0	1 (<0.1)
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	95 (0.7)	111 (0.8)	206 (0.7)
Blood pressure increased	36 (0.2)	30 (0.2)	66 (0.2)
Blood pressure systolic increased	18 (0.1)	19 (0.1)	37 (0.1)
Blood pressure diastolic increased	8 (<0.1)	11 (<0.1)	19 (<0.1)
Body temperature increased	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hepatic enzyme increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Transaminases increased	0	4 (<0.1)	4 (<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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Investigations (Cont.)			
Glycosylated haemoglobin increased	3 (<0.1)	3 (<0.1)	6 (<0.1)
Heart rate increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Blood cholesterol increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Blood glucose increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	2 (<0.1)
Heart rate irregular	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hormone level abnormal	0	2 (<0.1)	2 (<0.1)
Human rhinovirus test positive	0	2 (<0.1)	2 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	2 (<0.1)	3 (<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 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 parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Blood testosterone decreased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood uric acid increased	0	1 (<0.1)	1 (<0.1)
Blood urine present	0	1 (<0.1)	1 (<0.1)
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	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 Preferred Term	Placebo (N=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Investigations (Cont.)			
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Haemoglobin decreased	0	1 (<0.1)	1 (<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	0	1 (<0.1)	1 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Transaminases	0	1 (<0.1)	1 (<0.1)
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)
Viral test positive	2 (<0.1)	1 (<0.1)	3 (<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 endometrium	1 (<0.1)	0	1 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood prolactin increased	1 (<0.1)	0	1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
Breath sounds abnormal	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Investigations (Cont.)			
C-reactive protein increased	2 (<0.1)	0	2 (<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	367 (2.5)	319 (2.2)	686 (2.4)
Muscle strain	33 (0.2)	37 (0.3)	70 (0.2)
Ligament sprain	27 (0.2)	28 (0.2)	55 (0.2)
Skin laceration	33 (0.2)	24 (0.2)	57 (0.2)
Arthropod bite	27 (0.2)	23 (0.2)	50 (0.2)
Contusion	27 (0.2)	19 (0.1)	46 (0.2)
Tooth fracture	15 (0.1)	17 (0.1)	32 (0.1)
Fall	20 (0.1)	15 (0.1)	35 (0.1)
Foot fracture	14 (<0.1)	14 (<0.1)	28 (<0.1)
Procedural pain	25 (0.2)	14 (<0.1)	39 (0.1)
Limb injury	9 (<0.1)	13 (<0.1)	22 (<0.1)
Skin abrasion	23 (0.2)	9 (<0.1)	32 (0.1)
Animal bite	8 (<0.1)	8 (<0.1)	16 (<0.1)
Arthropod sting	16 (0.1)	7 (<0.1)	23 (<0.1)
Concussion	3 (<0.1)	7 (<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 Preferred Term	Placebo (N=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
Road traffic accident	8 (<0.1)	7 (<0.1)	15 (<0.1)
Meniscus injury	3 (<0.1)	6 (<0.1)	9 (<0.1)
Hand fracture	1 (<0.1)	5 (<0.1)	6 (<0.1)
Joint injury	6 (<0.1)	5 (<0.1)	11 (<0.1)
Thermal burn	1 (<0.1)	5 (<0.1)	6 (<0.1)
Head injury	1 (<0.1)	4 (<0.1)	5 (<0.1)
Post-traumatic pain	5 (<0.1)	4 (<0.1)	9 (<0.1)
Rib fracture	2 (<0.1)	4 (<0.1)	6 (<0.1)
Wrist fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Corneal abrasion	2 (<0.1)	3 (<0.1)	5 (<0.1)
Epicondylitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Tendon rupture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Ankle fracture	6 (<0.1)	2 (<0.1)	8 (<0.1)
Back injury	4 (<0.1)	2 (<0.1)	6 (<0.1)
Bone contusion	4 (<0.1)	2 (<0.1)	6 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)	3 (<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)

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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
Humerus fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ligament injury	0	2 (<0.1)	2 (<0.1)
Ligament rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Subdural haematoma	0	2 (<0.1)	2 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vaccination complication	4 (<0.1)	2 (<0.1)	6 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<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)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)	1 (<0.1)
Exposure to SARS-CoV-2	3 (<0.1)	1 (<0.1)	4 (<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)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.9
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
Hypobarism	0	1 (<0.1)	1 (<0.1)
Incision site pain	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)
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)
Muscle hernia	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 procedural swelling	0	1 (<0.1)	1 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<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)

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MedDRA version 23.0.
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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications (Cont.)			
Scar	1 (<0.1)	1 (<0.1)	2 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal column injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal compression fracture	0	1 (<0.1)	1 (<0.1)
Stab wound	0	1 (<0.1)	1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)	6 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Traumatic fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Uterine rupture	0	1 (<0.1)	1 (<0.1)
Wound	4 (<0.1)	1 (<0.1)	5 (<0.1)
Buttock injury	1 (<0.1)	0	1 (<0.1)
Ear injury	1 (<0.1)	0	1 (<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)
Gun shot wound	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) 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)
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	2 (<0.1)	0	2 (<0.1)
Pulmonary contusion	1 (<0.1)	0	1 (<0.1)
Repetitive strain injury	1 (<0.1)	0	1 (<0.1)
Skeletal injury	1 (<0.1)	0	1 (<0.1)
Sports injury	1 (<0.1)	0	1 (<0.1)
Sunburn	3 (<0.1)	0	3 (<0.1)
Superficial injury of eye	1 (<0.1)	0	1 (<0.1)
Trunk injury	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)
Vascular access site pain	1 (<0.1)	0	1 (<0.1)
Vascular access site swelling	1 (<0.1)	0	1 (<0.1)
Venomous sting	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 14.3.1.8.9
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Surgical and medical procedures	18 (0.1)	18 (0.1)	36 (0.1)
Endodontic procedure	4 (<0.1)	2 (<0.1)	6 (<0.1)
Skin neoplasm excision	0	2 (<0.1)	2 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cataract operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curetting of chalazion	0	1 (<0.1)	1 (<0.1)
Dental operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Influenza immunisation	0	1 (<0.1)	1 (<0.1)
Knee arthroplasty	0	1 (<0.1)	1 (<0.1)
Pancreatic stent placement	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)
Tendon sheath incision	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Tooth extraction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Transfusion	0	1 (<0.1)	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Foot operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Jaw operation	1 (<0.1)	0	1 (<0.1)
Spinal fusion surgery	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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Surgical and medical procedures (Cont.)			
Tooth repair	3 (<0.1)	0	3 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)	3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)	7 (<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)
Device physical property issue	1 (<0.1)	0	1 (<0.1)
Lead dislodgement	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: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	78 (23.1)	68 (19.8)	146 (21.5)
Number of Unsolicited Adverse Events	149	140	289
Infections and infestations	16 (4.7)	20 (5.8)	36 (5.3)
COVID-19	5 (1.5)	7 (2.0)	12 (1.8)
Viral infection	3 (0.9)	3 (0.9)	6 (0.9)
Upper respiratory tract infection	4 (1.2)	2 (0.6)	6 (0.9)
Asymptomatic COVID-19	2 (0.6)	1 (0.3)	3 (0.4)
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)
Respiratory tract infection	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)
Vulvovaginal candidiasis	1 (0.3)	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: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Blood and lymphatic system disorders	2 (0.6)	1 (0.3)	3 (0.4)
Lymphadenopathy	2 (0.6)	1 (0.3)	3 (0.4)
Immune system disorders	1 (0.3)	0	1 (0.1)
Seasonal allergy	1 (0.3)	0	1 (0.1)
Metabolism and nutrition disorders	6 (1.8)	3 (0.9)	9 (1.3)
Hyperlipidaemia	0	2 (0.6)	2 (0.3)
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)
Metabolic acidosis	1 (0.3)	0	1 (0.1)
Psychiatric disorders	0	2 (0.6)	2 (0.3)
Anxiety	0	1 (0.3)	1 (0.1)
Depression	0	1 (0.3)	1 (0.1)
Nervous system disorders	19 (5.6)	14 (4.1)	33 (4.9)
Headache	15 (4.5)	10 (2.9)	25 (3.7)

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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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Nervous system disorders (Cont.)			
Dizziness	0	2 (0.6)	2 (0.3)
Ageusia	0	1 (0.3)	1 (0.1)
Hypoaesthesia	0	1 (0.3)	1 (0.1)
Sciatica	0	1 (0.3)	1 (0.1)
Syncope	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)
Eye disorders	0	1 (0.3)	1 (0.1)
Vision blurred	0	1 (0.3)	1 (0.1)
Ear and labyrinth disorders	4 (1.2)	1 (0.3)	5 (0.7)
Cerumen impaction	0	1 (0.3)	1 (0.1)
Ear pain	1 (0.3)	0	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)	1 (0.3)	2 (0.3)
Angina pectoris	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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Cardiac disorders (Cont.)			
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)	3 (0.9)	5 (0.7)
Hypertension	2 (0.6)	3 (0.9)	5 (0.7)
Respiratory, thoracic and mediastinal disorders	13 (3.9)	11 (3.2)	24 (3.5)
Nasal congestion	4 (1.2)	4 (1.2)	8 (1.2)
Rhinorrhoea	3 (0.9)	4 (1.2)	7 (1.0)
Cough	2 (0.6)	2 (0.6)	4 (0.6)
Oropharyngeal pain	3 (0.9)	2 (0.6)	5 (0.7)
Dyspnoea	0	1 (0.3)	1 (0.1)
Epistaxis	1 (0.3)	1 (0.3)	2 (0.3)
Pharyngeal erythema	0	1 (0.3)	1 (0.1)
Productive cough	0	1 (0.3)	1 (0.1)
Respiratory tract congestion	0	1 (0.3)	1 (0.1)
Throat irritation	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)
Tachypnoea	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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Gastrointestinal disorders	5 (1.5)	8 (2.3)	13 (1.9)
Diarrhoea	1 (0.3)	5 (1.5)	6 (0.9)
Gastrooesophageal reflux disease	3 (0.9)	2 (0.6)	5 (0.7)
Nausea	1 (0.3)	2 (0.6)	3 (0.4)
Gastric ulcer	0	1 (0.3)	1 (0.1)
Oesophageal ulcer	0	1 (0.3)	1 (0.1)
Umbilical hernia	0	1 (0.3)	1 (0.1)
Abdominal pain	1 (0.3)	0	1 (0.1)
Dyspepsia	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	7 (2.1)	6 (1.7)	13 (1.9)
Urticaria	1 (0.3)	2 (0.6)	3 (0.4)
Acne	0	1 (0.3)	1 (0.1)
Ecchymosis	0	1 (0.3)	1 (0.1)
Hyperhidrosis	0	1 (0.3)	1 (0.1)
Rash macular	0	1 (0.3)	1 (0.1)
Blister	1 (0.3)	0	1 (0.1)
Dermatitis	1 (0.3)	0	1 (0.1)
Dermatitis contact	1 (0.3)	0	1 (0.1)
Erythema	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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Night sweats	1 (0.3)	0	1 (0.1)
Rash	1 (0.3)	0	1 (0.1)
Musculoskeletal and connective tissue disorders	19 (5.6)	13 (3.8)	32 (4.7)
Myalgia	3 (0.9)	5 (1.5)	8 (1.2)
Arthralgia	2 (0.6)	2 (0.6)	4 (0.6)
Back pain	4 (1.2)	2 (0.6)	6 (0.9)
Pain in extremity	0	2 (0.6)	2 (0.3)
Bursitis	0	1 (0.3)	1 (0.1)
Limb discomfort	0	1 (0.3)	1 (0.1)
Muscle spasms	0	1 (0.3)	1 (0.1)
Muscle tightness	0	1 (0.3)	1 (0.1)
Neck pain	3 (0.9)	1 (0.3)	4 (0.6)
Arthritis	2 (0.6)	0	2 (0.3)
Axillary mass	1 (0.3)	0	1 (0.1)
Muscle twitching	1 (0.3)	0	1 (0.1)
Musculoskeletal pain	4 (1.2)	0	4 (0.6)
Musculoskeletal stiffness	1 (0.3)	0	1 (0.1)
Osteoarthritis	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 14.3.1.8.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Renal and urinary disorders	4 (1.2)	1 (0.3)	5 (0.7)
Dysuria	1 (0.3)	1 (0.3)	2 (0.3)
Chromaturia	1 (0.3)	0	1 (0.1)
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)	1 (0.3)	2 (0.3)
Postmenopausal haemorrhage	0	1 (0.3)	1 (0.1)
Nipple pain	1 (0.3)	0	1 (0.1)
General disorders and administration site conditions	12 (3.6)	18 (5.2)	30 (4.4)
Fatigue	6 (1.8)	4 (1.2)	10 (1.5)
Injection site pain	1 (0.3)	3 (0.9)	4 (0.6)
Feeling hot	0	2 (0.6)	2 (0.3)
Injection site erythema	0	2 (0.6)	2 (0.3)
Chest discomfort	0	1 (0.3)	1 (0.1)
Chest pain	0	1 (0.3)	1 (0.1)
Chills	1 (0.3)	1 (0.3)	2 (0.3)
Hangover	0	1 (0.3)	1 (0.1)
Injection site bruising	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 14.3.1.8.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
General disorders and administration site conditions (Cont.)			
Injection site induration	0	1 (0.3)	1 (0.1)
Injection site lymphadenopathy	0	1 (0.3)	1 (0.1)
Injection site swelling	1 (0.3)	1 (0.3)	2 (0.3)
Oedema peripheral	0	1 (0.3)	1 (0.1)
Pain	1 (0.3)	1 (0.3)	2 (0.3)
Pyrexia	0	1 (0.3)	1 (0.1)
Swelling face	0	1 (0.3)	1 (0.1)
Axillary pain	1 (0.3)	0	1 (0.1)
Non-cardiac chest pain	1 (0.3)	0	1 (0.1)
Investigations	4 (1.2)	3 (0.9)	7 (1.0)
Blood glucose increased	0	1 (0.3)	1 (0.1)
Blood pressure increased	1 (0.3)	1 (0.3)	2 (0.3)
Heart rate increased	0	1 (0.3)	1 (0.1)
Blood pressure systolic increased	1 (0.3)	0	1 (0.1)
Heart rate irregular	1 (0.3)	0	1 (0.1)
International normalised ratio increased	1 (0.3)	0	1 (0.1)
Injury, poisoning and procedural complications	5 (1.5)	4 (1.2)	9 (1.3)
Fall	0	1 (0.3)	1 (0.1)
Head injury	0	1 (0.3)	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 14.3.1.8.9
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Injury, poisoning and procedural complications (Cont.)			
Ligament sprain	2 (0.6)	1 (0.3)	3 (0.4)
Road traffic accident	0	1 (0.3)	1 (0.1)
Concussion	1 (0.3)	0	1 (0.1)
Contusion	1 (0.3)	0	1 (0.1)
Facial bones fracture	1 (0.3)	0	1 (0.1)
Joint injury	1 (0.3)	0	1 (0.1)
Skin laceration	1 (0.3)	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 14.3.1.8.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	45 (19.1)	60 (20.8)	105 (20.1)
Number of Unsolicited Adverse Events	75	120	195
Infections and infestations	10 (4.3)	12 (4.2)	22 (4.2)
Pharyngitis	0	2 (0.7)	2 (0.4)
COVID-19	4 (1.7)	1 (0.3)	5 (1.0)
Conjunctivitis	1 (0.4)	1 (0.3)	2 (0.4)
Folliculitis	0	1 (0.3)	1 (0.2)
Gastroenteritis viral	0	1 (0.3)	1 (0.2)
Herpes simplex	0	1 (0.3)	1 (0.2)
Herpes zoster	0	1 (0.3)	1 (0.2)
Infected bite	0	1 (0.3)	1 (0.2)
Laryngitis	0	1 (0.3)	1 (0.2)
Lyme disease	0	1 (0.3)	1 (0.2)
Pharyngitis streptococcal	1 (0.4)	1 (0.3)	2 (0.4)
Sinusitis bacterial	0	1 (0.3)	1 (0.2)
Staphylococcal infection	0	1 (0.3)	1 (0.2)
Urinary tract infection	2 (0.9)	1 (0.3)	3 (0.6)
Breast abscess	1 (0.4)	0	1 (0.2)
Upper respiratory tract infection	1 (0.4)	0	1 (0.2)
Vulvovaginal mycotic infection	1 (0.4)	0	1 (0.2)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.3)	1 (0.2)
Squamous cell carcinoma of skin	0	1 (0.3)	1 (0.2)
Blood and lymphatic system disorders	2 (0.9)	1 (0.3)	3 (0.6)
Lymphadenopathy	2 (0.9)	1 (0.3)	3 (0.6)
Immune system disorders	0	1 (0.3)	1 (0.2)
Seasonal allergy	0	1 (0.3)	1 (0.2)
Psychiatric disorders	0	2 (0.7)	2 (0.4)
Depression	0	1 (0.3)	1 (0.2)
Mental fatigue	0	1 (0.3)	1 (0.2)
Nervous system disorders	13 (5.5)	11 (3.8)	24 (4.6)
Headache	10 (4.3)	7 (2.4)	17 (3.3)
Anosmia	0	1 (0.3)	1 (0.2)
Dizziness	0	1 (0.3)	1 (0.2)
Dizziness postural	0	1 (0.3)	1 (0.2)
Essential tremor	0	1 (0.3)	1 (0.2)
Nerve compression	1 (0.4)	1 (0.3)	2 (0.4)
Horner's syndrome	1 (0.4)	0	1 (0.2)
Migraine	1 (0.4)	0	1 (0.2)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Ear and labyrinth disorders	2 (0.9)	3 (1.0)	5 (1.0)
Vertigo	1 (0.4)	2 (0.7)	3 (0.6)
Meniere's disease	0	1 (0.3)	1 (0.2)
Vertigo positional	0	1 (0.3)	1 (0.2)
Ear discomfort	1 (0.4)	0	1 (0.2)
Cardiac disorders	0	1 (0.3)	1 (0.2)
Cardiac failure congestive	0	1 (0.3)	1 (0.2)
Vascular disorders	2 (0.9)	4 (1.4)	6 (1.1)
Hypertension	1 (0.4)	3 (1.0)	4 (0.8)
Haematoma	0	1 (0.3)	1 (0.2)
Hypotension	1 (0.4)	0	1 (0.2)
Respiratory, thoracic and mediastinal disorders	10 (4.3)	11 (3.8)	21 (4.0)
Oropharyngeal pain	2 (0.9)	7 (2.4)	9 (1.7)
Nasal congestion	3 (1.3)	4 (1.4)	7 (1.3)
Cough	0	2 (0.7)	2 (0.4)
Dry throat	0	1 (0.3)	1 (0.2)
Dysphonia	0	1 (0.3)	1 (0.2)
Dyspnoea	0	1 (0.3)	1 (0.2)
Respiratory tract congestion	1 (0.4)	1 (0.3)	2 (0.4)
Rhinorrhoea	2 (0.9)	1 (0.3)	3 (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: Missing

System Organ Class Preferred Term	Placebo (N=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Sinus congestion	1 (0.4)	1 (0.3)	2 (0.4)
Sneezing	0	1 (0.3)	1 (0.2)
Upper-airway cough syndrome	0	1 (0.3)	1 (0.2)
Haemoptysis	1 (0.4)	0	1 (0.2)
Oropharyngeal discomfort	1 (0.4)	0	1 (0.2)
Productive cough	1 (0.4)	0	1 (0.2)
Tachypnoea	1 (0.4)	0	1 (0.2)
Gastrointestinal disorders	9 (3.8)	9 (3.1)	18 (3.4)
Diarrhoea	4 (1.7)	6 (2.1)	10 (1.9)
Nausea	1 (0.4)	2 (0.7)	3 (0.6)
Abdominal pain upper	0	1 (0.3)	1 (0.2)
Dyspepsia	0	1 (0.3)	1 (0.2)
Stomatitis	0	1 (0.3)	1 (0.2)
Tongue disorder	0	1 (0.3)	1 (0.2)
Constipation	1 (0.4)	0	1 (0.2)
Inguinal hernia	1 (0.4)	0	1 (0.2)
Paraesthesia oral	1 (0.4)	0	1 (0.2)
Toothache	1 (0.4)	0	1 (0.2)
Vomiting	2 (0.9)	0	2 (0.4)

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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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Skin and subcutaneous tissue disorders	1 (0.4)	5 (1.7)	6 (1.1)
Erythema	0	1 (0.3)	1 (0.2)
Nail disorder	0	1 (0.3)	1 (0.2)
Pruritus	0	1 (0.3)	1 (0.2)
Rash erythematous	0	1 (0.3)	1 (0.2)
Urticaria	0	1 (0.3)	1 (0.2)
Rash	1 (0.4)	0	1 (0.2)
Musculoskeletal and connective tissue disorders	4 (1.7)	7 (2.4)	11 (2.1)
Back pain	0	2 (0.7)	2 (0.4)
Joint swelling	0	1 (0.3)	1 (0.2)
Musculoskeletal pain	0	1 (0.3)	1 (0.2)
Myalgia	0	1 (0.3)	1 (0.2)
Neck mass	0	1 (0.3)	1 (0.2)
Pain in extremity	0	1 (0.3)	1 (0.2)
Arthralgia	2 (0.9)	0	2 (0.4)
Muscle spasms	1 (0.4)	0	1 (0.2)
Pain in jaw	1 (0.4)	0	1 (0.2)
Reproductive system and breast disorders	0	1 (0.3)	1 (0.2)
Adenomyosis	0	1 (0.3)	1 (0.2)

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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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
General disorders and administration site conditions	5 (2.1)	19 (6.6)	24 (4.6)
Fatigue	0	6 (2.1)	6 (1.1)
Injection site pain	1 (0.4)	4 (1.4)	5 (1.0)
Pyrexia	2 (0.9)	4 (1.4)	6 (1.1)
Chills	0	3 (1.0)	3 (0.6)
Pain	0	3 (1.0)	3 (0.6)
Injection site erythema	1 (0.4)	2 (0.7)	3 (0.6)
Hernia	0	1 (0.3)	1 (0.2)
Injection site pruritus	0	1 (0.3)	1 (0.2)
Injection site swelling	1 (0.4)	1 (0.3)	2 (0.4)
Vaccination site lymphadenopathy	0	1 (0.3)	1 (0.2)
Investigations	1 (0.4)	1 (0.3)	2 (0.4)
Blood pressure increased	1 (0.4)	1 (0.3)	2 (0.4)
Injury, poisoning and procedural complications	6 (2.6)	3 (1.0)	9 (1.7)
Joint injury	0	1 (0.3)	1 (0.2)
Procedural pain	1 (0.4)	1 (0.3)	2 (0.4)
Wound	0	1 (0.3)	1 (0.2)
Corneal abrasion	1 (0.4)	0	1 (0.2)
Ligament sprain	1 (0.4)	0	1 (0.2)
Limb injury	1 (0.4)	0	1 (0.2)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.9
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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Injury, poisoning and procedural complications (Cont.)			
Skin abrasion	1 (0.4)	0	1 (0.2)
Superficial injury of eye	1 (0.4)	0	1 (0.2)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	664 (4.5)	1216 (8.4)	1880 (6.4)
Number of Unsolicited Adverse Events	1095	2024	3119
Infections and infestations	17 (0.1)	13 (<0.1)	30 (0.1)
Conjunctivitis	0	2 (<0.1)	2 (<0.1)
Injection site cellulitis	0	2 (<0.1)	2 (<0.1)
COVID-19	0	1 (<0.1)	1 (<0.1)
Clostridium difficile infection	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)
Injection site infection	0	1 (<0.1)	1 (<0.1)
Oral herpes	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory tract infection viral	0	1 (<0.1)	1 (<0.1)
Sinusitis	0	1 (<0.1)	1 (<0.1)
Viral infection	0	1 (<0.1)	1 (<0.1)
Cellulitis	1 (<0.1)	0	1 (<0.1)
Gingivitis	1 (<0.1)	0	1 (<0.1)
Herpes simplex	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Onychomycosis	1 (<0.1)	0	1 (<0.1)
Rhinitis	2 (<0.1)	0	2 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Infections and infestations (Cont.)			
Tinea pedis	1 (<0.1)	0	1 (<0.1)
Upper respiratory tract infection	7 (<0.1)	0	7 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	51 (0.3)	99 (0.7)	150 (0.5)
Lymphadenopathy	45 (0.3)	91 (0.6)	136 (0.5)
Lymphadenitis	2 (<0.1)	7 (<0.1)	9 (<0.1)
Lymph node pain	5 (<0.1)	2 (<0.1)	7 (<0.1)
Anaemia	0	1 (<0.1)	1 (<0.1)
Immune system disorders	2 (<0.1)	2 (<0.1)	4 (<0.1)
Seasonal allergy	0	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Hypersensitivity	1 (<0.1)	0	1 (<0.1)
Serum sickness	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	4 (<0.1)	7 (<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)
Dyslipidaemia	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 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Psychiatric disorders	0	14 (<0.1)	14 (<0.1)
Insomnia	0	5 (<0.1)	5 (<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)
Anxiety	0	1 (<0.1)	1 (<0.1)
Depressed mood	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Nightmare	0	1 (<0.1)	1 (<0.1)
Suicidal ideation	0	1 (<0.1)	1 (<0.1)
Nervous system disorders	170 (1.2)	279 (1.9)	449 (1.5)
Headache	132 (0.9)	206 (1.4)	338 (1.2)
Dizziness	13 (<0.1)	26 (0.2)	39 (0.1)
Paraesthesia	7 (<0.1)	11 (<0.1)	18 (<0.1)
Dysgeusia	6 (<0.1)	10 (<0.1)	16 (<0.1)
Hyperaesthesia	0	5 (<0.1)	5 (<0.1)
Hypoaesthesia	0	4 (<0.1)	4 (<0.1)
Syncope	0	3 (<0.1)	3 (<0.1)
Disturbance in attention	1 (<0.1)	2 (<0.1)	3 (<0.1)
Somnolence	0	2 (<0.1)	2 (<0.1)
Ageusia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Autonomic nervous system imbalance	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 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Nervous system disorders (Cont.)			
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)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Mental impairment	0	1 (<0.1)	1 (<0.1)
Migraine	5 (<0.1)	1 (<0.1)	6 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<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)
Presyncope	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sciatica	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sinus headache	0	1 (<0.1)	1 (<0.1)
Taste disorder	2 (<0.1)	1 (<0.1)	3 (<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)
Tension headache	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 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Eye disorders	3 (<0.1)	6 (<0.1)	9 (<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)
Vision blurred	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)	9 (<0.1)	12 (<0.1)
Tinnitus	1 (<0.1)	5 (<0.1)	6 (<0.1)
Vertigo	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ear discomfort	0	1 (<0.1)	1 (<0.1)
Vertigo positional	0	1 (<0.1)	1 (<0.1)
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	1 (<0.1)	0	1 (<0.1)
Atrial fibrillation	1 (<0.1)	0	1 (<0.1)
Bradycardia	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 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Cardiac disorders (Cont.)			
Palpitations	2 (<0.1)	0	2 (<0.1)
Vascular disorders	16 (0.1)	21 (0.1)	37 (0.1)
Hypertension	13 (<0.1)	8 (<0.1)	21 (<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	42 (0.3)	53 (0.4)	95 (0.3)
Nasal congestion	9 (<0.1)	19 (0.1)	28 (<0.1)
Cough	6 (<0.1)	13 (<0.1)	19 (<0.1)
Rhinorrhoea	10 (<0.1)	12 (<0.1)	22 (<0.1)
Oropharyngeal pain	16 (0.1)	11 (<0.1)	27 (<0.1)
Dyspnoea	4 (<0.1)	6 (<0.1)	10 (<0.1)
Throat irritation	3 (<0.1)	4 (<0.1)	7 (<0.1)
Sinus congestion	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asthma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypoxia	0	1 (<0.1)	1 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sinus pain	0	1 (<0.1)	1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Dysphonia	2 (<0.1)	0	2 (<0.1)
Pleurisy	1 (<0.1)	0	1 (<0.1)
Pleuritic pain	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	78 (0.5)	86 (0.6)	164 (0.6)
Diarrhoea	28 (0.2)	39 (0.3)	67 (0.2)
Nausea	39 (0.3)	31 (0.2)	70 (0.2)
Vomiting	5 (<0.1)	7 (<0.1)	12 (<0.1)
Abdominal pain	1 (<0.1)	6 (<0.1)	7 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Dyspepsia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gastrooesophageal reflux disease	0	2 (<0.1)	2 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swollen tongue	0	2 (<0.1)	2 (<0.1)
Toothache	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abdominal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Gastrointestinal disorders (Cont.)			
Abdominal pain upper	2 (<0.1)	1 (<0.1)	3 (<0.1)
Aphthous ulcer	0	1 (<0.1)	1 (<0.1)
Dry mouth	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)	1 (<0.1)
Mouth ulceration	0	1 (<0.1)	1 (<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	33 (0.2)	86 (0.6)	119 (0.4)
Urticaria	4 (<0.1)	16 (0.1)	20 (<0.1)
Rash	3 (<0.1)	15 (0.1)	18 (<0.1)
Erythema	0	9 (<0.1)	9 (<0.1)
Pruritus	9 (<0.1)	8 (<0.1)	17 (<0.1)
Hyperhidrosis	7 (<0.1)	7 (<0.1)	14 (<0.1)
Night sweats	4 (<0.1)	6 (<0.1)	10 (<0.1)
Rash maculo-papular	0	6 (<0.1)	6 (<0.1)
Rash macular	0	3 (<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 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash pruritic	1 (<0.1)	3 (<0.1)	4 (<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 papular	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)
Ecchymosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Macule	0	1 (<0.1)	1 (<0.1)
Mechanical urticaria	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	2 (<0.1)	0	2 (<0.1)
Skin discolouration	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	154 (1.1)	226 (1.6)	380 (1.3)
Myalgia	75 (0.5)	118 (0.8)	193 (0.7)
Arthralgia	88 (0.6)	96 (0.7)	184 (0.6)
Pain in extremity	12 (<0.1)	16 (0.1)	28 (<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\t1403011103.sas 03DEC2020 07:01

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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Back pain	3 (<0.1)	9 (<0.1)	12 (<0.1)
Neck pain	1 (<0.1)	9 (<0.1)	10 (<0.1)
Musculoskeletal pain	5 (<0.1)	6 (<0.1)	11 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)	6 (<0.1)
Muscle spasms	4 (<0.1)	5 (<0.1)	9 (<0.1)
Musculoskeletal stiffness	2 (<0.1)	3 (<0.1)	5 (<0.1)
Axillary mass	0	2 (<0.1)	2 (<0.1)
Bone pain	0	2 (<0.1)	2 (<0.1)
Limb discomfort	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscular weakness	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tendonitis	0	2 (<0.1)	2 (<0.1)
Arthritis	1 (<0.1)	1 (<0.1)	2 (<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)
Musculoskeletal chest pain	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	1 (<0.1)	1 (<0.1)	2 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)	1 (<0.1)
Fibromyalgia	1 (<0.1)	0	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	4 (<0.1)	4 (<0.1)	8 (<0.1)
Menorrhagia	0	2 (<0.1)	2 (<0.1)
Erectile dysfunction	0	1 (<0.1)	1 (<0.1)
Menstrual disorder	0	1 (<0.1)	1 (<0.1)
Breast pain	1 (<0.1)	0	1 (<0.1)
Dysmenorrhoea	1 (<0.1)	0	1 (<0.1)
Haematospermia	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	306 (2.1)	666 (4.6)	972 (3.3)
Fatigue	173 (1.2)	219 (1.5)	392 (1.3)
Injection site pain	38 (0.3)	117 (0.8)	155 (0.5)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Injection site erythema	17 (0.1)	113 (0.8)	130 (0.4)
Injection site swelling	14 (<0.1)	74 (0.5)	88 (0.3)
Injection site pruritus	11 (<0.1)	63 (0.4)	74 (0.3)
Chills	17 (0.1)	44 (0.3)	61 (0.2)
Pyrexia	12 (<0.1)	42 (0.3)	54 (0.2)
Injection site rash	1 (<0.1)	32 (0.2)	33 (0.1)
Injection site induration	7 (<0.1)	29 (0.2)	36 (0.1)
Pain	8 (<0.1)	23 (0.2)	31 (0.1)
Axillary pain	4 (<0.1)	19 (0.1)	23 (<0.1)
Injection site macule	2 (<0.1)	18 (0.1)	20 (<0.1)
Injection site lymphadenopathy	3 (<0.1)	15 (0.1)	18 (<0.1)
Injection site urticaria	0	12 (<0.1)	12 (<0.1)
Malaise	4 (<0.1)	7 (<0.1)	11 (<0.1)
Swelling	1 (<0.1)	7 (<0.1)	8 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)	6 (<0.1)
Vaccination site lymphadenopathy	0	5 (<0.1)	5 (<0.1)
Injection site irritation	0	4 (<0.1)	4 (<0.1)
Injection site reaction	0	4 (<0.1)	4 (<0.1)
Chest discomfort	1 (<0.1)	3 (<0.1)	4 (<0.1)
Chest pain	0	3 (<0.1)	3 (<0.1)
Injection site bruising	10 (<0.1)	3 (<0.1)	13 (<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 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
Injection site haemorrhage	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tenderness	0	3 (<0.1)	3 (<0.1)
Vaccination site erythema	0	3 (<0.1)	3 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	2 (<0.1)
Injection site mass	1 (<0.1)	2 (<0.1)	3 (<0.1)
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)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Feeling abnormal	2 (<0.1)	1 (<0.1)	3 (<0.1)
Feeling hot	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injection site discolouration	0	1 (<0.1)	1 (<0.1)
Injection site haematoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site papule	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site paraesthesia	3 (<0.1)	1 (<0.1)	4 (<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)
Reactogenicity event	2 (<0.1)	1 (<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.
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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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
General disorders and administration site conditions (Cont.)			
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)
Discomfort	1 (<0.1)	0	1 (<0.1)
Injection site discomfort	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Instillation site vesicles	1 (<0.1)	0	1 (<0.1)
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Investigations	5 (<0.1)	15 (0.1)	20 (<0.1)
Blood pressure increased	3 (<0.1)	5 (<0.1)	8 (<0.1)
Body temperature increased	0	3 (<0.1)	3 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)	2 (<0.1)
Blood pressure systolic 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)

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 14.3.1.11.3
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=14594) n (%)	mRNA-1273 (N=14554) n (%)	Total (N=29148) n (%)
Injury, poisoning and procedural complications	8 (<0.1)	5 (<0.1)	13 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fall	1 (<0.1)	0	1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	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 14.3.1.11.3
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	14 (4.2)	16 (4.7)	30 (4.4)
Number of Unsolicited Adverse Events	29	28	57
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)	5 (1.5)	12 (1.8)
Headache	6 (1.8)	4 (1.2)	10 (1.5)
Ageusia	0	1 (0.3)	1 (0.1)
Dizziness	0	1 (0.3)	1 (0.1)
Migraine	1 (0.3)	0	1 (0.1)
Cardiac disorders	0	1 (0.3)	1 (0.1)
Angina pectoris	0	1 (0.3)	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)

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 14.3.1.11.3
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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
Gastrointestinal disorders (Cont.)			
Dyspepsia	1 (0.3)	0	1 (0.1)
Nausea	1 (0.3)	0	1 (0.1)
Skin and subcutaneous tissue disorders	2 (0.6)	1 (0.3)	3 (0.4)
Urticaria	1 (0.3)	1 (0.3)	2 (0.3)
Rash	1 (0.3)	0	1 (0.1)
Musculoskeletal and connective tissue disorders	6 (1.8)	5 (1.5)	11 (1.6)
Myalgia	2 (0.6)	3 (0.9)	5 (0.7)
Arthralgia	1 (0.3)	1 (0.3)	2 (0.3)
Limb discomfort	0	1 (0.3)	1 (0.1)
Pain in extremity	0	1 (0.3)	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)
General disorders and administration site conditions	5 (1.5)	8 (2.3)	13 (1.9)
Injection site erythema	0	2 (0.6)	2 (0.3)
Injection site pain	0	2 (0.6)	2 (0.3)
Chills	1 (0.3)	1 (0.3)	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.
MedDRA version 23.0.
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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=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)
General disorders and administration site conditions (Cont.)			
Fatigue	5 (1.5)	1 (0.3)	6 (0.9)
Injection site induration	0	1 (0.3)	1 (0.1)
Injection site lymphadenopathy	0	1 (0.3)	1 (0.1)
Injection site swelling	0	1 (0.3)	1 (0.1)
Pain	0	1 (0.3)	1 (0.1)
Pyrexia	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.
MedDRA version 23.0.
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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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	8 (3.4)	10 (3.5)	18 (3.4)
Number of Unsolicited Adverse Events	13	11	24
Blood and lymphatic system disorders	1 (0.4)	0	1 (0.2)
Lymphadenopathy	1 (0.4)	0	1 (0.2)
Nervous system disorders	5 (2.1)	2 (0.7)	7 (1.3)
Essential tremor	0	1 (0.3)	1 (0.2)
Headache	5 (2.1)	1 (0.3)	6 (1.1)
Respiratory, thoracic and mediastinal disorders	0	1 (0.3)	1 (0.2)
Nasal congestion	0	1 (0.3)	1 (0.2)
Gastrointestinal disorders	3 (1.3)	0	3 (0.6)
Diarrhoea	2 (0.9)	0	2 (0.4)
Paraesthesia oral	1 (0.4)	0	1 (0.2)
Skin and subcutaneous tissue disorders	0	1 (0.3)	1 (0.2)
Urticaria	0	1 (0.3)	1 (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.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011103.sas 03DEC2020 07:01

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=235) n (%)	mRNA-1273 (N=288) n (%)	Total (N=523) n (%)
Musculoskeletal and connective tissue disorders	1 (0.4)	0	1 (0.2)
Arthralgia	1 (0.4)	0	1 (0.2)
General disorders and administration site conditions	2 (0.9)	7 (2.4)	9 (1.7)
Fatigue	0	2 (0.7)	2 (0.4)
Chills	0	1 (0.3)	1 (0.2)
Injection site erythema	1 (0.4)	1 (0.3)	2 (0.4)
Injection site pain	0	1 (0.3)	1 (0.2)
Pyrexia	0	1 (0.3)	1 (0.2)
Vaccination site lymphadenopathy	0	1 (0.3)	1 (0.2)
Injection site swelling	1 (0.4)	0	1 (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.
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	89 (0.6)	93 (0.6)	182 (0.6)
Number of Unsolicited Adverse Events	120	127	247
Infections and infestations	15 (<0.1)	12 (<0.1)	27 (<0.1)
Pneumonia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
COVID-19	2 (<0.1)	1 (<0.1)	3 (<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)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Urosepsis	0	1 (<0.1)	1 (<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)
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.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (<0.1)	9 (<0.1)	14 (<0.1)
Prostate cancer	2 (<0.1)	2 (<0.1)	4 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Colorectal cancer	0	1 (<0.1)	1 (<0.1)
Invasive lobular breast carcinoma	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)
Papillary thyroid cancer	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Renal cancer	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)
Prostate cancer metastatic	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	3 (<0.1)	2 (<0.1)	5 (<0.1)
Dehydration	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypokalaemia	1 (<0.1)	0	1 (<0.1)
Hyponatraemia	1 (<0.1)	0	1 (<0.1)
Metabolic acidosis	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 14.3.1.13.1
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
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)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	6 (<0.1)	11 (<0.1)	17 (<0.1)
Cerebrovascular accident	0	2 (<0.1)	2 (<0.1)
Syncope	2 (<0.1)	2 (<0.1)	4 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	1 (<0.1)
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Seizure	0	1 (<0.1)	1 (<0.1)
Subarachnoid haemorrhage	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)

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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
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	15 (<0.1)	14 (<0.1)	29 (<0.1)
Atrial fibrillation	3 (<0.1)	3 (<0.1)	6 (<0.1)
Cardiac failure congestive	3 (<0.1)	3 (<0.1)	6 (<0.1)
Myocardial infarction	0	3 (<0.1)	3 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Coronary artery disease	2 (<0.1)	1 (<0.1)	3 (<0.1)
Coronary artery thrombosis	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)
Pericarditis	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)
Aortic aneurysm	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.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Vascular disorders (Cont.)			
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 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	12 (<0.1)	9 (<0.1)	21 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)	6 (<0.1)
Dyspnoea	0	2 (<0.1)	2 (<0.1)
Respiratory failure	0	2 (<0.1)	2 (<0.1)
Acute respiratory failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Chronic obstructive pulmonary disease	3 (<0.1)	0	3 (<0.1)
Emphysema	1 (<0.1)	0	1 (<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	8 (<0.1)	14 (<0.1)	22 (<0.1)
Colitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hiatus hernia	0	2 (<0.1)	2 (<0.1)
Nausea	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Percentages are based on the number of safety subjects.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
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)
Rectal prolapse	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)
Gastric perforation	1 (<0.1)	0	1 (<0.1)
Umbilical hernia	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	4 (<0.1)	4 (<0.1)
Cholecystitis	0	2 (<0.1)	2 (<0.1)
Bile duct stone	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)

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Percentages are based on the number of safety subjects.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Musculoskeletal and connective tissue disorders	4 (<0.1)	8 (<0.1)	12 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arthritis	0	1 (<0.1)	1 (<0.1)
Back pain	0	1 (<0.1)	1 (<0.1)
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	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)
Cervical spinal stenosis	1 (<0.1)	0	1 (<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)	3 (<0.1)	4 (<0.1)
Nephrolithiasis	0	3 (<0.1)	3 (<0.1)
Acute kidney injury	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	0	3 (<0.1)	3 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)	1 (<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	5 (<0.1)	6 (<0.1)	11 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chest pain	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 14.3.1.13.1
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Hernia	0	1 (<0.1)	1 (<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	11 (<0.1)	9 (<0.1)	20 (<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	2 (<0.1)	1 (<0.1)	3 (<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)
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)
Wrist fracture	0	1 (<0.1)	1 (<0.1)
Ankle 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 14.3.1.13.1
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Cartilage 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)
Ligament rupture	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)
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)	2 (<0.1)	4 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Foot operation	1 (<0.1)	0	1 (<0.1)
Hip arthroplasty	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.
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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Number of Unsolicited Adverse Events	211	207	418
Infections and infestations	39	23	62
Pneumonia	7	5	12
Appendicitis	3	2	5
Bronchitis	0	1	1
COVID-19	15	1	16
Cellulitis	0	1	1
Clostridium difficile infection	0	1	1
Gastroenteritis	0	1	1
Hepatitis A	0	1	1
Pneumonia staphylococcal	0	1	1
Postoperative abscess	0	1	1
Postoperative wound infection	0	1	1
Pyelonephritis acute	1	1	2
Salpingitis	0	1	1
Sepsis	1	1	2
Toxic shock syndrome	0	1	1
Urosepsis	0	1	1
Viral pharyngitis	0	1	1
Wound infection	0	1	1
COVID-19 pneumonia	1	0	1
Clostridium difficile colitis	1	0	1
Diverticulitis	2	0	2
Osteomyelitis	1	0	1

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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Infections and infestations (Cont.)			
Pharyngitis streptococcal	1	0	1
Septic shock	1	0	1
Streptococcal sepsis	1	0	1
Urinary tract infection	4	0	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10	16	26
Prostate cancer	3	3	6
B-cell small lymphocytic lymphoma	0	1	1
Chronic lymphocytic leukaemia	0	1	1
Colorectal cancer	0	1	1
Gastric cancer	0	1	1
Invasive lobular breast carcinoma	0	1	1
Lung cancer metastatic	0	1	1
Malignant melanoma	0	1	1
Meningioma	0	1	1
Oesophageal carcinoma	0	1	1
Papillary thyroid cancer	0	1	1
Pelvic neoplasm	0	1	1
Renal cancer	0	1	1
Renal cell carcinoma	0	1	1
Breast cancer stage I	1	0	1
Colon cancer stage III	1	0	1
Intraductal proliferative breast lesion	2	0	2

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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Leiomyosarcoma metastatic	1	0	1
Penile cancer	1	0	1
Prostate cancer metastatic	1	0	1
Blood and lymphatic system disorders	2	1	3
Blood loss anaemia	0	1	1
Anaemia	2	0	2
Endocrine disorders	0	1	1
Thyroid disorder	0	1	1
Metabolism and nutrition disorders	9	6	15
Dehydration	4	3	7
Diabetic ketoacidosis	0	1	1
Hypokalaemia	1	1	2
Hyponatraemia	1	1	2
Gout	1	0	1
Hypomagnesaemia	1	0	1
Metabolic acidosis	1	0	1
Psychiatric disorders	13	6	19
Alcohol withdrawal syndrome	0	2	2
Alcohol abuse	1	1	2

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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Psychiatric disorders (Cont.)			
Completed suicide	0	1	1
Intentional self-injury	0	1	1
Schizoaffective disorder	0	1	1
Anxiety	2	0	2
Anxiety disorder	1	0	1
Confusional state	2	0	2
Depression	3	0	3
Major depression	3	0	3
Psychotic disorder	1	0	1
Nervous system disorders	12	16	28
Cerebrovascular accident	1	3	4
Embolic stroke	0	2	2
Seizure	0	2	2
Syncope	4	2	6
Autonomic nervous system imbalance	0	1	1
Cervical radiculopathy	0	1	1
Dizziness	0	1	1
Facial paralysis	0	1	1
Subarachnoid haemorrhage	0	1	1
Toxic encephalopathy	0	1	1
Transient ischaemic attack	0	1	1
Basal ganglia haemorrhage	1	0	1
Ischaemic stroke	1	0	1

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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Nervous system disorders (Cont.)			
Migraine	1	0	1
Multiple sclerosis	1	0	1
Paraesthesia	2	0	2
Speech disorder	1	0	1
Eye disorders	2	0	2
Retinal detachment	1	0	1
Retinal tear	1	0	1
Cardiac disorders	28	25	53
Atrial fibrillation	5	5	10
Myocardial infarction	3	5	8
Cardiac failure congestive	3	3	6
Acute coronary syndrome	0	2	2
Acute myocardial infarction	4	2	6
Coronary artery disease	2	2	4
Acute left ventricular failure	1	1	2
Bradycardia	1	1	2
Cardiac failure	1	1	2
Cardio-respiratory arrest	1	1	2
Coronary artery thrombosis	0	1	1
Pericarditis	3	1	4
Atrial flutter	1	0	1
Cardiac failure acute	2	0	2

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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Cardiac disorders (Cont.)			
Tachycardia	1	0	1
Vascular disorders	11	10	21
Deep vein thrombosis	0	2	2
Hypertension	2	2	4
Aortic aneurysm	1	1	2
Arteriosclerosis	0	1	1
Axillary vein thrombosis	0	1	1
Haematoma	0	1	1
Hypertensive urgency	1	1	2
Hypotension	1	1	2
Accelerated hypertension	1	0	1
Aortic stenosis	1	0	1
Fibromuscular dysplasia	1	0	1
Hypertensive emergency	2	0	2
Peripheral artery aneurysm	1	0	1
Respiratory, thoracic and mediastinal disorders	21	14	35
Pulmonary embolism	5	4	9
Dyspnoea	0	3	3
Acute respiratory failure	2	2	4
Respiratory failure	1	2	3
Atelectasis	0	1	1
Cough	0	1	1

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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Emphysema	1	1	2
Asthma	1	0	1
Chronic obstructive pulmonary disease	4	0	4
Hypoxia	1	0	1
Laryngeal oedema	1	0	1
Organising pneumonia	1	0	1
Pleural effusion	1	0	1
Pleuritic pain	1	0	1
Pneumonia aspiration	1	0	1
Pneumothorax	1	0	1
Gastrointestinal disorders	12	26	38
Abdominal pain upper	0	3	3
Nausea	1	3	4
Colitis	1	2	3
Diarrhoea	1	2	3
Hiatus hernia	1	2	3
Rectal prolapse	0	2	2
Constipation	0	1	1
Diverticular perforation	0	1	1
Duodenal ulcer	0	1	1
Gastrointestinal haemorrhage	0	1	1
Gastrooesophageal reflux disease	0	1	1

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MedDRA version 23.0.
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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Gastrointestinal disorders (Cont.)			
Intestinal perforation	0	1	1
Large intestine perforation	0	1	1
Pancreatitis	0	1	1
Pancreatitis acute	0	1	1
Small intestinal obstruction	1	1	2
Volvulus	0	1	1
Vomiting	1	1	2
Abdominal pain	2	0	2
Duodenal ulcer haemorrhage	1	0	1
Food poisoning	1	0	1
Gastric perforation	1	0	1
Umbilical hernia	1	0	1
Hepatobiliary disorders	0	5	5
Cholecystitis	0	3	3
Bile duct stone	0	1	1
Hepatic mass	0	1	1
Skin and subcutaneous tissue disorders	2	2	4
Rash	0	1	1
Rash vesicular	0	1	1
Angioedema	1	0	1
Dermatitis bullous	1	0	1

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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Musculoskeletal and connective tissue disorders	9	12	21
Arthritis	1	2	3
Spinal stenosis	1	2	3
Back pain	0	1	1
Flank pain	0	1	1
Fracture nonunion	0	1	1
Intervertebral disc degeneration	0	1	1
Musculoskeletal chest pain	1	1	2
Neck pain	0	1	1
Osteoarthritis	2	1	3
Rheumatoid arthritis	0	1	1
Cervical spinal stenosis	1	0	1
Intervertebral disc protrusion	1	0	1
Polymyalgia rheumatica	1	0	1
Rhabdomyolysis	1	0	1
Renal and urinary disorders	4	4	8
Nephrolithiasis	0	3	3
Acute kidney injury	3	1	4
Chronic kidney disease	1	0	1
Pregnancy, puerperium and perinatal conditions	1	0	1
Abortion spontaneous	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.
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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Reproductive system and breast disorders	0	5	5
Benign prostatic hyperplasia	0	2	2
Uterine haemorrhage	0	2	2
Ovarian cyst	0	1	1
General disorders and administration site conditions	7	7	14
Chest pain	1	2	3
Swelling face	1	2	3
Hernia	0	1	1
Non-cardiac chest pain	1	1	2
Oedema peripheral	0	1	1
Feeling hot	1	0	1
Incarcerated hernia	1	0	1
Precancerous condition	1	0	1
Systemic inflammatory response syndrome	1	0	1
Investigations	0	1	1
Transaminases increased	0	1	1
Injury, poisoning and procedural complications	23	24	47
Cervical vertebral fracture	0	2	2
Fall	3	2	5
Road traffic accident	1	2	3
Subdural haematoma	0	2	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.
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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Injury, poisoning and procedural complications (Cont.)			
Animal bite	0	1	1
Back injury	0	1	1
Concussion	0	1	1
Craniocerebral injury	0	1	1
Facial bones fracture	0	1	1
Femoral neck fracture	0	1	1
Femur fracture	1	1	2
Head injury	0	1	1
Hip fracture	2	1	3
Humerus fracture	0	1	1
Incision site pain	0	1	1
Overdose	0	1	1
Skin laceration	1	1	2
Tendon rupture	0	1	1
Traumatic liver injury	0	1	1
Wrist fracture	0	1	1
Ankle fracture	3	0	3
Cartilage injury	1	0	1
Foot fracture	1	0	1
Gun shot wound	1	0	1
Immunisation anxiety related reaction	1	0	1
Joint injury	2	0	2
Ligament rupture	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.
MedDRA version 23.0.
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Table 14.3.1.13.10
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Injury, poisoning and procedural complications (Cont.)			
Post procedural haematoma	1	0	1
Post procedural haemorrhage	1	0	1
Procedural haemorrhage	1	0	1
Rib fracture	1	0	1
Thoracic vertebral fracture	1	0	1
Surgical and medical procedures	4	3	7
Ankle arthroplasty	0	1	1
Knee arthroplasty	0	1	1
Thyroidectomy	0	1	1
Foot operation	1	0	1
Hip arthroplasty	1	0	1
Jaw operation	1	0	1
Spinal fusion surgery	1	0	1
Social circumstances	1	0	1
Sexual abuse	1	0	1
Product issues	1	0	1
Lead dislodgement	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.
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Table 14.3.1.14.10
Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Number of Unsolicited Adverse Events	8	8	16
Nervous system disorders	2	1	3
Autonomic nervous system imbalance	0	1	1
Paraesthesia	2	0	2
Respiratory, thoracic and mediastinal disorders	1	1	2
Dyspnoea	0	1	1
Pulmonary embolism	1	0	1
Gastrointestinal disorders	0	2	2
Nausea	0	1	1
Vomiting	0	1	1
Musculoskeletal and connective tissue disorders	1	1	2
Rheumatoid arthritis	0	1	1
Polymyalgia rheumatica	1	0	1
General disorders and administration site conditions	2	3	5
Swelling face	1	2	3
Oedema peripheral	0	1	1
Feeling hot	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.
MedDRA version 23.0.
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Table 14.3.1.14.10
Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15166)	 mRNA-1273 (N=15185)	 Total (N=30351)
Injury, poisoning and procedural complications	2	0	2
Immunisation anxiety related reaction	1	0	1
Procedural haemorrhage	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.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	28 (0.2)	71 (0.5)	99 (0.3)
Number of Unsolicited Adverse Events	32	83	115
Blood and lymphatic system disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lymphadenopathy	1 (<0.1)	1 (<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)	4 (<0.1)	13 (<0.1)
Hypertension	9 (<0.1)	4 (<0.1)	13 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders	0	1 (<0.1)	1 (<0.1)
Nausea	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	0	3 (<0.1)	3 (<0.1)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Rash	0	1 (<0.1)	1 (<0.1)
Rash macular	0	1 (<0.1)	1 (<0.1)
Musculoskeletal and connective tissue disorders	4 (<0.1)	11 (<0.1)	15 (<0.1)
Myalgia	0	6 (<0.1)	6 (<0.1)
Arthralgia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Muscle spasms	0	2 (<0.1)	2 (<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	4 (<0.1)	37 (0.2)	41 (0.1)
Injection site erythema	0	11 (<0.1)	11 (<0.1)
Fatigue	2 (<0.1)	9 (<0.1)	11 (<0.1)
Injection site swelling	0	4 (<0.1)	4 (<0.1)
Injection site macule	0	3 (<0.1)	3 (<0.1)
Chills	0	2 (<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.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Injection site lymphadenopathy	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)
Chest discomfort	0	1 (<0.1)	1 (<0.1)
Injection site induration	0	1 (<0.1)	1 (<0.1)
Injection site rash	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)
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)

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 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1958 (12.9)	1745 (11.5)	3703 (12.2)
Number of Unsolicited Adverse Events	3119	2863	5982
Infections and infestations	840 (5.5)	582 (3.8)	1422 (4.7)
Urinary tract infection	110 (0.7)	82 (0.5)	192 (0.6)
Upper respiratory tract infection	60 (0.4)	55 (0.4)	115 (0.4)
Sinusitis	44 (0.3)	50 (0.3)	94 (0.3)
COVID-19	269 (1.8)	29 (0.2)	298 (1.0)
Viral infection	40 (0.3)	29 (0.2)	69 (0.2)
Pharyngitis streptococcal	20 (0.1)	19 (0.1)	39 (0.1)
Herpes zoster	14 (<0.1)	18 (0.1)	32 (0.1)
Tooth infection	16 (0.1)	17 (0.1)	33 (0.1)
Cellulitis	11 (<0.1)	16 (0.1)	27 (<0.1)
Tooth abscess	19 (0.1)	16 (0.1)	35 (0.1)
Ear infection	13 (<0.1)	15 (<0.1)	28 (<0.1)
Rhinovirus infection	16 (0.1)	14 (<0.1)	30 (<0.1)
Pharyngitis	17 (0.1)	12 (<0.1)	29 (<0.1)
Bronchitis	9 (<0.1)	10 (<0.1)	19 (<0.1)
Diverticulitis	8 (<0.1)	10 (<0.1)	18 (<0.1)
Localised infection	8 (<0.1)	10 (<0.1)	18 (<0.1)
Conjunctivitis	6 (<0.1)	8 (<0.1)	14 (<0.1)
Gastroenteritis	8 (<0.1)	8 (<0.1)	16 (<0.1)
Pneumonia	12 (<0.1)	8 (<0.1)	20 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Otitis externa	8 (<0.1)	7 (<0.1)	15 (<0.1)
Enterovirus infection	1 (<0.1)	6 (<0.1)	7 (<0.1)
Hordeolum	8 (<0.1)	6 (<0.1)	14 (<0.1)
Otitis media	8 (<0.1)	6 (<0.1)	14 (<0.1)
Paronychia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Suspected COVID-19	9 (<0.1)	6 (<0.1)	15 (<0.1)
Acute sinusitis	6 (<0.1)	5 (<0.1)	11 (<0.1)
Fungal infection	6 (<0.1)	5 (<0.1)	11 (<0.1)
Gingivitis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Respiratory tract infection	5 (<0.1)	5 (<0.1)	10 (<0.1)
Skin infection	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bacterial vaginosis	5 (<0.1)	4 (<0.1)	9 (<0.1)
Cystitis	5 (<0.1)	4 (<0.1)	9 (<0.1)
Folliculitis	4 (<0.1)	4 (<0.1)	8 (<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	2 (<0.1)	3 (<0.1)	5 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Herpes simplex	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Lyme disease	0	3 (<0.1)	3 (<0.1)
Postoperative wound infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Staphylococcal infection	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 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Subcutaneous abscess	0	3 (<0.1)	3 (<0.1)
Viral upper respiratory tract infection	8 (<0.1)	3 (<0.1)	11 (<0.1)
Vulvovaginal candidiasis	4 (<0.1)	3 (<0.1)	7 (<0.1)
Wound infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Appendicitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	0	2 (<0.1)	2 (<0.1)
Clostridium difficile colitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Impetigo	0	2 (<0.1)	2 (<0.1)
Infected bite	0	2 (<0.1)	2 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oral herpes	2 (<0.1)	2 (<0.1)	4 (<0.1)
Otitis media acute	4 (<0.1)	2 (<0.1)	6 (<0.1)
Rhinitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sepsis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Sinusitis bacterial	3 (<0.1)	2 (<0.1)	5 (<0.1)
Staphylococcal skin infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tonsillitis	6 (<0.1)	2 (<0.1)	8 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vulvovaginal mycotic infection	10 (<0.1)	2 (<0.1)	12 (<0.1)
Abscess	0	1 (<0.1)	1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Campylobacter gastroenteritis	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 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
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)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Furuncle	0	1 (<0.1)	1 (<0.1)
Gastroenteritis viral	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastrointestinal infection	0	1 (<0.1)	1 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Infected dermal cyst	1 (<0.1)	1 (<0.1)	2 (<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)
Nail infection	0	1 (<0.1)	1 (<0.1)
Nasopharyngitis	6 (<0.1)	1 (<0.1)	7 (<0.1)
Oral candidiasis	4 (<0.1)	1 (<0.1)	5 (<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)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Parotitis	0	1 (<0.1)	1 (<0.1)
Periodontitis	0	1 (<0.1)	1 (<0.1)
Pertussis	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)
Pulpitis dental	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pyelonephritis	0	1 (<0.1)	1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)	1 (<0.1)
Rash pustular	0	1 (<0.1)	1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Salpingitis	0	1 (<0.1)	1 (<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)
Upper respiratory tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Urosepsis	0	1 (<0.1)	1 (<0.1)
Uterine infection	0	1 (<0.1)	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Viral rhinitis	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 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Balanitis candida	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)
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0	2 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Conjunctivitis bacterial	3 (<0.1)	0	3 (<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 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)
Genital herpes	1 (<0.1)	0	1 (<0.1)
Infected skin ulcer	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)
Respiratory tract infection viral	9 (<0.1)	0	9 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Skin bacterial infection	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 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Streptococcal sepsis	1 (<0.1)	0	1 (<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)
Trichomoniasis	1 (<0.1)	0	1 (<0.1)
Viral sinusitis	2 (<0.1)	0	2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	47 (0.3)	52 (0.3)	99 (0.3)
Basal cell carcinoma	14 (<0.1)	7 (<0.1)	21 (<0.1)
Squamous cell carcinoma	6 (<0.1)	4 (<0.1)	10 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)	6 (<0.1)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Prostate cancer	4 (<0.1)	3 (<0.1)	7 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Angiolipoma	0	1 (<0.1)	1 (<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 cancer in situ	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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Colorectal cancer	0	1 (<0.1)	1 (<0.1)
Gastric cancer	0	1 (<0.1)	1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)	1 (<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)
Papillary thyroid cancer	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)
Prostate cancer stage I	0	1 (<0.1)	1 (<0.1)
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Renal cell carcinoma	0	1 (<0.1)	1 (<0.1)
Renal neoplasm	0	1 (<0.1)	1 (<0.1)
Skin cancer	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Uterine leiomyoma	0	1 (<0.1)	1 (<0.1)
Benign breast neoplasm	1 (<0.1)	0	1 (<0.1)
Benign neoplasm of 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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
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)
Haemangioma of liver	1 (<0.1)	0	1 (<0.1)
Hepatic cancer	1 (<0.1)	0	1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0	1 (<0.1)
Metastases to bone	1 (<0.1)	0	1 (<0.1)
Penile cancer	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0	1 (<0.1)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	28 (0.2)	37 (0.2)	65 (0.2)
Lymphadenopathy	17 (0.1)	24 (0.2)	41 (0.1)
Anaemia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Thrombocytopenia	0	3 (<0.1)	3 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lymphadenitis	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Blood and lymphatic system disorders (Cont.)			
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Immune system disorders	17 (0.1)	10 (<0.1)	27 (<0.1)
Seasonal allergy	7 (<0.1)	4 (<0.1)	11 (<0.1)
Drug hypersensitivity	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anaphylactic reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypersensitivity	3 (<0.1)	1 (<0.1)	4 (<0.1)
Immune system disorder	0	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to metals	1 (<0.1)	0	1 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Food allergy	1 (<0.1)	0	1 (<0.1)
Serum sickness	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	6 (<0.1)	13 (<0.1)	19 (<0.1)
Hypothyroidism	3 (<0.1)	6 (<0.1)	9 (<0.1)
Thyroid mass	0	2 (<0.1)	2 (<0.1)
Goitre	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperparathyroidism	0	1 (<0.1)	1 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Thyroid disorder	0	1 (<0.1)	1 (<0.1)
Thyroiditis	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Endocrine disorders (Cont.)			
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Hypogonadism	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	77 (0.5)	61 (0.4)	138 (0.5)
Hyperlipidaemia	14 (<0.1)	13 (<0.1)	27 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	11 (<0.1)	12 (<0.1)
Vitamin D deficiency	3 (<0.1)	7 (<0.1)	10 (<0.1)
Hypercholesterolaemia	14 (<0.1)	6 (<0.1)	20 (<0.1)
Dehydration	10 (<0.1)	4 (<0.1)	14 (<0.1)
Hyponatraemia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hyperglycaemia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Decreased appetite	3 (<0.1)	2 (<0.1)	5 (<0.1)
Diabetes mellitus	3 (<0.1)	2 (<0.1)	5 (<0.1)
Gout	7 (<0.1)	2 (<0.1)	9 (<0.1)
Hypertriglyceridaemia	0	2 (<0.1)	2 (<0.1)
Hypokalaemia	3 (<0.1)	2 (<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)
Glucose tolerance impaired	4 (<0.1)	1 (<0.1)	5 (<0.1)
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)
Hypocalcaemia	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Metabolism and nutrition disorders (Cont.)			
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	4 (<0.1)	0	4 (<0.1)
Electrolyte imbalance	1 (<0.1)	0	1 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hyperuricaemia	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	1 (<0.1)	0	1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Metabolic acidosis	1 (<0.1)	0	1 (<0.1)
Obesity	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	66 (0.4)	63 (0.4)	129 (0.4)
Anxiety	22 (0.1)	26 (0.2)	48 (0.2)
Depression	19 (0.1)	23 (0.2)	42 (0.1)
Attention deficit hyperactivity disorder	8 (<0.1)	6 (<0.1)	14 (<0.1)
Insomnia	3 (<0.1)	2 (<0.1)	5 (<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)
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Psychiatric disorders (Cont.)			
Major depression	3 (<0.1)	1 (<0.1)	4 (<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)
Dissociative disorder	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	167 (1.1)	158 (1.0)	325 (1.1)
Headache	94 (0.6)	80 (0.5)	174 (0.6)
Sciatica	6 (<0.1)	8 (<0.1)	14 (<0.1)
Dizziness	14 (<0.1)	7 (<0.1)	21 (<0.1)
Migraine	5 (<0.1)	7 (<0.1)	12 (<0.1)
Anosmia	4 (<0.1)	6 (<0.1)	10 (<0.1)
Paraesthesia	9 (<0.1)	6 (<0.1)	15 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
Cerebrovascular accident	1 (<0.1)	4 (<0.1)	5 (<0.1)
Cervical radiculopathy	0	4 (<0.1)	4 (<0.1)
Syncope	12 (<0.1)	4 (<0.1)	16 (<0.1)
Ageusia	6 (<0.1)	3 (<0.1)	9 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	3 (<0.1)	5 (<0.1)
Facial paralysis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Presyncope	5 (<0.1)	3 (<0.1)	8 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Hypoaesthesia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Nerve compression	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)
Autonomic nervous system imbalance	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)
Cerebral small vessel ischaemic disease	0	1 (<0.1)	1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)	2 (<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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Piriformis syndrome	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)	1 (<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)
Subarachnoid haemorrhage	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Thoracic outlet syndrome	0	1 (<0.1)	1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Aphasia	1 (<0.1)	0	1 (<0.1)
Arachnoid cyst	1 (<0.1)	0	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dementia	1 (<0.1)	0	1 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Multiple sclerosis	1 (<0.1)	0	1 (<0.1)
Neuralgia	2 (<0.1)	0	2 (<0.1)
Neuropathy peripheral	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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
Tension headache	1 (<0.1)	0	1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0	1 (<0.1)
Eye disorders	26 (0.2)	25 (0.2)	51 (0.2)
Retinal detachment	2 (<0.1)	3 (<0.1)	5 (<0.1)
Blepharitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cataract	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vision blurred	2 (<0.1)	2 (<0.1)	4 (<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)
Dry eye	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eye discharge	0	1 (<0.1)	1 (<0.1)
Eye disorder	0	1 (<0.1)	1 (<0.1)
Eye haemorrhage	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)
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)
Orbital haematoma	0	1 (<0.1)	1 (<0.1)
Scleritis	0	1 (<0.1)	1 (<0.1)
Vitreous disorder	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Eye disorders (Cont.)			
Vitreous floaters	1 (<0.1)	1 (<0.1)	2 (<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)
Ocular rosacea	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Retinal haemorrhage	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)
Vitreous detachment	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	36 (0.2)	22 (0.1)	58 (0.2)
Vertigo	5 (<0.1)	7 (<0.1)	12 (<0.1)
Vertigo positional	2 (<0.1)	5 (<0.1)	7 (<0.1)
Ear pain	6 (<0.1)	4 (<0.1)	10 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Ear and labyrinth disorders (Cont.)			
Cerumen impaction	3 (<0.1)	1 (<0.1)	4 (<0.1)
Deafness neurosensory	0	1 (<0.1)	1 (<0.1)
Ear canal erythema	3 (<0.1)	1 (<0.1)	4 (<0.1)
Ear discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniere's disease	0	1 (<0.1)	1 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Motion sickness	0	1 (<0.1)	1 (<0.1)
Tinnitus	4 (<0.1)	1 (<0.1)	5 (<0.1)
Ear congestion	2 (<0.1)	0	2 (<0.1)
Ear pruritus	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 hyperaemia	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	0	4 (<0.1)
Cardiac disorders	48 (0.3)	51 (0.3)	99 (0.3)
Atrial fibrillation	9 (<0.1)	14 (<0.1)	23 (<0.1)
Coronary artery disease	4 (<0.1)	5 (<0.1)	9 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Tachycardia	6 (<0.1)	5 (<0.1)	11 (<0.1)
Angina pectoris	1 (<0.1)	4 (<0.1)	5 (<0.1)
Cardiac failure congestive	5 (<0.1)	4 (<0.1)	9 (<0.1)
Palpitations	3 (<0.1)	4 (<0.1)	7 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Cardiac disorders (Cont.)			
Cardiac failure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Sinus tachycardia	0	3 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	2 (<0.1)	2 (<0.1)
Acute myocardial infarction	4 (<0.1)	2 (<0.1)	6 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arrhythmia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Bradycardia	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)
Coronary artery thrombosis	0	1 (<0.1)	1 (<0.1)
Mitral valve incompetence	0	1 (<0.1)	1 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Supraventricular extrasystoles	0	1 (<0.1)	1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	1 (<0.1)
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Atrial tachycardia	2 (<0.1)	0	2 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Sinus arrest	1 (<0.1)	0	1 (<0.1)
Sinus bradycardia	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	103 (0.7)	102 (0.7)	205 (0.7)
Hypertension	80 (0.5)	80 (0.5)	160 (0.5)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Vascular disorders (Cont.)			
Deep vein thrombosis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypertensive urgency	2 (<0.1)	3 (<0.1)	5 (<0.1)
Haematoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hot flush	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)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Arteriosclerosis	0	1 (<0.1)	1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)	1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)	2 (<0.1)
Flushing	0	1 (<0.1)	1 (<0.1)
Hypertensive emergency	2 (<0.1)	1 (<0.1)	3 (<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)
Systolic hypertension	0	1 (<0.1)	1 (<0.1)
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Blood pressure inadequately controlled	1 (<0.1)	0	1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0	1 (<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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Vascular disorders (Cont.)			
Phlebitis	1 (<0.1)	0	1 (<0.1)
Varicose vein	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	220 (1.5)	186 (1.2)	406 (1.3)
Cough	86 (0.6)	76 (0.5)	162 (0.5)
Nasal congestion	60 (0.4)	66 (0.4)	126 (0.4)
Rhinorrhoea	50 (0.3)	60 (0.4)	110 (0.4)
Oropharyngeal pain	63 (0.4)	49 (0.3)	112 (0.4)
Dyspnoea	26 (0.2)	28 (0.2)	54 (0.2)
Asthma	8 (<0.1)	7 (<0.1)	15 (<0.1)
Upper-airway cough syndrome	3 (<0.1)	6 (<0.1)	9 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	5 (<0.1)	13 (<0.1)
Pulmonary embolism	5 (<0.1)	5 (<0.1)	10 (<0.1)
Respiratory tract congestion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Sinus congestion	8 (<0.1)	5 (<0.1)	13 (<0.1)
Paranasal sinus discomfort	0	3 (<0.1)	3 (<0.1)
Rhinitis allergic	4 (<0.1)	3 (<0.1)	7 (<0.1)
Sneezing	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dysphonia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Throat irritation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wheezing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acute respiratory failure	2 (<0.1)	1 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchiectasis	0	1 (<0.1)	1 (<0.1)
Dyspnoea exertional	1 (<0.1)	1 (<0.1)	2 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)
Pharyngeal erythema	5 (<0.1)	1 (<0.1)	6 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleuritic pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Productive cough	0	1 (<0.1)	1 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory symptom	0	1 (<0.1)	1 (<0.1)
Tachypnoea	0	1 (<0.1)	1 (<0.1)
Tonsillolith	2 (<0.1)	1 (<0.1)	3 (<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)
Lower respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Nasal ulcer	1 (<0.1)	0	1 (<0.1)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Painful respiration	1 (<0.1)	0	1 (<0.1)
Paranasal sinus hypersecretion	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pleural effusion	2 (<0.1)	0	2 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Pneumothorax	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	1 (<0.1)	0	1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Rales	1 (<0.1)	0	1 (<0.1)
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Throat tightness	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	176 (1.2)	191 (1.3)	367 (1.2)
Diarrhoea	42 (0.3)	47 (0.3)	89 (0.3)
Nausea	34 (0.2)	40 (0.3)	74 (0.2)
Gastrooesophageal reflux disease	9 (<0.1)	21 (0.1)	30 (<0.1)
Toothache	12 (<0.1)	16 (0.1)	28 (<0.1)
Vomiting	12 (<0.1)	14 (<0.1)	26 (<0.1)
Dental caries	9 (<0.1)	10 (<0.1)	19 (<0.1)
Abdominal pain	11 (<0.1)	9 (<0.1)	20 (<0.1)
Abdominal pain upper	3 (<0.1)	9 (<0.1)	12 (<0.1)
Constipation	4 (<0.1)	6 (<0.1)	10 (<0.1)
Colitis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Hiatus hernia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Inguinal hernia	3 (<0.1)	4 (<0.1)	7 (<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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
Abdominal pain lower	4 (<0.1)	3 (<0.1)	7 (<0.1)
Gastric ulcer	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematochezia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Diverticulum	1 (<0.1)	2 (<0.1)	3 (<0.1)
Food poisoning	4 (<0.1)	2 (<0.1)	6 (<0.1)
Large intestine polyp	4 (<0.1)	2 (<0.1)	6 (<0.1)
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Pancreatitis	0	2 (<0.1)	2 (<0.1)
Stomatitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tooth impacted	2 (<0.1)	2 (<0.1)	4 (<0.1)
Umbilical hernia	2 (<0.1)	2 (<0.1)	4 (<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)
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)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Haemorrhoids	0	1 (<0.1)	1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
Impaired gastric emptying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intestinal perforation	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)
Melaena	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)
Oral mucosal blistering	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)
Periodontal disease	0	1 (<0.1)	1 (<0.1)
Proctalgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)
Rectal prolapse	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)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tongue disorder	0	1 (<0.1)	1 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Abdominal tenderness	1 (<0.1)	0	1 (<0.1)
Aphthous ulcer	1 (<0.1)	0	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
Dyspepsia	3 (<0.1)	0	3 (<0.1)
Dysphagia	1 (<0.1)	0	1 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Flatulence	1 (<0.1)	0	1 (<0.1)
Gastric perforation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0	1 (<0.1)
Gingival swelling	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	1 (<0.1)	0	1 (<0.1)
Lip swelling	2 (<0.1)	0	2 (<0.1)
Loose tooth	1 (<0.1)	0	1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0	1 (<0.1)
Oral cavity fistula	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)
Peptic ulcer	1 (<0.1)	0	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	2 (<0.1)	15 (<0.1)	17 (<0.1)
Cholelithiasis	0	6 (<0.1)	6 (<0.1)
Cholecystitis	0	4 (<0.1)	4 (<0.1)
Hepatic mass	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 steatosis	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Hepatobiliary disorders (Cont.)			
Hepatic cyst	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	86 (0.6)	87 (0.6)	173 (0.6)
Rash	14 (<0.1)	12 (<0.1)	26 (<0.1)
Dermatitis contact	12 (<0.1)	10 (<0.1)	22 (<0.1)
Pruritus	4 (<0.1)	6 (<0.1)	10 (<0.1)
Urticaria	5 (<0.1)	6 (<0.1)	11 (<0.1)
Acne	6 (<0.1)	5 (<0.1)	11 (<0.1)
Dermatitis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Skin lesion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Actinic keratosis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Erythema	3 (<0.1)	4 (<0.1)	7 (<0.1)
Rosacea	2 (<0.1)	4 (<0.1)	6 (<0.1)
Rash maculo-papular	0	3 (<0.1)	3 (<0.1)
Dermatitis atopic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hyperhidrosis	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)
Rash vesicular	0	2 (<0.1)	2 (<0.1)
Alopecia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blister	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood blister	0	1 (<0.1)	1 (<0.1)
Dermal cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dermatitis allergic	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Eczema	0	1 (<0.1)	1 (<0.1)
Hand dermatitis	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)
Precancerous skin lesion	0	1 (<0.1)	1 (<0.1)
Rash erythematous	0	1 (<0.1)	1 (<0.1)
Rash macular	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rash pruritic	2 (<0.1)	1 (<0.1)	3 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin ulcer	0	1 (<0.1)	1 (<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)
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)
Myxoid cyst	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 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Night sweats	1 (<0.1)	0	1 (<0.1)
Psoriasis	1 (<0.1)	0	1 (<0.1)
Scab	1 (<0.1)	0	1 (<0.1)
Skin mass	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	209 (1.4)	219 (1.4)	428 (1.4)
Arthralgia	37 (0.2)	35 (0.2)	72 (0.2)
Myalgia	38 (0.3)	27 (0.2)	65 (0.2)
Back pain	37 (0.2)	24 (0.2)	61 (0.2)
Neck pain	7 (<0.1)	16 (0.1)	23 (<0.1)
Pain in extremity	18 (0.1)	15 (<0.1)	33 (0.1)
Muscle spasms	9 (<0.1)	13 (<0.1)	22 (<0.1)
Musculoskeletal pain	6 (<0.1)	13 (<0.1)	19 (<0.1)
Arthritis	2 (<0.1)	9 (<0.1)	11 (<0.1)
Osteoarthritis	15 (<0.1)	9 (<0.1)	24 (<0.1)
Tendonitis	7 (<0.1)	9 (<0.1)	16 (<0.1)
Bursitis	5 (<0.1)	6 (<0.1)	11 (<0.1)
Musculoskeletal chest pain	6 (<0.1)	6 (<0.1)	12 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	5 (<0.1)	8 (<0.1)
Rotator cuff syndrome	5 (<0.1)	4 (<0.1)	9 (<0.1)
Flank pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Joint swelling	0	3 (<0.1)	3 (<0.1)
Muscle tightness	0	3 (<0.1)	3 (<0.1)
Musculoskeletal stiffness	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteopenia	0	3 (<0.1)	3 (<0.1)
Spinal stenosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Trigger finger	0	3 (<0.1)	3 (<0.1)
Exostosis	2 (<0.1)	2 (<0.1)	4 (<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 osteoarthritis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bone pain	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	1 (<0.1)
Fibromyalgia	2 (<0.1)	1 (<0.1)	3 (<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	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)
Limb mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle twitching	0	1 (<0.1)	1 (<0.1)
Osteonecrosis	0	1 (<0.1)	1 (<0.1)
Periarthritis	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Plantar fasciitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)	1 (<0.1)
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Tenosynovitis stenosans	0	1 (<0.1)	1 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)	2 (<0.1)
Axillary mass	2 (<0.1)	0	2 (<0.1)
Bone lesion	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)
Musculoskeletal disorder	1 (<0.1)	0	1 (<0.1)
Myositis	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)
Rhabdomyolysis	1 (<0.1)	0	1 (<0.1)
Synovial cyst	2 (<0.1)	0	2 (<0.1)
Synovitis	1 (<0.1)	0	1 (<0.1)
Systemic lupus erythematosus	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.3
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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Renal and urinary disorders	40 (0.3)	34 (0.2)	74 (0.2)
Nephrolithiasis	20 (0.1)	14 (<0.1)	34 (0.1)
Chronic kidney disease	1 (<0.1)	3 (<0.1)	4 (<0.1)
Acute kidney injury	3 (<0.1)	2 (<0.1)	5 (<0.1)
Dysuria	2 (<0.1)	2 (<0.1)	4 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
Haematuria	6 (<0.1)	1 (<0.1)	7 (<0.1)
Hydronephrosis	0	1 (<0.1)	1 (<0.1)
Hypertonic bladder	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)
Renal cyst	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	2 (<0.1)	0	2 (<0.1)
Renal mass	1 (<0.1)	0	1 (<0.1)
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hyperemesis gravidarum	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Pregnancy, puerperium and perinatal conditions (Cont.)			
Pregnancy	0	1 (<0.1)	1 (<0.1)
Abortion spontaneous	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	26 (0.2)	35 (0.2)	61 (0.2)
Pelvic pain	0	3 (<0.1)	3 (<0.1)
Benign prostatic hyperplasia	6 (<0.1)	2 (<0.1)	8 (<0.1)
Dysmenorrhoea	0	2 (<0.1)	2 (<0.1)
Ovarian cyst	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostatitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Uterine haemorrhage	0	2 (<0.1)	2 (<0.1)
Uterine polyp	0	2 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Adnexa uteri pain	0	1 (<0.1)	1 (<0.1)
Adnexal torsion	0	1 (<0.1)	1 (<0.1)
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Breast cyst	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	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)
Erectile dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fibrocystic breast disease	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Reproductive system and breast disorders (Cont.)			
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Menopausal symptoms	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menorrhagia	0	1 (<0.1)	1 (<0.1)
Menstrual disorder	0	1 (<0.1)	1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)	1 (<0.1)
Postmenopausal haemorrhage	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)
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0	1 (<0.1)
Congenital, familial and genetic disorders	2 (<0.1)	3 (<0.1)	5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)	2 (<0.1)
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Hydrocele	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions	154 (1.0)	149 (1.0)	303 (1.0)
Fatigue	76 (0.5)	61 (0.4)	137 (0.5)
Pain	29 (0.2)	28 (0.2)	57 (0.2)
Chills	21 (0.1)	20 (0.1)	41 (0.1)
Pyrexia	19 (0.1)	19 (0.1)	38 (0.1)
Injection site erythema	1 (<0.1)	9 (<0.1)	10 (<0.1)
Injection site pain	4 (<0.1)	9 (<0.1)	13 (<0.1)
Chest discomfort	11 (<0.1)	8 (<0.1)	19 (<0.1)
Chest pain	3 (<0.1)	8 (<0.1)	11 (<0.1)
Injection site induration	0	6 (<0.1)	6 (<0.1)
Injection site swelling	0	5 (<0.1)	5 (<0.1)
Injection site rash	0	4 (<0.1)	4 (<0.1)
Non-cardiac chest pain	4 (<0.1)	3 (<0.1)	7 (<0.1)
Swelling face	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hernia	0	2 (<0.1)	2 (<0.1)
Oedema peripheral	5 (<0.1)	2 (<0.1)	7 (<0.1)
Swelling	0	2 (<0.1)	2 (<0.1)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)
Asthenia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Axillary pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Crying	0	1 (<0.1)	1 (<0.1)
Cyst	3 (<0.1)	1 (<0.1)	4 (<0.1)
Early satiety	0	1 (<0.1)	1 (<0.1)
Feeling hot	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
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 lymphadenopathy	1 (<0.1)	1 (<0.1)	2 (<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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Peripheral swelling	5 (<0.1)	1 (<0.1)	6 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Facial pain	1 (<0.1)	0	1 (<0.1)
Feeling abnormal	1 (<0.1)	0	1 (<0.1)
Gait disturbance	2 (<0.1)	0	2 (<0.1)
Hangover	1 (<0.1)	0	1 (<0.1)
Impaired healing	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 bruising	2 (<0.1)	0	2 (<0.1)
Medical device site inflammation	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Systemic inflammatory response syndrome	1 (<0.1)	0	1 (<0.1)
Investigations	34 (0.2)	39 (0.3)	73 (0.2)
Blood pressure increased	6 (<0.1)	4 (<0.1)	10 (<0.1)
Transaminases increased	0	4 (<0.1)	4 (<0.1)
Blood pressure systolic increased	4 (<0.1)	3 (<0.1)	7 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hepatic enzyme increased	0	3 (<0.1)	3 (<0.1)
Blood cholesterol 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)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Blood glucose decreased	0	1 (<0.1)	1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood triglycerides increased	0	1 (<0.1)	1 (<0.1)
Blood urine present	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)
Haemoglobin decreased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatic enzyme abnormal	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Investigations (Cont.)			
Hepatitis B antibody positive	0	1 (<0.1)	1 (<0.1)
Human rhinovirus test 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	1 (<0.1)	1 (<0.1)	2 (<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)
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)
Biopsy endometrium	1 (<0.1)	0	1 (<0.1)
Blood glucose increased	2 (<0.1)	0	2 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Blood prolactin increased	1 (<0.1)	0	1 (<0.1)
Blood testosterone decreased	2 (<0.1)	0	2 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
Breath sounds abnormal	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)
International normalised ratio increased	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	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications	212 (1.4)	199 (1.3)	411 (1.4)
Skin laceration	30 (0.2)	20 (0.1)	50 (0.2)
Ligament sprain	9 (<0.1)	18 (0.1)	27 (<0.1)
Muscle strain	11 (<0.1)	14 (<0.1)	25 (<0.1)
Foot fracture	12 (<0.1)	13 (<0.1)	25 (<0.1)
Limb injury	6 (<0.1)	10 (<0.1)	16 (<0.1)
Procedural pain	16 (0.1)	10 (<0.1)	26 (<0.1)
Arthropod bite	8 (<0.1)	9 (<0.1)	17 (<0.1)
Tooth fracture	10 (<0.1)	9 (<0.1)	19 (<0.1)
Fall	8 (<0.1)	8 (<0.1)	16 (<0.1)
Concussion	4 (<0.1)	7 (<0.1)	11 (<0.1)
Animal bite	7 (<0.1)	6 (<0.1)	13 (<0.1)
Meniscus injury	3 (<0.1)	6 (<0.1)	9 (<0.1)
Hand fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Head injury	1 (<0.1)	4 (<0.1)	5 (<0.1)
Joint injury	4 (<0.1)	4 (<0.1)	8 (<0.1)
Rib fracture	2 (<0.1)	4 (<0.1)	6 (<0.1)
Wrist fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Arthropod sting	4 (<0.1)	3 (<0.1)	7 (<0.1)
Contusion	9 (<0.1)	3 (<0.1)	12 (<0.1)
Corneal abrasion	3 (<0.1)	3 (<0.1)	6 (<0.1)
Post-traumatic pain	2 (<0.1)	3 (<0.1)	5 (<0.1)
Road traffic accident	6 (<0.1)	3 (<0.1)	9 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)
Ankle fracture	6 (<0.1)	2 (<0.1)	8 (<0.1)

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Percentages are based on the number of safety subjects.
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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Bone contusion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Clavicle fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Epicondylitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Facial bones fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Humerus fracture	0	2 (<0.1)	2 (<0.1)
Ligament injury	0	2 (<0.1)	2 (<0.1)
Ligament rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Subdural haematoma	0	2 (<0.1)	2 (<0.1)
Tendon rupture	2 (<0.1)	2 (<0.1)	4 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<0.1)
Back injury	4 (<0.1)	1 (<0.1)	5 (<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)
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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Foreign body in respiratory tract	0	1 (<0.1)	1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Incision site pain	0	1 (<0.1)	1 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	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)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post procedural swelling	0	1 (<0.1)	1 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Procedural nausea	0	1 (<0.1)	1 (<0.1)
Scar	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal column injury	0	1 (<0.1)	1 (<0.1)
Spinal compression fracture	0	1 (<0.1)	1 (<0.1)
Stab wound	0	1 (<0.1)	1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)	6 (<0.1)
Tendon 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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Thermal burn	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Traumatic fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Uterine rupture	0	1 (<0.1)	1 (<0.1)
Wound	3 (<0.1)	1 (<0.1)	4 (<0.1)
Ear injury	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)
Gun shot wound	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)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0	2 (<0.1)
Pulmonary contusion	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)

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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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Skin abrasion	5 (<0.1)	0	5 (<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)
Vaccination complication	2 (<0.1)	0	2 (<0.1)
Surgical and medical procedures	15 (<0.1)	16 (0.1)	31 (0.1)
Endodontic procedure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Skin neoplasm excision	0	2 (<0.1)	2 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Cataract operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cholecystectomy	0	1 (<0.1)	1 (<0.1)
Curetting of chalazion	0	1 (<0.1)	1 (<0.1)
Dental operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hip arthroplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Influenza immunisation	0	1 (<0.1)	1 (<0.1)
Knee arthroplasty	0	1 (<0.1)	1 (<0.1)
Pancreatic stent placement	0	1 (<0.1)	1 (<0.1)
Skin cyst excision	0	1 (<0.1)	1 (<0.1)
Thyroidectomy	0	1 (<0.1)	1 (<0.1)
Tooth extraction	2 (<0.1)	1 (<0.1)	3 (<0.1)
Transfusion	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=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Surgical and medical procedures (Cont.)			
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Foot operation	1 (<0.1)	0	1 (<0.1)
Fracture treatment	1 (<0.1)	0	1 (<0.1)
Jaw operation	1 (<0.1)	0	1 (<0.1)
Spinal fusion surgery	1 (<0.1)	0	1 (<0.1)
Tooth repair	3 (<0.1)	0	3 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)	3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)	7 (<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)
Device physical property issue	1 (<0.1)	0	1 (<0.1)
Lead dislodgement	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	124 (0.8)	124 (0.8)	248 (0.8)
Number of Unsolicited Adverse Events	148	158	306
Infections and infestations	22 (0.1)	16 (0.1)	38 (0.1)
Pneumonia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinusitis	0	2 (<0.1)	2 (<0.1)
Abscess	0	1 (<0.1)	1 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Clostridium difficile infection	0	1 (<0.1)	1 (<0.1)
Conjunctivitis	0	1 (<0.1)	1 (<0.1)
Ear infection	0	1 (<0.1)	1 (<0.1)
Fungal infection	0	1 (<0.1)	1 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	1 (<0.1)	3 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Tooth infection	0	1 (<0.1)	1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Urinary tract infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bacterial vaginosis	1 (<0.1)	0	1 (<0.1)
Bronchitis	2 (<0.1)	0	2 (<0.1)
COVID-19	3 (<0.1)	0	3 (<0.1)
Cellulitis	1 (<0.1)	0	1 (<0.1)
Diverticulitis	3 (<0.1)	0	3 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Genital herpes	1 (<0.1)	0	1 (<0.1)
Gingivitis	1 (<0.1)	0	1 (<0.1)
Osteomyelitis	1 (<0.1)	0	1 (<0.1)
Tooth abscess	1 (<0.1)	0	1 (<0.1)
Viral infection	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (<0.1)	9 (<0.1)	16 (<0.1)
Prostate cancer	1 (<0.1)	2 (<0.1)	3 (<0.1)
Basal cell carcinoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)	1 (<0.1)
Lung cancer metastatic	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)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Malignant melanoma	1 (<0.1)	0	1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0	1 (<0.1)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	0	1 (<0.1)	1 (<0.1)
Lymphadenopathy	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Immune system disorders	2 (<0.1)	2 (<0.1)	4 (<0.1)
Seasonal allergy	0	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Drug hypersensitivity	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	2 (<0.1)	5 (<0.1)
Decreased appetite	0	1 (<0.1)	1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Dehydration	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	1 (<0.1)	0	1 (<0.1)
Hypokalaemia	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	6 (<0.1)	1 (<0.1)	7 (<0.1)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Anxiety	3 (<0.1)	0	3 (<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)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	10 (<0.1)	12 (<0.1)	22 (<0.1)
Headache	3 (<0.1)	7 (<0.1)	10 (<0.1)
Syncope	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cerebrovascular accident	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
Post herpetic neuralgia	0	1 (<0.1)	1 (<0.1)
Sciatica	0	1 (<0.1)	1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)	1 (<0.1)
Aphasia	1 (<0.1)	0	1 (<0.1)
Dizziness	2 (<0.1)	0	2 (<0.1)
Migraine	1 (<0.1)	0	1 (<0.1)
Presyncope	1 (<0.1)	0	1 (<0.1)
Seizure	1 (<0.1)	0	1 (<0.1)
Eye disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)	2 (<0.1)
Scleritis	0	1 (<0.1)	1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0	1 (<0.1)
Vertigo	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	6 (<0.1)	9 (<0.1)	15 (<0.1)
Atrial fibrillation	3 (<0.1)	4 (<0.1)	7 (<0.1)
Coronary artery disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiomyopathy	0	1 (<0.1)	1 (<0.1)
Myocardial infarction	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Vascular disorders	15 (<0.1)	6 (<0.1)	21 (<0.1)
Hypertension	10 (<0.1)	2 (<0.1)	12 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
Systolic hypertension	0	1 (<0.1)	1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	9 (<0.1)	8 (<0.1)	17 (<0.1)
Cough	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rhinorrhoea	0	2 (<0.1)	2 (<0.1)
Asthma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal congestion	0	1 (<0.1)	1 (<0.1)
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)
Pleurisy	0	1 (<0.1)	1 (<0.1)
Pulmonary embolism	2 (<0.1)	1 (<0.1)	3 (<0.1)
Chronic obstructive pulmonary disease	2 (<0.1)	0	2 (<0.1)
Dyspnoea	1 (<0.1)	0	1 (<0.1)
Emphysema	1 (<0.1)	0	1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0	1 (<0.1)
Respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Wheezing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders	12 (<0.1)	16 (0.1)	28 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Diarrhoea	0	3 (<0.1)	3 (<0.1)
Nausea	1 (<0.1)	3 (<0.1)	4 (<0.1)
Abdominal pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abdominal pain upper	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diverticulum	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	0	1 (<0.1)	1 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Small intestinal obstruction	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)
Abdominal discomfort	1 (<0.1)	0	1 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Food poisoning	1 (<0.1)	0	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)	3 (<0.1)
Cholelithiasis	0	2 (<0.1)	2 (<0.1)
Cholecystitis	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 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Skin and subcutaneous tissue disorders	1 (<0.1)	4 (<0.1)	5 (<0.1)
Rash	0	2 (<0.1)	2 (<0.1)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Pruritus	0	1 (<0.1)	1 (<0.1)
Rash macular	0	1 (<0.1)	1 (<0.1)
Angioedema	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	15 (<0.1)	11 (<0.1)	26 (<0.1)
Arthralgia	0	3 (<0.1)	3 (<0.1)
Myalgia	0	2 (<0.1)	2 (<0.1)
Neck pain	0	2 (<0.1)	2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Back pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Muscle spasms	0	1 (<0.1)	1 (<0.1)
Tendonitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arthritis	1 (<0.1)	0	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0	1 (<0.1)
Costochondritis	1 (<0.1)	0	1 (<0.1)
Musculoskeletal chest pain	2 (<0.1)	0	2 (<0.1)
Osteoarthritis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Rotator cuff syndrome	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	3 (<0.1)	2 (<0.1)	5 (<0.1)
Nephrolithiasis	2 (<0.1)	2 (<0.1)	4 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Renal and urinary disorders (Cont.)			
Acute kidney injury	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	0	3 (<0.1)	3 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)	1 (<0.1)
Breast mass	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
General disorders and administration site conditions	9 (<0.1)	18 (0.1)	27 (<0.1)
Injection site erythema	0	4 (<0.1)	4 (<0.1)
Injection site pain	0	2 (<0.1)	2 (<0.1)
Pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)
Chest discomfort	0	1 (<0.1)	1 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fatigue	4 (<0.1)	1 (<0.1)	5 (<0.1)
Hernia	0	1 (<0.1)	1 (<0.1)
Injection site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oedema peripheral	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)
Gait disturbance	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Investigations	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)	2 (<0.1)
Blood pressure increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood pressure systolic increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	13 (<0.1)	15 (<0.1)	28 (<0.1)
Skin laceration	0	3 (<0.1)	3 (<0.1)
Foot fracture	0	2 (<0.1)	2 (<0.1)
Limb injury	0	2 (<0.1)	2 (<0.1)
Ankle fracture	0	1 (<0.1)	1 (<0.1)
Burns second degree	0	1 (<0.1)	1 (<0.1)
Cervical vertebral fracture	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)
Fibula fracture	0	1 (<0.1)	1 (<0.1)
Head injury	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)
Ligament injury	0	1 (<0.1)	1 (<0.1)
Ligament sprain	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 14.3.1.19.10
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Stab wound	0	1 (<0.1)	1 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Wrist fracture	0	1 (<0.1)	1 (<0.1)
Cartilage injury	1 (<0.1)	0	1 (<0.1)
Foreign body	1 (<0.1)	0	1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0	1 (<0.1)
Muscle rupture	1 (<0.1)	0	1 (<0.1)
Muscle strain	2 (<0.1)	0	2 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Procedural pain	1 (<0.1)	0	1 (<0.1)
Road traffic accident	1 (<0.1)	0	1 (<0.1)
Tibia fracture	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	2 (<0.1)	0	2 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Endodontic procedure	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	169 (1.1)	179 (1.2)	348 (1.1)
Number of Unsolicited Adverse Events	206	234	440
Infections and infestations	36 (0.2)	25 (0.2)	61 (0.2)
Pneumonia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Appendicitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Sinusitis	0	2 (<0.1)	2 (<0.1)
Abscess	0	1 (<0.1)	1 (<0.1)
Bronchitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Cellulitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	1 (<0.1)	1 (<0.1)
Conjunctivitis	0	1 (<0.1)	1 (<0.1)
Ear infection	0	1 (<0.1)	1 (<0.1)
Fungal infection	0	1 (<0.1)	1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)	1 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	1 (<0.1)	3 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Salpingitis	0	1 (<0.1)	1 (<0.1)
Sepsis	0	1 (<0.1)	1 (<0.1)
Skin infection	0	1 (<0.1)	1 (<0.1)
Tooth infection	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Infections and infestations (Cont.)			
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Urinary tract infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Wound infection	0	1 (<0.1)	1 (<0.1)
Bacterial vaginosis	1 (<0.1)	0	1 (<0.1)
COVID-19	16 (0.1)	0	16 (<0.1)
Diverticulitis	3 (<0.1)	0	3 (<0.1)
Genital herpes	1 (<0.1)	0	1 (<0.1)
Gingivitis	2 (<0.1)	0	2 (<0.1)
Osteomyelitis	1 (<0.1)	0	1 (<0.1)
Tooth abscess	1 (<0.1)	0	1 (<0.1)
Viral infection	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (<0.1)	15 (<0.1)	25 (<0.1)
Prostate cancer	1 (<0.1)	3 (<0.1)	4 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Basal cell carcinoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastric cancer	0	1 (<0.1)	1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)	1 (<0.1)
Lung cancer metastatic	0	1 (<0.1)	1 (<0.1)
Meningioma	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)	1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Malignant melanoma	1 (<0.1)	0	1 (<0.1)
Penile cancer	1 (<0.1)	0	1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Skin cancer	1 (<0.1)	0	1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0	1 (<0.1)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Anaemia	1 (<0.1)	0	1 (<0.1)
Immune system disorders	2 (<0.1)	2 (<0.1)	4 (<0.1)
Seasonal allergy	0	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Drug hypersensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	0	2 (<0.1)	2 (<0.1)
Hyperthyroidism	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Endocrine disorders (Cont.)			
Thyroid disorder	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	5 (<0.1)	3 (<0.1)	8 (<0.1)
Decreased appetite	0	1 (<0.1)	1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)	1 (<0.1)
Dehydration	2 (<0.1)	0	2 (<0.1)
Dyslipidaemia	1 (<0.1)	0	1 (<0.1)
Gout	1 (<0.1)	0	1 (<0.1)
Hypokalaemia	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	7 (<0.1)	2 (<0.1)	9 (<0.1)
Intentional self-injury	0	1 (<0.1)	1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Anxiety	3 (<0.1)	0	3 (<0.1)
Confusional state	1 (<0.1)	0	1 (<0.1)
Depression	2 (<0.1)	0	2 (<0.1)
Depression suicidal	1 (<0.1)	0	1 (<0.1)
Major depression	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	13 (<0.1)	15 (<0.1)	28 (<0.1)
Headache	4 (<0.1)	7 (<0.1)	11 (<0.1)
Syncope	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Nervous system disorders (Cont.)			
Cerebrovascular accident	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)	1 (<0.1)
Sciatica	0	1 (<0.1)	1 (<0.1)
Seizure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)	1 (<0.1)
Aphasia	1 (<0.1)	0	1 (<0.1)
Dizziness	3 (<0.1)	0	3 (<0.1)
Migraine	1 (<0.1)	0	1 (<0.1)
Presyncope	1 (<0.1)	0	1 (<0.1)
Eye disorders	1 (<0.1)	3 (<0.1)	4 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)	3 (<0.1)
Scleritis	0	1 (<0.1)	1 (<0.1)
Retinal tear	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vertigo	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac disorders	9 (<0.1)	14 (<0.1)	23 (<0.1)
Atrial fibrillation	3 (<0.1)	6 (<0.1)	9 (<0.1)
Coronary artery disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Myocardial infarction	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Cardiac disorders (Cont.)			
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Cardiac failure congestive	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cardiomyopathy	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)
Acute myocardial infarction	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	20 (0.1)	10 (<0.1)	30 (<0.1)
Hypertension	15 (<0.1)	3 (<0.1)	18 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Deep vein thrombosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Haematoma	0	1 (<0.1)	1 (<0.1)
Hypertensive emergency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
Systolic hypertension	0	1 (<0.1)	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	14 (<0.1)	11 (<0.1)	25 (<0.1)
Cough	3 (<0.1)	3 (<0.1)	6 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)	6 (<0.1)
Rhinorrhoea	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Asthma	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dyspnoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal congestion	0	1 (<0.1)	1 (<0.1)
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)
Pleurisy	0	1 (<0.1)	1 (<0.1)
Acute respiratory failure	1 (<0.1)	0	1 (<0.1)
Chronic obstructive pulmonary disease	2 (<0.1)	0	2 (<0.1)
Emphysema	1 (<0.1)	0	1 (<0.1)
Hypoxia	1 (<0.1)	0	1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0	1 (<0.1)
Respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Wheezing	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	13 (<0.1)	27 (0.2)	40 (0.1)
Diarrhoea	0	5 (<0.1)	5 (<0.1)
Colitis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Nausea	1 (<0.1)	4 (<0.1)	5 (<0.1)
Abdominal pain	2 (<0.1)	3 (<0.1)	5 (<0.1)
Abdominal pain upper	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abdominal pain lower	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	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Gastrointestinal disorders (Cont.)			
Gastritis	0	1 (<0.1)	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrooesophageal reflux disease	0	1 (<0.1)	1 (<0.1)
Intestinal perforation	0	1 (<0.1)	1 (<0.1)
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Rectal prolapse	0	1 (<0.1)	1 (<0.1)
Small intestinal obstruction	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)
Abdominal discomfort	1 (<0.1)	0	1 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Food poisoning	1 (<0.1)	0	1 (<0.1)
Hiatus hernia	1 (<0.1)	0	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)	3 (<0.1)
Cholelithiasis	0	2 (<0.1)	2 (<0.1)
Cholecystitis	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	5 (<0.1)	6 (<0.1)
Rash	0	3 (<0.1)	3 (<0.1)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Pruritus	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 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash macular	0	1 (<0.1)	1 (<0.1)
Angioedema	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	19 (0.1)	18 (0.1)	37 (0.1)
Arthralgia	0	5 (<0.1)	5 (<0.1)
Back pain	6 (<0.1)	2 (<0.1)	8 (<0.1)
Flank pain	0	2 (<0.1)	2 (<0.1)
Myalgia	0	2 (<0.1)	2 (<0.1)
Neck pain	0	2 (<0.1)	2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle spasms	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteonecrosis	0	1 (<0.1)	1 (<0.1)
Pain in extremity	0	1 (<0.1)	1 (<0.1)
Tendonitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arthritis	1 (<0.1)	0	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0	1 (<0.1)
Costochondritis	1 (<0.1)	0	1 (<0.1)
Musculoskeletal chest pain	3 (<0.1)	0	3 (<0.1)
Osteoarthritis	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Rotator cuff syndrome	1 (<0.1)	0	1 (<0.1)
Undifferentiated connective tissue disease	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\t1403011911.sas 03DEC2020 07:03

Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Renal and urinary disorders	4 (<0.1)	6 (<0.1)	10 (<0.1)
Nephrolithiasis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urinary retention	0	1 (<0.1)	1 (<0.1)
Chronic kidney disease	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	0	4 (<0.1)	4 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)	1 (<0.1)
Breast mass	0	1 (<0.1)	1 (<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	13 (<0.1)	21 (0.1)	34 (0.1)
Injection site erythema	0	4 (<0.1)	4 (<0.1)
Injection site pain	0	3 (<0.1)	3 (<0.1)
Chest discomfort	0	2 (<0.1)	2 (<0.1)
Chest pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pyrexia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)
Fatigue	7 (<0.1)	1 (<0.1)	8 (<0.1)
Hernia	0	1 (<0.1)	1 (<0.1)
Injection site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Non-cardiac chest pain	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.
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Table 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Oedema peripheral	1 (<0.1)	1 (<0.1)	2 (<0.1)
Swelling face	0	1 (<0.1)	1 (<0.1)
Asthenia	1 (<0.1)	0	1 (<0.1)
Chills	1 (<0.1)	0	1 (<0.1)
Gait disturbance	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Investigations	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)	2 (<0.1)
Blood pressure increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood pressure systolic increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury, poisoning and procedural complications	17 (0.1)	20 (0.1)	37 (0.1)
Skin laceration	1 (<0.1)	3 (<0.1)	4 (<0.1)
Foot fracture	0	2 (<0.1)	2 (<0.1)
Limb injury	0	2 (<0.1)	2 (<0.1)
Subdural haematoma	0	2 (<0.1)	2 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Ankle fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Burns second degree	0	1 (<0.1)	1 (<0.1)
Cervical vertebral fracture	0	1 (<0.1)	1 (<0.1)
Facial bones fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fall	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 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injury, poisoning and procedural complications (Cont.)			
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Femur fracture	0	1 (<0.1)	1 (<0.1)
Fibula fracture	0	1 (<0.1)	1 (<0.1)
Head injury	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)
Ligament injury	0	1 (<0.1)	1 (<0.1)
Ligament sprain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus injury	0	1 (<0.1)	1 (<0.1)
Procedural nausea	0	1 (<0.1)	1 (<0.1)
Procedural pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stab wound	0	1 (<0.1)	1 (<0.1)
Wrist fracture	0	1 (<0.1)	1 (<0.1)
Cartilage injury	1 (<0.1)	0	1 (<0.1)
Foreign body	2 (<0.1)	0	2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0	1 (<0.1)
Muscle rupture	1 (<0.1)	0	1 (<0.1)
Muscle strain	2 (<0.1)	0	2 (<0.1)
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Road traffic accident	1 (<0.1)	0	1 (<0.1)
Tibia fracture	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 14.3.1.19.11
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Surgical and medical procedures	4 (<0.1)	1 (<0.1)	5 (<0.1)
Transfusion	0	1 (<0.1)	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Endodontic procedure	1 (<0.1)	0	1 (<0.1)
Jaw operation	1 (<0.1)	0	1 (<0.1)
Spinal fusion surgery	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 14.3.1.22.1
Subject Incidence of Vasculitis [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Vasculitis [1]	0	0	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Number of Vasculitis [1]	0	0	0	1	0	1	1	0	1
Polymyalgia rheumatica	0	0	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Vasculitis is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Hypersensitivity [1]	128 (1.1)	165 (1.4)	293 (1.3)	38 (1.0)	68 (1.8)	106 (1.4)	166 (1.1)	233 (1.5)	399 (1.3)
Number of Hypersensitivity [1]	140	184	324	45	74	119	185	258	443
Allergic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anaphylactic reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Angioedema	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	0	1 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bronchospasm	0	0	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Dermatitis	7 (<0.1)	6 (<0.1)	13 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	8 (<0.1)	8 (<0.1)	16 (<0.1)
Dermatitis allergic	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	0	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Dermatitis atopic	7 (<0.1)	1 (<0.1)	8 (<0.1)	0	3 (<0.1)	3 (<0.1)	7 (<0.1)	4 (<0.1)	11 (<0.1)
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	2 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Dermatitis contact	18 (0.2)	16 (0.1)	34 (0.1)	11 (0.3)	5 (0.1)	16 (0.2)	29 (0.2)	21 (0.1)	50 (0.2)
Drug hypersensitivity	3 (<0.1)	2 (<0.1)	5 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	4 (<0.1)	4 (<0.1)	8 (<0.1)
Eczema	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Exfoliative rash	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Eye swelling	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gingival swelling	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)	0	0	0	0	2 (<0.1)	2 (<0.1)
Hypersensitivity	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site rash	1 (<0.1)	28 (0.2)	29 (0.1)	0	9 (0.2)	9 (0.1)	1 (<0.1)	37 (0.2)	38 (0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Injection site urticaria	0	11 (<0.1)	11 (<0.1)	0	4 (0.1)	4 (<0.1)	0	15 (<0.1)	15 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	0	0	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	2 (<0.1)
Rash	27 (0.2)	31 (0.3)	58 (0.3)	7 (0.2)	14 (0.4)	21 (0.3)	34 (0.2)	45 (0.3)	79 (0.3)
Rash erythematous	2 (<0.1)	5 (<0.1)	7 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	6 (<0.1)	8 (<0.1)
Rash follicular	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Rash macular	1 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	4 (0.1)	7 (<0.1)	4 (<0.1)	6 (<0.1)	10 (<0.1)
Rash maculo-papular	2 (<0.1)	9 (<0.1)	11 (<0.1)	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	11 (<0.1)	13 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Rash pruritic	3 (<0.1)	4 (<0.1)	7 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	4 (<0.1)	6 (<0.1)	10 (<0.1)
Rash pustular	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Rash vesicular	0	3 (<0.1)	3 (<0.1)	0	0	0	0	3 (<0.1)	3 (<0.1)
Rhinitis allergic	9 (<0.1)	8 (<0.1)	17 (<0.1)	4 (0.1)	2 (<0.1)	6 (<0.1)	13 (<0.1)	10 (<0.1)	23 (<0.1)
Serum sickness	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Swelling face	2 (<0.1)	4 (<0.1)	6 (<0.1)	0	0	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Swelling of eyelid	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	0	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)
Urticaria	17 (0.1)	17 (0.1)	34 (0.1)	6 (0.2)	10 (0.3)	16 (0.2)	23 (0.2)	27 (0.2)	50 (0.2)
Urticaria papular	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (<0.1)	0	1 (<0.1)	5 (<0.1)	3 (<0.1)	8 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Vaccination site rash	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.3
Subject Incidence of Arthritis [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Arthritis [1]	19 (0.2)	20 (0.2)	39 (0.2)	20 (0.5)	16 (0.4)	36 (0.5)	39 (0.3)	36 (0.2)	75 (0.2)
Number of Arthritis [1]	20	22	42	20	16	36	40	38	78
Arthritis	3 (<0.1)	5 (<0.1)	8 (<0.1)	0	6 (0.2)	6 (<0.1)	3 (<0.1)	11 (<0.1)	14 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Gout	5 (<0.1)	1 (<0.1)	6 (<0.1)	4 (0.1)	4 (0.1)	8 (0.1)	9 (<0.1)	5 (<0.1)	14 (<0.1)
Osteoarthritis	9 (<0.1)	8 (<0.1)	17 (<0.1)	12 (0.3)	3 (<0.1)	15 (0.2)	21 (0.1)	11 (<0.1)	32 (0.1)
Periarthritis	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Spinal osteoarthritis	0	2 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	3 (<0.1)	3 (<0.1)	6 (<0.1)
Spondylitis	0	0	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)
Synovitis	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Arthritis is identified through selected SMQ.
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Table 14.3.1.22.3
Subject Incidence of Arthritis [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Temporomandibular joint syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	1 (<0.1)	2 (<0.1)	3 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Arthritis is identified through selected SMQ.
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Table 14.3.1.22.4
Subject Incidence of Angioedema [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Angioedema [1]	32 (0.3)	28 (0.2)	60 (0.3)	11 (0.3)	13 (0.3)	24 (0.3)	43 (0.3)	41 (0.3)	84 (0.3)
Number of Angioedema [1]	35	31	66	13	15	28	48	46	94
Angioedema	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	0	1 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)
Eye swelling	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gingival swelling	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	0	0	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	2 (<0.1)
Swelling face	2 (<0.1)	4 (<0.1)	6 (<0.1)	0	0	0	2 (<0.1)	4 (<0.1)	6 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Angioedema is identified through selected SMQ.
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Table 14.3.1.22.4
Subject Incidence of Angioedema [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Swelling of eyelid	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	2 (<0.1)
Urticaria	17 (0.1)	17 (0.1)	34 (0.1)	6 (0.2)	10 (0.3)	16 (0.2)	23 (0.2)	27 (0.2)	50 (0.2)
Urticaria papular	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (<0.1)	0	1 (<0.1)	5 (<0.1)	3 (<0.1)	8 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Angioedema is identified through selected SMQ.
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Table 14.3.1.22.5
Subject Incidence of Peripheral Neuropathy [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Peripheral Neuropathy [1]	2 (<0.1)	5 (<0.1)	7 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	5 (<0.1)	6 (<0.1)	11 (<0.1)
Number of Peripheral Neuropathy [1]	2	5	7	4	1	5	6	6	12
Neuralgia	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	0	2 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)
Neuropathy peripheral	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)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Peripheral Neuropathy is identified through selected SMQ.
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Table 14.3.1.22.6
Subject Incidence of Demyelinating Disease of Central Nervous System [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Demyelinating Disease of Central Nervous System [1]	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Number of Demyelinating Disease of Central Nervous System [1]	1	0	1	0	0	0	1	0	1
Multiple sclerosis	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Demyelinating Disease of Central Nervous System is identified through selected SMQ.
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Table 14.3.1.22.7
Subject Incidence of Convulsions [1] by Preferred Term
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Preferred Term	Placebo (N=11416) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22831) n (%)	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Convulsions [1]	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Number of Convulsions [1]	1	3	4	0	0	0	1	3	4
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	0	1 (<0.1)	3 (<0.1)	4 (<0.1)

Percentages are based on the number of safety subjects.
MedDRA version 23.0.
[1] Convulsions is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403012207.sas 03DEC2020 07:05

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	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	72 (0.5)	83 (0.5)	8 (<0.1)	4 (<0.1)	2 (<0.1)	0	169 (1.1)
Grade 0	23 (0.2)	12679 (83.6)	551 (3.6)	188 (1.2)	31 (0.2)	0	13472 (88.8)
Grade 1	1 (<0.1)	602 (4.0)	183 (1.2)	103 (0.7)	27 (0.2)	0	916 (6.0)
Grade 2	2 (<0.1)	187 (1.2)	87 (0.6)	96 (0.6)	26 (0.2)	0	398 (2.6)
Grade 3	0	48 (0.3)	41 (0.3)	58 (0.4)	62 (0.4)	0	209 (1.4)
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	98 (0.6)	13601 (89.7)	870 (5.7)	449 (3.0)	148 (1.0)	0	15166 (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=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	38 (0.3)	471 (3.1)	33 (0.2)	15 (<0.1)	11 (<0.1)	0	568 (3.7)
Grade 0	53 (0.3)	11985 (79.0)	520 (3.4)	200 (1.3)	41 (0.3)	0	12799 (84.4)
Grade 1	4 (<0.1)	759 (5.0)	184 (1.2)	105 (0.7)	29 (0.2)	0	1081 (7.1)
Grade 2	2 (<0.1)	316 (2.1)	95 (0.6)	82 (0.5)	23 (0.2)	0	518 (3.4)
Grade 3	1 (<0.1)	70 (0.5)	38 (0.3)	47 (0.3)	44 (0.3)	0	200 (1.3)
Grade 4	0	0	0	0	0	0	0
Total	98 (0.6)	13601 (89.7)	870 (5.7)	449 (3.0)	148 (1.0)	0	15166 (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 03DEC2020 07:05

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	62 (0.4)	4377 (28.9)	289 (1.9)	156 (1.0)	55 (0.4)	0	4939 (32.6)
Grade 0	36 (0.2)	8799 (58.0)	427 (2.8)	166 (1.1)	41 (0.3)	0	9469 (62.4)
Grade 1	0	283 (1.9)	89 (0.6)	71 (0.5)	20 (0.1)	0	463 (3.1)
Grade 2	0	114 (0.8)	48 (0.3)	40 (0.3)	17 (0.1)	0	219 (1.4)
Grade 3	0	28 (0.2)	17 (0.1)	16 (0.1)	15 (<0.1)	0	76 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	98 (0.6)	13601 (89.7)	870 (5.7)	449 (3.0)	148 (1.0)	0	15166 (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 03DEC2020 07:05

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	98 (0.6)	13600 (89.7)	870 (5.7)	449 (3.0)	148 (1.0)	0	15165 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	98 (0.6)	13601 (89.7)	870 (5.7)	449 (3.0)	148 (1.0)	0	15166 (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 03DEC2020 07:05

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	24 (1.9)	2 (0.2)	1 (<0.1)	0	0	27 (2.2)
Grade 0	3 (0.2)	1025 (82.7)	45 (3.6)	12 (1.0)	1 (<0.1)	0	1086 (87.6)
Grade 1	0	52 (4.2)	12 (1.0)	7 (0.6)	1 (<0.1)	0	72 (5.8)
Grade 2	0	20 (1.6)	2 (0.2)	3 (0.2)	1 (<0.1)	0	26 (2.1)
Grade 3	0	21 (1.7)	5 (0.4)	2 (0.2)	1 (<0.1)	0	29 (2.3)
Grade 4	0	0	0	0	0	0	0
Total	3 (0.2)	1142 (92.1)	66 (5.3)	25 (2.0)	4 (0.3)	0	1240 (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=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (2.7)	0	0	0	0	2 (2.7)
Grade 0	0	64 (85.3)	3 (4.0)	0	0	0	67 (89.3)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	4 (5.3)	0	0	0	0	4 (5.3)
Grade 3	0	1 (1.3)	0	1 (1.3)	0	0	2 (2.7)
Grade 4	0	0	0	0	0	0	0
Total	0	71 (94.7)	3 (4.0)	1 (1.3)	0	0	75 (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 03DEC2020 07:05

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	9 (100)	0	0	0	0	9 (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	9 (100)	0	0	0	0	9 (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 03DEC2020 07:05

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 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: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 0	1 (0.8)	108 (86.4)	7 (5.6)	0	0	0	116 (92.8)
Grade 1	0	2 (1.6)	2 (1.6)	2 (1.6)	0	0	6 (4.8)
Grade 2	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 3	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 4	0	0	0	0	0	0	0
Total	1 (0.8)	113 (90.4)	9 (7.2)	2 (1.6)	0	0	125 (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=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (100)	0	0	0	0	4 (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 (100)	0	0	0	0	4 (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=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 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: Placebo (N=15166)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	34 (0.2)	6 (<0.1)	0	0	1 (<0.1)	0	41 (0.3)
Grade 0	55 (0.4)	11631 (76.7)	366 (2.4)	93 (0.6)	19 (0.1)	0	12164 (80.2)
Grade 1	5 (<0.1)	1269 (8.4)	255 (1.7)	121 (0.8)	22 (0.1)	0	1672 (11.0)
Grade 2	3 (<0.1)	547 (3.6)	160 (1.1)	137 (0.9)	30 (0.2)	0	877 (5.8)
Grade 3	1 (<0.1)	146 (1.0)	89 (0.6)	98 (0.6)	76 (0.5)	0	410 (2.7)
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	98 (0.6)	13601 (89.7)	870 (5.7)	449 (3.0)	148 (1.0)	0	15166 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	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	72 (0.5)	105 (0.7)	1 (<0.1)	1 (<0.1)	0	0	179 (1.2)
Grade 0	23 (0.2)	13333 (87.9)	241 (1.6)	28 (0.2)	5 (<0.1)	0	13630 (89.9)
Grade 1	3 (<0.1)	654 (4.3)	261 (1.7)	42 (0.3)	4 (<0.1)	0	964 (6.4)
Grade 2	0	127 (0.8)	112 (0.7)	58 (0.4)	12 (<0.1)	0	309 (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	98 (0.6)	14239 (93.9)	627 (4.1)	156 (1.0)	46 (0.3)	0	15166 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	38 (0.3)	509 (3.4)	15 (<0.1)	5 (<0.1)	0	0	567 (3.7)
Grade 0	58 (0.4)	12846 (84.7)	285 (1.9)	43 (0.3)	5 (<0.1)	0	13237 (87.3)
Grade 1	1 (<0.1)	699 (4.6)	234 (1.5)	49 (0.3)	9 (<0.1)	0	992 (6.5)
Grade 2	0	154 (1.0)	80 (0.5)	43 (0.3)	13 (<0.1)	0	290 (1.9)
Grade 3	1 (<0.1)	31 (0.2)	13 (<0.1)	16 (0.1)	19 (0.1)	0	80 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	98 (0.6)	14239 (93.9)	627 (4.1)	156 (1.0)	46 (0.3)	0	15166 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	62 (0.4)	4608 (30.4)	205 (1.4)	55 (0.4)	10 (<0.1)	0	4940 (32.6)
Grade 0	33 (0.2)	9384 (61.9)	325 (2.1)	53 (0.3)	15 (<0.1)	0	9810 (64.7)
Grade 1	3 (<0.1)	194 (1.3)	73 (0.5)	30 (0.2)	6 (<0.1)	0	306 (2.0)
Grade 2	0	45 (0.3)	21 (0.1)	12 (<0.1)	6 (<0.1)	0	84 (0.6)
Grade 3	0	8 (<0.1)	3 (<0.1)	6 (<0.1)	9 (<0.1)	0	26 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	98 (0.6)	14239 (93.9)	627 (4.1)	156 (1.0)	46 (0.3)	0	15166 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	98 (0.6)	14239 (93.9)	626 (4.1)	156 (1.0)	46 (0.3)	0	15165 (>99.9)
Grade 0	0	0	1 (<0.1)	0	0	0	1 (<0.1)
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	98 (0.6)	14239 (93.9)	627 (4.1)	156 (1.0)	46 (0.3)	0	15166 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	15 (1.2)	2 (0.2)	0	0	0	17 (1.4)
Grade 0	2 (0.2)	1150 (92.7)	36 (2.9)	10 (0.8)	1 (<0.1)	0	1199 (96.7)
Grade 1	0	10 (0.8)	3 (0.2)	1 (<0.1)	0	0	14 (1.1)
Grade 2	0	1 (<0.1)	3 (0.2)	3 (0.2)	1 (<0.1)	0	8 (0.6)
Grade 3	0	1 (<0.1)	0	0	1 (<0.1)	0	2 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	2 (0.2)	1177 (94.9)	44 (3.5)	14 (1.1)	3 (0.2)	0	1240 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 0	0	69 (92.0)	2 (2.7)	1 (1.3)	0	0	72 (96.0)
Grade 1	0	1 (1.3)	1 (1.3)	0	0	0	2 (2.7)
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	71 (94.7)	3 (4.0)	1 (1.3)	0	0	75 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	9 (100)	0	0	0	0	9 (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	9 (100)	0	0	0	0	9 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 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: Placebo (N=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 0	1 (0.8)	118 (94.4)	1 (0.8)	2 (1.6)	0	0	122 (97.6)
Grade 1	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 2	0	0	0	0	1 (0.8)	0	1 (0.8)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (0.8)	120 (96.0)	1 (0.8)	2 (1.6)	1 (0.8)	0	125 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (100)	0	0	0	0	4 (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 (100)	0	0	0	0	4 (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=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 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: Placebo (N=15166)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	34 (0.2)	8 (<0.1)	0	0	0	0	42 (0.3)
Grade 0	58 (0.4)	12739 (84.0)	141 (0.9)	15 (<0.1)	1 (<0.1)	0	12954 (85.4)
Grade 1	5 (<0.1)	1168 (7.7)	298 (2.0)	33 (0.2)	4 (<0.1)	0	1508 (9.9)
Grade 2	0	266 (1.8)	160 (1.1)	65 (0.4)	10 (<0.1)	0	501 (3.3)
Grade 3	1 (<0.1)	58 (0.4)	28 (0.2)	43 (0.3)	31 (0.2)	0	161 (1.1)
Grade 4	0	0	0	0	0	0	0
Total	98 (0.6)	14239 (93.9)	627 (4.1)	156 (1.0)	46 (0.3)	0	15166 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	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	72 (0.5)	105 (0.7)	2 (<0.1)	0	0	0	179 (1.2)
Grade 0	25 (0.2)	14711 (97.0)	145 (1.0)	3 (<0.1)	0	0	14884 (98.1)
Grade 1	0	44 (0.3)	48 (0.3)	2 (<0.1)	0	0	94 (0.6)
Grade 2	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	0	9 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	98 (0.6)	14862 (98.0)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	38 (0.3)	521 (3.4)	8 (<0.1)	0	0	0	567 (3.7)
Grade 0	58 (0.4)	14127 (93.1)	137 (0.9)	1 (<0.1)	1 (<0.1)	0	14324 (94.4)
Grade 1	1 (<0.1)	196 (1.3)	48 (0.3)	4 (<0.1)	1 (<0.1)	0	250 (1.6)
Grade 2	1 (<0.1)	16 (0.1)	4 (<0.1)	1 (<0.1)	0	0	22 (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	98 (0.6)	14862 (98.0)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	62 (0.4)	4815 (31.7)	59 (0.4)	4 (<0.1)	0	0	4940 (32.6)
Grade 0	36 (0.2)	9928 (65.5)	105 (0.7)	2 (<0.1)	1 (<0.1)	0	10072 (66.4)
Grade 1	0	109 (0.7)	32 (0.2)	1 (<0.1)	1 (<0.1)	0	143 (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	98 (0.6)	14862 (98.0)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	98 (0.6)	14861 (98.0)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15165 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	98 (0.6)	14862 (98.0)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	17 (1.4)	0	0	0	0	17 (1.4)
Grade 0	2 (0.2)	1161 (93.6)	12 (1.0)	0	0	0	1175 (94.8)
Grade 1	0	39 (3.1)	4 (0.3)	0	0	0	43 (3.5)
Grade 2	0	3 (0.2)	0	0	0	0	3 (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)	1222 (98.5)	16 (1.3)	0	0	0	1240 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 0	0	63 (84.0)	1 (1.3)	0	0	0	64 (85.3)
Grade 1	0	8 (10.7)	1 (1.3)	0	0	0	9 (12.0)
Grade 2	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	73 (97.3)	2 (2.7)	0	0	0	75 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	8 (88.9)	0	0	0	0	8 (88.9)
Grade 1	0	1 (11.1)	0	0	0	0	1 (11.1)
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	0	9 (100)	0	0	0	0	9 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 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: Placebo (N=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 0	1 (0.8)	123 (98.4)	0	0	0	0	124 (99.2)
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 (0.8)	124 (99.2)	0	0	0	0	125 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (100)	0	0	0	0	4 (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 (100)	0	0	0	0	4 (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=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 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: Placebo (N=15166)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	34 (0.2)	8 (<0.1)	0	0	0	0	42 (0.3)
Grade 0	61 (0.4)	14488 (95.5)	100 (0.7)	1 (<0.1)	0	0	14650 (96.6)
Grade 1	1 (<0.1)	334 (2.2)	90 (0.6)	3 (<0.1)	0	0	428 (2.8)
Grade 2	2 (<0.1)	28 (0.2)	7 (<0.1)	2 (<0.1)	2 (<0.1)	0	41 (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	98 (0.6)	14862 (98.0)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	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	72 (0.5)	89 (0.6)	32 (0.2)	1 (<0.1)	0	0	194 (1.3)
Grade 0	45 (0.3)	10167 (67.0)	1342 (8.8)	43 (0.3)	3 (<0.1)	0	11600 (76.5)
Grade 1	7 (<0.1)	1311 (8.6)	1877 (12.4)	59 (0.4)	1 (<0.1)	0	3255 (21.5)
Grade 2	1 (<0.1)	47 (0.3)	38 (0.3)	22 (0.1)	0	0	108 (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	125 (0.8)	11619 (76.6)	3290 (21.7)	127 (0.8)	5 (<0.1)	0	15166 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	39 (0.3)	387 (2.6)	139 (0.9)	4 (<0.1)	0	0	569 (3.8)
Grade 0	45 (0.3)	8921 (58.8)	1442 (9.5)	47 (0.3)	3 (<0.1)	0	10458 (69.0)
Grade 1	41 (0.3)	2260 (14.9)	1658 (10.9)	68 (0.4)	2 (<0.1)	0	4029 (26.6)
Grade 2	0	47 (0.3)	49 (0.3)	8 (<0.1)	0	0	104 (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	125 (0.8)	11619 (76.6)	3290 (21.7)	127 (0.8)	5 (<0.1)	0	15166 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	66 (0.4)	3792 (25.0)	1044 (6.9)	36 (0.2)	2 (<0.1)	0	4940 (32.6)
Grade 0	50 (0.3)	6749 (44.5)	1309 (8.6)	52 (0.3)	2 (<0.1)	0	8162 (53.8)
Grade 1	9 (<0.1)	1063 (7.0)	913 (6.0)	37 (0.2)	1 (<0.1)	0	2023 (13.3)
Grade 2	0	13 (<0.1)	23 (0.2)	1 (<0.1)	0	0	37 (0.2)
Grade 3	0	2 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	4 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	125 (0.8)	11619 (76.6)	3290 (21.7)	127 (0.8)	5 (<0.1)	0	15166 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	125 (0.8)	11618 (76.6)	3290 (21.7)	127 (0.8)	5 (<0.1)	0	15165 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	125 (0.8)	11619 (76.6)	3290 (21.7)	127 (0.8)	5 (<0.1)	0	15166 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	20 (1.6)	5 (0.4)	0	0	0	25 (2.0)
Grade 0	4 (0.3)	727 (58.6)	150 (12.1)	5 (0.4)	0	0	886 (71.5)
Grade 1	0	201 (16.2)	106 (8.5)	6 (0.5)	0	0	313 (25.2)
Grade 2	0	8 (0.6)	7 (0.6)	0	0	0	15 (1.2)
Grade 3	0	0	1 (<0.1)	0	0	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	4 (0.3)	956 (77.1)	269 (21.7)	11 (0.9)	0	0	1240 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (2.7)	0	0	0	0	2 (2.7)
Grade 0	0	42 (56.0)	10 (13.3)	1 (1.3)	0	0	53 (70.7)
Grade 1	0	13 (17.3)	5 (6.7)	0	0	0	18 (24.0)
Grade 2	0	2 (2.7)	0	0	0	0	2 (2.7)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	59 (78.7)	15 (20.0)	1 (1.3)	0	0	75 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	5 (55.6)	3 (33.3)	0	0	0	8 (88.9)
Grade 1	0	1 (11.1)	0	0	0	0	1 (11.1)
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	0	6 (66.7)	3 (33.3)	0	0	0	9 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (33.3)	1 (33.3)	0	0	0	2 (66.7)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	1 (33.3)	0	0	0	1 (33.3)
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: Placebo (N=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 0	1 (0.8)	90 (72.0)	14 (11.2)	0	0	0	105 (84.0)
Grade 1	0	15 (12.0)	4 (3.2)	0	0	0	19 (15.2)
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	1 (0.8)	106 (84.8)	18 (14.4)	0	0	0	125 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (100)	0	0	0	0	4 (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 (100)	0	0	0	0	4 (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=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 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: Placebo (N=15166)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	34 (0.2)	6 (<0.1)	2 (<0.1)	0	0	0	42 (0.3)
Grade 0	42 (0.3)	8016 (52.9)	716 (4.7)	20 (0.1)	1 (<0.1)	0	8795 (58.0)
Grade 1	48 (0.3)	3477 (22.9)	2462 (16.2)	74 (0.5)	3 (<0.1)	0	6064 (40.0)
Grade 2	1 (<0.1)	109 (0.7)	105 (0.7)	30 (0.2)	0	0	245 (1.6)
Grade 3	0	11 (<0.1)	5 (<0.1)	3 (<0.1)	1 (<0.1)	0	20 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	125 (0.8)	11619 (76.6)	3290 (21.7)	127 (0.8)	5 (<0.1)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	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	72 (0.5)	97 (0.6)	0	0	0	0	169 (1.1)
Grade 0	27 (0.2)	14909 (98.3)	28 (0.2)	6 (<0.1)	2 (<0.1)	0	14972 (98.7)
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	99 (0.7)	15030 (99.1)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	38 (0.3)	529 (3.5)	1 (<0.1)	0	0	0	568 (3.7)
Grade 0	61 (0.4)	14447 (95.3)	25 (0.2)	6 (<0.1)	1 (<0.1)	0	14540 (95.9)
Grade 1	0	35 (0.2)	2 (<0.1)	0	0	0	37 (0.2)
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	99 (0.7)	15030 (99.1)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	62 (0.4)	4865 (32.1)	10 (<0.1)	1 (<0.1)	1 (<0.1)	0	4939 (32.6)
Grade 0	37 (0.2)	10144 (66.9)	17 (0.1)	5 (<0.1)	1 (<0.1)	0	10204 (67.3)
Grade 1	0	15 (<0.1)	1 (<0.1)	0	0	0	16 (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	99 (0.7)	15030 (99.1)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	99 (0.7)	15029 (99.1)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15165 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	99 (0.7)	15030 (99.1)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	27 (2.2)	0	0	0	0	27 (2.2)
Grade 0	3 (0.2)	1202 (96.9)	3 (0.2)	1 (<0.1)	1 (<0.1)	0	1210 (97.6)
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 (0.2)	1232 (99.4)	3 (0.2)	1 (<0.1)	1 (<0.1)	0	1240 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (2.7)	0	0	0	0	2 (2.7)
Grade 0	0	72 (96.0)	0	0	0	0	72 (96.0)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	75 (100)	0	0	0	0	75 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	9 (100)	0	0	0	0	9 (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	9 (100)	0	0	0	0	9 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 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: Placebo (N=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 0	1 (0.8)	123 (98.4)	0	0	0	0	124 (99.2)
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 (0.8)	124 (99.2)	0	0	0	0	125 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (100)	0	0	0	0	4 (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 (100)	0	0	0	0	4 (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=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 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: Placebo (N=15166)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	34 (0.2)	7 (<0.1)	0	0	0	0	41 (0.3)
Grade 0	65 (0.4)	14934 (98.5)	24 (0.2)	6 (<0.1)	1 (<0.1)	0	15030 (99.1)
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	99 (0.7)	15030 (99.1)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	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	72 (0.5)	75 (0.5)	15 (<0.1)	2 (<0.1)	5 (<0.1)	0	169 (1.1)
Grade 0	22 (0.1)	11313 (74.6)	836 (5.5)	128 (0.8)	97 (0.6)	0	12396 (81.7)
Grade 1	3 (<0.1)	804 (5.3)	527 (3.5)	107 (0.7)	127 (0.8)	0	1568 (10.3)
Grade 2	2 (<0.1)	133 (0.9)	129 (0.9)	50 (0.3)	50 (0.3)	0	364 (2.4)
Grade 3	0	135 (0.9)	173 (1.1)	86 (0.6)	272 (1.8)	0	666 (4.4)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	3 (<0.1)
Total	99 (0.7)	12461 (82.2)	1681 (11.1)	374 (2.5)	551 (3.6)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	38 (0.3)	444 (2.9)	53 (0.3)	10 (<0.1)	23 (0.2)	0	568 (3.7)
Grade 0	48 (0.3)	10570 (69.7)	865 (5.7)	132 (0.9)	145 (1.0)	0	11760 (77.5)
Grade 1	10 (<0.1)	1078 (7.1)	471 (3.1)	108 (0.7)	111 (0.7)	0	1778 (11.7)
Grade 2	0	197 (1.3)	124 (0.8)	54 (0.4)	65 (0.4)	0	440 (2.9)
Grade 3	3 (<0.1)	172 (1.1)	168 (1.1)	70 (0.5)	207 (1.4)	0	620 (4.1)
Grade 4	0	0	0	0	0	0	0
Total	99 (0.7)	12461 (82.2)	1681 (11.1)	374 (2.5)	551 (3.6)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	62 (0.4)	3991 (26.3)	576 (3.8)	122 (0.8)	188 (1.2)	0	4939 (32.6)
Grade 0	32 (0.2)	7805 (51.5)	725 (4.8)	144 (0.9)	165 (1.1)	0	8871 (58.5)
Grade 1	4 (<0.1)	493 (3.3)	249 (1.6)	52 (0.3)	82 (0.5)	0	880 (5.8)
Grade 2	0	70 (0.5)	61 (0.4)	22 (0.1)	33 (0.2)	0	186 (1.2)
Grade 3	1 (<0.1)	102 (0.7)	70 (0.5)	34 (0.2)	83 (0.5)	0	290 (1.9)
Grade 4	0	0	0	0	0	0	0
Total	99 (0.7)	12461 (82.2)	1681 (11.1)	374 (2.5)	551 (3.6)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	99 (0.7)	12460 (82.2)	1681 (11.1)	374 (2.5)	551 (3.6)	0	15165 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	99 (0.7)	12461 (82.2)	1681 (11.1)	374 (2.5)	551 (3.6)	0	15166 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	22 (1.8)	3 (0.2)	0	2 (0.2)	0	27 (2.2)
Grade 0	3 (0.2)	965 (77.8)	52 (4.2)	10 (0.8)	8 (0.6)	0	1038 (83.7)
Grade 1	0	75 (6.0)	19 (1.5)	7 (0.6)	8 (0.6)	0	109 (8.8)
Grade 2	0	17 (1.4)	9 (0.7)	2 (0.2)	1 (<0.1)	0	29 (2.3)
Grade 3	0	22 (1.8)	10 (0.8)	1 (<0.1)	4 (0.3)	0	37 (3.0)
Grade 4	0	0	0	0	0	0	0
Total	3 (0.2)	1101 (88.8)	93 (7.5)	20 (1.6)	23 (1.9)	0	1240 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (2.7)	0	0	0	0	2 (2.7)
Grade 0	0	64 (85.3)	3 (4.0)	1 (1.3)	0	0	68 (90.7)
Grade 1	0	3 (4.0)	1 (1.3)	1 (1.3)	0	0	5 (6.7)
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	69 (92.0)	4 (5.3)	2 (2.7)	0	0	75 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	8 (88.9)	1 (11.1)	0	0	0	9 (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	8 (88.9)	1 (11.1)	0	0	0	9 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 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: Placebo (N=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	1 (0.8)	0	0	0	0	1 (0.8)
Grade 0	1 (0.8)	107 (85.6)	5 (4.0)	0	1 (0.8)	0	114 (91.2)
Grade 1	0	3 (2.4)	2 (1.6)	1 (0.8)	0	0	6 (4.8)
Grade 2	0	2 (1.6)	0	0	0	0	2 (1.6)
Grade 3	0	1 (0.8)	1 (0.8)	0	0	0	2 (1.6)
Grade 4	0	0	0	0	0	0	0
Total	1 (0.8)	114 (91.2)	8 (6.4)	1 (0.8)	1 (0.8)	0	125 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (100)	0	0	0	0	4 (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 (100)	0	0	0	0	4 (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=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 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: Placebo (N=15166)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	34 (0.2)	5 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	41 (0.3)
Grade 0	48 (0.3)	9974 (65.8)	474 (3.1)	55 (0.4)	46 (0.3)	0	10597 (69.9)
Grade 1	13 (<0.1)	1775 (11.7)	645 (4.3)	111 (0.7)	92 (0.6)	0	2636 (17.4)
Grade 2	1 (<0.1)	328 (2.2)	217 (1.4)	64 (0.4)	54 (0.4)	0	664 (4.4)
Grade 3	3 (<0.1)	378 (2.5)	343 (2.3)	143 (0.9)	358 (2.4)	0	1225 (8.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	3 (<0.1)
Total	99 (0.7)	12461 (82.2)	1681 (11.1)	374 (2.5)	551 (3.6)	0	15166 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	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	68 (0.4)	107 (0.7)	0	0	0	0	175 (1.2)
Grade 0	30 (0.2)	14958 (98.6)	1 (<0.1)	0	0	0	14989 (98.8)
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	1 (<0.1)	0	0	0	0	1 (<0.1)
Total	98 (0.6)	15067 (99.3)	1 (<0.1)	0	0	0	15166 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	39 (0.3)	527 (3.5)	0	0	0	0	566 (3.7)
Grade 0	59 (0.4)	14535 (95.8)	1 (<0.1)	0	0	0	14595 (96.2)
Grade 1	0	1 (<0.1)	0	0	0	0	1 (<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	1 (<0.1)	0	0	0	0	1 (<0.1)
Total	98 (0.6)	15067 (99.3)	1 (<0.1)	0	0	0	15166 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	61 (0.4)	4884 (32.2)	0	0	0	0	4945 (32.6)
Grade 0	37 (0.2)	10175 (67.1)	1 (<0.1)	0	0	0	10213 (67.3)
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	3 (<0.1)	0	0	0	0	3 (<0.1)
Total	98 (0.6)	15067 (99.3)	1 (<0.1)	0	0	0	15166 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	98 (0.6)	15066 (99.3)	1 (<0.1)	0	0	0	15165 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	98 (0.6)	15067 (99.3)	1 (<0.1)	0	0	0	15166 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	2 (0.2)	1222 (98.5)	0	0	0	0	1224 (98.7)
Grade 1	0	10 (0.8)	0	0	0	0	10 (0.8)
Grade 2	0	4 (0.3)	0	0	0	0	4 (0.3)
Grade 3	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 4	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Total	2 (0.2)	1238 (99.8)	0	0	0	0	1240 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	73 (97.3)	0	0	0	0	73 (97.3)
Grade 1	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 2	0	1 (1.3)	0	0	0	0	1 (1.3)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	75 (100)	0	0	0	0	75 (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=15166)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	9 (100)	0	0	0	0	9 (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	9 (100)	0	0	0	0	9 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 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: Placebo (N=15166)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	1 (0.8)	124 (99.2)	0	0	0	0	125 (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 (0.8)	124 (99.2)	0	0	0	0	125 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	4 (100)	0	0	0	0	4 (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 (100)	0	0	0	0	4 (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=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 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: Placebo (N=15166)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	34 (0.2)	8 (<0.1)	0	0	0	0	42 (0.3)
Grade 0	64 (0.4)	15037 (99.1)	1 (<0.1)	0	0	0	15102 (99.6)
Grade 1	0	8 (<0.1)	0	0	0	0	8 (<0.1)
Grade 2	0	9 (<0.1)	0	0	0	0	9 (<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	98 (0.6)	15067 (99.3)	1 (<0.1)	0	0	0	15166 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	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	79 (0.5)	67 (0.4)	5 (<0.1)	3 (<0.1)	3 (<0.1)	0	157 (1.0)
Grade 0	32 (0.2)	12647 (83.3)	573 (3.8)	168 (1.1)	41 (0.3)	0	13461 (88.6)
Grade 1	2 (<0.1)	580 (3.8)	203 (1.3)	102 (0.7)	26 (0.2)	0	913 (6.0)
Grade 2	3 (<0.1)	198 (1.3)	122 (0.8)	107 (0.7)	31 (0.2)	0	461 (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	117 (0.8)	13553 (89.3)	933 (6.1)	425 (2.8)	157 (1.0)	0	15185 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	41 (0.3)	445 (2.9)	32 (0.2)	15 (<0.1)	11 (<0.1)	0	544 (3.6)
Grade 0	58 (0.4)	11967 (78.8)	580 (3.8)	192 (1.3)	54 (0.4)	0	12851 (84.6)
Grade 1	10 (<0.1)	742 (4.9)	181 (1.2)	99 (0.7)	23 (0.2)	0	1055 (6.9)
Grade 2	4 (<0.1)	314 (2.1)	103 (0.7)	76 (0.5)	32 (0.2)	0	529 (3.5)
Grade 3	4 (<0.1)	85 (0.6)	37 (0.2)	43 (0.3)	37 (0.2)	0	206 (1.4)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	13553 (89.3)	933 (6.1)	425 (2.8)	157 (1.0)	0	15185 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	80 (0.5)	4247 (28.0)	295 (1.9)	132 (0.9)	62 (0.4)	0	4816 (31.7)
Grade 0	32 (0.2)	8822 (58.1)	463 (3.0)	178 (1.2)	49 (0.3)	0	9544 (62.9)
Grade 1	4 (<0.1)	310 (2.0)	119 (0.8)	63 (0.4)	19 (0.1)	0	515 (3.4)
Grade 2	1 (<0.1)	133 (0.9)	37 (0.2)	37 (0.2)	14 (<0.1)	0	222 (1.5)
Grade 3	0	41 (0.3)	19 (0.1)	15 (<0.1)	13 (<0.1)	0	88 (0.6)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	13553 (89.3)	933 (6.1)	425 (2.8)	157 (1.0)	0	15185 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	117 (0.8)	13552 (89.2)	933 (6.1)	425 (2.8)	157 (1.0)	0	15184 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	117 (0.8)	13553 (89.3)	933 (6.1)	425 (2.8)	157 (1.0)	0	15185 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	24 (2.6)	1 (0.1)	0	0	0	25 (2.7)
Grade 0	1 (0.1)	776 (84.7)	32 (3.5)	7 (0.8)	5 (0.5)	0	821 (89.6)
Grade 1	0	33 (3.6)	1 (0.1)	2 (0.2)	0	0	36 (3.9)
Grade 2	0	18 (2.0)	4 (0.4)	2 (0.2)	0	0	24 (2.6)
Grade 3	0	7 (0.8)	0	3 (0.3)	0	0	10 (1.1)
Grade 4	0	0	0	0	0	0	0
Total	1 (0.1)	858 (93.7)	38 (4.1)	14 (1.5)	5 (0.5)	0	916 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (3.1)	0	0	0	0	2 (3.1)
Grade 0	0	56 (86.2)	2 (3.1)	1 (1.5)	1 (1.5)	0	60 (92.3)
Grade 1	0	3 (4.6)	0	0	0	0	3 (4.6)
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	61 (93.8)	2 (3.1)	1 (1.5)	1 (1.5)	0	65 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	5 (100)	0	0	0	0	5 (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	5 (100)	0	0	0	0	5 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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: mRNA-1273 (N=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	32 (97.0)	0	1 (3.0)	0	0	33 (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	32 (97.0)	0	1 (3.0)	0	0	33 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	2 (100)	0	0	0	0	2 (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	2 (100)	0	0	0	0	2 (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=15185)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	40 (0.3)	4 (<0.1)	0	1 (<0.1)	0	0	45 (0.3)
Grade 0	53 (0.3)	11550 (76.1)	393 (2.6)	92 (0.6)	22 (0.1)	0	12110 (79.7)
Grade 1	13 (<0.1)	1257 (8.3)	276 (1.8)	100 (0.7)	24 (0.2)	0	1670 (11.0)
Grade 2	6 (<0.1)	566 (3.7)	188 (1.2)	145 (1.0)	37 (0.2)	0	942 (6.2)
Grade 3	5 (<0.1)	176 (1.2)	76 (0.5)	87 (0.6)	74 (0.5)	0	418 (2.8)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	13553 (89.3)	933 (6.1)	425 (2.8)	157 (1.0)	0	15185 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	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	79 (0.5)	78 (0.5)	2 (<0.1)	1 (<0.1)	0	0	160 (1.1)
Grade 0	37 (0.2)	13429 (88.4)	256 (1.7)	25 (0.2)	6 (<0.1)	0	13753 (90.6)
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)	62 (0.4)	7 (<0.1)	0	266 (1.8)
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	117 (0.8)	14278 (94.0)	608 (4.0)	151 (1.0)	31 (0.2)	0	15185 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	42 (0.3)	486 (3.2)	13 (<0.1)	3 (<0.1)	0	0	544 (3.6)
Grade 0	67 (0.4)	12912 (85.0)	306 (2.0)	47 (0.3)	7 (<0.1)	0	13339 (87.8)
Grade 1	5 (<0.1)	709 (4.7)	175 (1.2)	41 (0.3)	4 (<0.1)	0	934 (6.2)
Grade 2	0	146 (1.0)	95 (0.6)	43 (0.3)	9 (<0.1)	0	293 (1.9)
Grade 3	3 (<0.1)	25 (0.2)	19 (0.1)	17 (0.1)	11 (<0.1)	0	75 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	14278 (94.0)	608 (4.0)	151 (1.0)	31 (0.2)	0	15185 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	80 (0.5)	4491 (29.6)	190 (1.3)	47 (0.3)	10 (<0.1)	0	4818 (31.7)
Grade 0	36 (0.2)	9555 (62.9)	322 (2.1)	57 (0.4)	8 (<0.1)	0	9978 (65.7)
Grade 1	0	204 (1.3)	78 (0.5)	22 (0.1)	5 (<0.1)	0	309 (2.0)
Grade 2	0	24 (0.2)	15 (<0.1)	20 (0.1)	7 (<0.1)	0	66 (0.4)
Grade 3	1 (<0.1)	4 (<0.1)	3 (<0.1)	5 (<0.1)	1 (<0.1)	0	14 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	14278 (94.0)	608 (4.0)	151 (1.0)	31 (0.2)	0	15185 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	117 (0.8)	14277 (94.0)	608 (4.0)	151 (1.0)	31 (0.2)	0	15184 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	117 (0.8)	14278 (94.0)	608 (4.0)	151 (1.0)	31 (0.2)	0	15185 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	11 (1.2)	1 (0.1)	0	0	0	12 (1.3)
Grade 0	1 (0.1)	836 (91.3)	39 (4.3)	4 (0.4)	1 (0.1)	0	881 (96.2)
Grade 1	0	11 (1.2)	6 (0.7)	1 (0.1)	0	0	18 (2.0)
Grade 2	0	1 (0.1)	1 (0.1)	1 (0.1)	0	0	3 (0.3)
Grade 3	0	2 (0.2)	0	0	0	0	2 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	1 (0.1)	861 (94.0)	47 (5.1)	6 (0.7)	1 (0.1)	0	916 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	0	1 (1.5)	0	0	0	1 (1.5)
Grade 0	0	62 (95.4)	1 (1.5)	1 (1.5)	0	0	64 (98.5)
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	62 (95.4)	2 (3.1)	1 (1.5)	0	0	65 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	5 (100)	0	0	0	0	5 (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	5 (100)	0	0	0	0	5 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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: mRNA-1273 (N=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	33 (100)	0	0	0	0	33 (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	33 (100)	0	0	0	0	33 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	2 (100)	0	0	0	0	2 (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	2 (100)	0	0	0	0	2 (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=15185)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	40 (0.3)	5 (<0.1)	0	0	0	0	45 (0.3)
Grade 0	68 (0.4)	12827 (84.5)	165 (1.1)	15 (<0.1)	2 (<0.1)	0	13077 (86.1)
Grade 1	6 (<0.1)	1170 (7.7)	254 (1.7)	35 (0.2)	4 (<0.1)	0	1469 (9.7)
Grade 2	0	230 (1.5)	156 (1.0)	69 (0.5)	9 (<0.1)	0	464 (3.1)
Grade 3	3 (<0.1)	46 (0.3)	33 (0.2)	32 (0.2)	16 (0.1)	0	130 (0.9)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	14278 (94.0)	608 (4.0)	151 (1.0)	31 (0.2)	0	15185 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	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	79 (0.5)	79 (0.5)	1 (<0.1)	1 (<0.1)	0	0	160 (1.1)
Grade 0	38 (0.3)	14701 (96.8)	169 (1.1)	11 (<0.1)	0	0	14919 (98.2)
Grade 1	0	41 (0.3)	46 (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	117 (0.8)	14823 (97.6)	218 (1.4)	26 (0.2)	1 (<0.1)	0	15185 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	42 (0.3)	490 (3.2)	9 (<0.1)	3 (<0.1)	0	0	544 (3.6)
Grade 0	75 (0.5)	14103 (92.9)	142 (0.9)	14 (<0.1)	0	0	14334 (94.4)
Grade 1	0	213 (1.4)	59 (0.4)	5 (<0.1)	1 (<0.1)	0	278 (1.8)
Grade 2	0	15 (<0.1)	8 (<0.1)	3 (<0.1)	0	0	26 (0.2)
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	117 (0.8)	14823 (97.6)	218 (1.4)	26 (0.2)	1 (<0.1)	0	15185 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	80 (0.5)	4658 (30.7)	72 (0.5)	8 (<0.1)	0	0	4818 (31.7)
Grade 0	37 (0.2)	10041 (66.1)	123 (0.8)	12 (<0.1)	1 (<0.1)	0	10214 (67.3)
Grade 1	0	116 (0.8)	18 (0.1)	4 (<0.1)	0	0	138 (0.9)
Grade 2	0	7 (<0.1)	5 (<0.1)	2 (<0.1)	0	0	14 (<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	117 (0.8)	14823 (97.6)	218 (1.4)	26 (0.2)	1 (<0.1)	0	15185 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	117 (0.8)	14822 (97.6)	218 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	117 (0.8)	14823 (97.6)	218 (1.4)	26 (0.2)	1 (<0.1)	0	15185 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	12 (1.3)	0	0	0	0	12 (1.3)
Grade 0	1 (0.1)	849 (92.7)	12 (1.3)	0	0	0	862 (94.1)
Grade 1	0	34 (3.7)	2 (0.2)	0	0	0	36 (3.9)
Grade 2	0	5 (0.5)	1 (0.1)	0	0	0	6 (0.7)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	1 (0.1)	900 (98.3)	15 (1.6)	0	0	0	916 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	1 (1.5)	0	0	0	0	1 (1.5)
Grade 0	0	59 (90.8)	1 (1.5)	0	0	0	60 (92.3)
Grade 1	0	2 (3.1)	1 (1.5)	0	0	0	3 (4.6)
Grade 2	0	1 (1.5)	0	0	0	0	1 (1.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	63 (96.9)	2 (3.1)	0	0	0	65 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	5 (100)	0	0	0	0	5 (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	5 (100)	0	0	0	0	5 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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: mRNA-1273 (N=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	33 (100)	0	0	0	0	33 (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	33 (100)	0	0	0	0	33 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	2 (100)	0	0	0	0	2 (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	2 (100)	0	0	0	0	2 (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=15185)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	40 (0.3)	5 (<0.1)	0	0	0	0	45 (0.3)
Grade 0	77 (0.5)	14434 (95.1)	122 (0.8)	7 (<0.1)	0	0	14640 (96.4)
Grade 1	0	353 (2.3)	81 (0.5)	12 (<0.1)	0	0	446 (2.9)
Grade 2	0	28 (0.2)	15 (<0.1)	6 (<0.1)	1 (<0.1)	0	50 (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	117 (0.8)	14823 (97.6)	218 (1.4)	26 (0.2)	1 (<0.1)	0	15185 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	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	80 (0.5)	63 (0.4)	25 (0.2)	0	0	0	168 (1.1)
Grade 0	48 (0.3)	10160 (66.9)	1383 (9.1)	31 (0.2)	1 (<0.1)	0	11623 (76.5)
Grade 1	8 (<0.1)	1355 (8.9)	1873 (12.3)	41 (0.3)	2 (<0.1)	0	3279 (21.6)
Grade 2	1 (<0.1)	38 (0.3)	41 (0.3)	26 (0.2)	0	0	106 (0.7)
Grade 3	0	3 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	0	9 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	137 (0.9)	11619 (76.5)	3324 (21.9)	101 (0.7)	4 (<0.1)	0	15185 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	41 (0.3)	356 (2.3)	146 (1.0)	1 (<0.1)	1 (<0.1)	0	545 (3.6)
Grade 0	61 (0.4)	8917 (58.7)	1495 (9.8)	47 (0.3)	0	0	10520 (69.3)
Grade 1	35 (0.2)	2289 (15.1)	1625 (10.7)	43 (0.3)	3 (<0.1)	0	3995 (26.3)
Grade 2	0	54 (0.4)	56 (0.4)	9 (<0.1)	0	0	119 (0.8)
Grade 3	0	3 (<0.1)	2 (<0.1)	1 (<0.1)	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	137 (0.9)	11619 (76.5)	3324 (21.9)	101 (0.7)	4 (<0.1)	0	15185 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	82 (0.5)	3671 (24.2)	1057 (7.0)	13 (<0.1)	2 (<0.1)	0	4825 (31.8)
Grade 0	45 (0.3)	6817 (44.9)	1336 (8.8)	53 (0.3)	1 (<0.1)	0	8252 (54.3)
Grade 1	10 (<0.1)	1112 (7.3)	914 (6.0)	33 (0.2)	1 (<0.1)	0	2070 (13.6)
Grade 2	0	18 (0.1)	16 (0.1)	2 (<0.1)	0	0	36 (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	137 (0.9)	11619 (76.5)	3324 (21.9)	101 (0.7)	4 (<0.1)	0	15185 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	137 (0.9)	11619 (76.5)	3323 (21.9)	101 (0.7)	4 (<0.1)	0	15184 (>99.9)
Grade 0	0	0	1 (<0.1)	0	0	0	1 (<0.1)
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	137 (0.9)	11619 (76.5)	3324 (21.9)	101 (0.7)	4 (<0.1)	0	15185 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	17 (1.9)	10 (1.1)	1 (0.1)	0	0	28 (3.1)
Grade 0	2 (0.2)	570 (62.2)	105 (11.5)	3 (0.3)	0	0	680 (74.2)
Grade 1	0	120 (13.1)	74 (8.1)	3 (0.3)	0	0	197 (21.5)
Grade 2	0	9 (1.0)	1 (0.1)	0	0	0	10 (1.1)
Grade 3	0	1 (0.1)	0	0	0	0	1 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	2 (0.2)	717 (78.3)	190 (20.7)	7 (0.8)	0	0	916 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (3.1)	1 (1.5)	0	0	0	3 (4.6)
Grade 0	0	32 (49.2)	5 (7.7)	0	0	0	37 (56.9)
Grade 1	0	14 (21.5)	8 (12.3)	1 (1.5)	0	0	23 (35.4)
Grade 2	0	2 (3.1)	0	0	0	0	2 (3.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	50 (76.9)	14 (21.5)	1 (1.5)	0	0	65 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	2 (40.0)	1 (20.0)	0	0	0	3 (60.0)
Grade 1	0	1 (20.0)	1 (20.0)	0	0	0	2 (40.0)
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 (60.0)	2 (40.0)	0	0	0	5 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 4 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	0	0	0	0	0	0
Grade 1	0	1 (100)	0	0	0	0	1 (100)
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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	24 (72.7)	2 (6.1)	0	0	0	26 (78.8)
Grade 1	0	5 (15.2)	2 (6.1)	0	0	0	7 (21.2)
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	29 (87.9)	4 (12.1)	0	0	0	33 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	1 (50.0)	1 (50.0)	0	0	0	2 (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 (50.0)	1 (50.0)	0	0	0	2 (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=15185)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	40 (0.3)	1 (<0.1)	4 (<0.1)	0	0	0	45 (0.3)
Grade 0	53 (0.3)	7977 (52.5)	737 (4.9)	11 (<0.1)	0	0	8778 (57.8)
Grade 1	43 (0.3)	3519 (23.2)	2472 (16.3)	54 (0.4)	3 (<0.1)	0	6091 (40.1)
Grade 2	1 (<0.1)	114 (0.8)	106 (0.7)	33 (0.2)	0	0	254 (1.7)
Grade 3	0	8 (<0.1)	5 (<0.1)	3 (<0.1)	1 (<0.1)	0	17 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	137 (0.9)	11619 (76.5)	3324 (21.9)	101 (0.7)	4 (<0.1)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	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	79 (0.5)	78 (0.5)	0	0	0	0	157 (1.0)
Grade 0	38 (0.3)	14945 (98.4)	17 (0.1)	6 (<0.1)	1 (<0.1)	0	15007 (98.8)
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	117 (0.8)	15042 (99.1)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	41 (0.3)	502 (3.3)	0	1 (<0.1)	0	0	544 (3.6)
Grade 0	75 (0.5)	14495 (95.5)	15 (<0.1)	5 (<0.1)	0	0	14590 (96.1)
Grade 1	1 (<0.1)	31 (0.2)	2 (<0.1)	0	1 (<0.1)	0	35 (0.2)
Grade 2	0	12 (<0.1)	2 (<0.1)	0	0	0	14 (<0.1)
Grade 3	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	15042 (99.1)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	80 (0.5)	4729 (31.1)	4 (<0.1)	2 (<0.1)	1 (<0.1)	0	4816 (31.7)
Grade 0	37 (0.2)	10288 (67.8)	14 (<0.1)	4 (<0.1)	0	0	10343 (68.1)
Grade 1	0	19 (0.1)	1 (<0.1)	0	0	0	20 (0.1)
Grade 2	0	4 (<0.1)	0	0	0	0	4 (<0.1)
Grade 3	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	15042 (99.1)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	117 (0.8)	15041 (99.1)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	117 (0.8)	15042 (99.1)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	25 (2.7)	0	0	0	0	25 (2.7)
Grade 0	1 (0.1)	886 (96.7)	1 (0.1)	1 (0.1)	0	0	889 (97.1)
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	1 (0.1)	0	0	0	0	1 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	1 (0.1)	913 (99.7)	1 (0.1)	1 (0.1)	0	0	916 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (3.1)	0	0	0	0	2 (3.1)
Grade 0	0	62 (95.4)	0	0	0	0	62 (95.4)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	1 (1.5)	0	0	0	0	1 (1.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	65 (100)	0	0	0	0	65 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	5 (100)	0	0	0	0	5 (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	5 (100)	0	0	0	0	5 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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: mRNA-1273 (N=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	33 (100)	0	0	0	0	33 (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	33 (100)	0	0	0	0	33 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	2 (100)	0	0	0	0	2 (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	2 (100)	0	0	0	0	2 (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=15185)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	40 (0.3)	5 (<0.1)	0	0	0	0	45 (0.3)
Grade 0	76 (0.5)	14956 (98.5)	14 (<0.1)	6 (<0.1)	0	0	15052 (99.1)
Grade 1	1 (<0.1)	55 (0.4)	2 (<0.1)	0	1 (<0.1)	0	59 (0.4)
Grade 2	0	18 (0.1)	3 (<0.1)	0	0	0	21 (0.1)
Grade 3	0	8 (<0.1)	0	0	0	0	8 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	15042 (99.1)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	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	79 (0.5)	65 (0.4)	6 (<0.1)	2 (<0.1)	5 (<0.1)	0	157 (1.0)
Grade 0	27 (0.2)	11244 (74.0)	831 (5.5)	117 (0.8)	91 (0.6)	0	12310 (81.1)
Grade 1	5 (<0.1)	886 (5.8)	548 (3.6)	121 (0.8)	129 (0.8)	0	1689 (11.1)
Grade 2	3 (<0.1)	134 (0.9)	146 (1.0)	66 (0.4)	66 (0.4)	0	415 (2.7)
Grade 3	3 (<0.1)	131 (0.9)	164 (1.1)	86 (0.6)	230 (1.5)	0	614 (4.0)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	12460 (82.1)	1695 (11.2)	392 (2.6)	521 (3.4)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	41 (0.3)	420 (2.8)	49 (0.3)	13 (<0.1)	21 (0.1)	0	544 (3.6)
Grade 0	47 (0.3)	10514 (69.2)	859 (5.7)	152 (1.0)	122 (0.8)	0	11694 (77.0)
Grade 1	19 (0.1)	1127 (7.4)	473 (3.1)	115 (0.8)	141 (0.9)	0	1875 (12.3)
Grade 2	2 (<0.1)	196 (1.3)	129 (0.8)	44 (0.3)	63 (0.4)	0	434 (2.9)
Grade 3	8 (<0.1)	203 (1.3)	185 (1.2)	68 (0.4)	174 (1.1)	0	638 (4.2)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	12460 (82.1)	1695 (11.2)	392 (2.6)	521 (3.4)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	80 (0.5)	3908 (25.7)	567 (3.7)	125 (0.8)	136 (0.9)	0	4816 (31.7)
Grade 0	28 (0.2)	7841 (51.6)	752 (5.0)	139 (0.9)	169 (1.1)	0	8929 (58.8)
Grade 1	4 (<0.1)	504 (3.3)	226 (1.5)	70 (0.5)	91 (0.6)	0	895 (5.9)
Grade 2	0	98 (0.6)	72 (0.5)	26 (0.2)	38 (0.3)	0	234 (1.5)
Grade 3	5 (<0.1)	109 (0.7)	78 (0.5)	32 (0.2)	87 (0.6)	0	311 (2.0)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	12460 (82.1)	1695 (11.2)	392 (2.6)	521 (3.4)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	117 (0.8)	12460 (82.1)	1694 (11.2)	392 (2.6)	521 (3.4)	0	15184 (>99.9)
Grade 0	0	0	1 (<0.1)	0	0	0	1 (<0.1)
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	117 (0.8)	12460 (82.1)	1695 (11.2)	392 (2.6)	521 (3.4)	0	15185 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	20 (2.2)	3 (0.3)	2 (0.2)	0	0	25 (2.7)
Grade 0	1 (0.1)	715 (78.1)	40 (4.4)	10 (1.1)	3 (0.3)	0	769 (84.0)
Grade 1	0	59 (6.4)	15 (1.6)	4 (0.4)	2 (0.2)	0	80 (8.7)
Grade 2	0	6 (0.7)	3 (0.3)	1 (0.1)	2 (0.2)	0	12 (1.3)
Grade 3	0	12 (1.3)	13 (1.4)	3 (0.3)	2 (0.2)	0	30 (3.3)
Grade 4	0	0	0	0	0	0	0
Total	1 (0.1)	812 (88.6)	74 (8.1)	20 (2.2)	9 (1.0)	0	916 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	2 (3.1)	0	0	0	0	2 (3.1)
Grade 0	0	49 (75.4)	3 (4.6)	2 (3.1)	0	0	54 (83.1)
Grade 1	0	9 (13.8)	0	0	0	0	9 (13.8)
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	60 (92.3)	3 (4.6)	2 (3.1)	0	0	65 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	5 (100)	0	0	0	0	5 (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	5 (100)	0	0	0	0	5 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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: mRNA-1273 (N=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	29 (87.9)	1 (3.0)	0	0	0	30 (90.9)
Grade 1	0	1 (3.0)	0	2 (6.1)	0	0	3 (9.1)
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	0	30 (90.9)	1 (3.0)	2 (6.1)	0	0	33 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	2 (100)	0	0	0	0	2 (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	2 (100)	0	0	0	0	2 (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=15185)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	40 (0.3)	4 (<0.1)	0	0	1 (<0.1)	0	45 (0.3)
Grade 0	44 (0.3)	9865 (65.0)	480 (3.2)	51 (0.3)	32 (0.2)	0	10472 (69.0)
Grade 1	18 (0.1)	1829 (12.0)	640 (4.2)	113 (0.7)	101 (0.7)	0	2701 (17.8)
Grade 2	4 (<0.1)	360 (2.4)	233 (1.5)	81 (0.5)	68 (0.4)	0	746 (4.9)
Grade 3	11 (<0.1)	402 (2.6)	342 (2.3)	147 (1.0)	319 (2.1)	0	1221 (8.0)
Grade 4	0	0	0	0	0	0	0
Total	117 (0.8)	12460 (82.1)	1695 (11.2)	392 (2.6)	521 (3.4)	0	15185 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	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	79 (0.5)	82 (0.5)	0	0	0	0	161 (1.1)
Grade 0	38 (0.3)	14979 (98.6)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15020 (98.9)
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	117 (0.8)	15065 (99.2)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15185 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	41 (0.3)	503 (3.3)	0	0	0	0	544 (3.6)
Grade 0	76 (0.5)	14556 (95.9)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	14635 (96.4)
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	117 (0.8)	15065 (99.2)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15185 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	78 (0.5)	4749 (31.3)	1 (<0.1)	1 (<0.1)	0	0	4829 (31.8)
Grade 0	39 (0.3)	10312 (67.9)	0	0	0	1 (<0.1)	10352 (68.2)
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	4 (<0.1)	0	0	0	0	4 (<0.1)
Total	117 (0.8)	15065 (99.2)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15185 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 119							
UNK	117 (0.8)	15064 (99.2)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15184 (>99.9)
Grade 0	0	1 (<0.1)	0	0	0	0	1 (<0.1)
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	117 (0.8)	15065 (99.2)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15185 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 1							
UNK	0	4 (0.4)	0	0	0	0	4 (0.4)
Grade 0	1 (0.1)	896 (97.8)	0	0	0	0	897 (97.9)
Grade 1	0	10 (1.1)	0	0	0	0	10 (1.1)
Grade 2	0	4 (0.4)	0	0	0	0	4 (0.4)
Grade 3	0	1 (0.1)	0	0	0	0	1 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	1 (0.1)	915 (99.9)	0	0	0	0	916 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	63 (96.9)	0	0	0	0	63 (96.9)
Grade 1	0	1 (1.5)	0	0	0	0	1 (1.5)
Grade 2	0	1 (1.5)	0	0	0	0	1 (1.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	65 (100)	0	0	0	0	65 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 3 Day 1							
UNK	0	0	0	0	0	0	0
Grade 0	0	5 (100)	0	0	0	0	5 (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	5 (100)	0	0	0	0	5 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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: mRNA-1273 (N=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit Day 28							
UNK	0	1 (3.0)	0	0	0	0	1 (3.0)
Grade 0	0	32 (97.0)	0	0	0	0	32 (97.0)
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	33 (100)	0	0	0	0	33 (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=15185)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Illness Visit 2 Day 28							
UNK	0	0	0	0	0	0	0
Grade 0	0	2 (100)	0	0	0	0	2 (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	2 (100)	0	0	0	0	2 (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=15185)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	40 (0.3)	5 (<0.1)	0	0	0	0	45 (0.3)
Grade 0	77 (0.5)	15029 (99.0)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15109 (99.5)
Grade 1	0	16 (0.1)	0	0	0	0	16 (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	6 (<0.1)	0	0	0	0	6 (<0.1)
Total	117 (0.8)	15065 (99.2)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	15185 (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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