Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598) n (%)	mRNA-1273 (N=14550) n (%)	Total (N=29148) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Number of Subjects									
Received First Injection	14598 (100)	14550 (100)	29148 (100)	337 (100)	343 (100)	680 (100)	15170 (99.7)	15181 (99.8)	30351 (99.8)
Received Second Injection	14165 (97.0)	14214 (97.7)	28379 (97.4)	235 (69.7)	232 (67.6)	467 (68.7)	14617 (96.1)	14711 (96.7)	29328 (96.4)
Discontinued Study Vaccine	229 (1.6)	163 (1.1)	392 (1.3)	43 (12.8)	52 (15.2)	95 (14.0)	290 (1.9)	233 (1.5)	523 (1.7)
Reason for Discontinuation of Study Vaccine									
Adverse Event	24 (0.2)	26 (0.2)	50 (0.2)	0	1 (0.3)	1 (0.1)	25 (0.2)	29 (0.2)	54 (0.2)
Serious Adverse Event	13 (<0.1)	8 (<0.1)	21 (<0.1)	2 (0.6)	0	2 (0.3)	15 (<0.1)	9 (<0.1)	24 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	0	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	24 (0.2)	21 (0.1)	45 (0.2)	0	5 (1.5)	5 (0.7)	24 (0.2)	27 (0.2)	51 (0.2)
Physician Decision	7 (<0.1)	14 (<0.1)	21 (<0.1)	0	0	0	9 (<0.1)	15 (<0.1)	24 (<0.1)
Pregnancy	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	1 (0.3)	1 (0.1)	2 (<0.1)	3 (<0.1)	5 (<0.1)
Protocol Deviation	5 (<0.1)	3 (<0.1)	8 (<0.1)	0	0	0	5 (<0.1)	3 (<0.1)	8 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598) n (%)	mRNA-1273 (N=14550) n (%)	Total (N=29148) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	82 (0.6)	50 (0.3)	132 (0.5)	6 (1.8)	2 (0.6)	8 (1.2)	97 (0.6)	56 (0.4)	153 (0.5)
Due to SARS-CoV-2	37 (0.3)	7 (<0.1)	44 (0.2)	32 (9.5)	37 (10.8)	69 (10.1)	69 (0.5)	45 (0.3)	114 (0.4)
Other	32 (0.2)	30 (0.2)	62 (0.2)	3 (0.9)	6 (1.7)	9 (1.3)	41 (0.3)	44 (0.3)	85 (0.3)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	171 (1.2)	132 (0.9)	303 (1.0)	10 (3.0)	8 (2.3)	18 (2.6)	206 (1.4)	159 (1.0)	365 (1.2)
Reason for Discontinuation of Study									
Adverse Event	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (0.3)	1 (0.1)	1 (<0.1)	4 (<0.1)	5 (<0.1)
Serious Adverse Event	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	0	2 (<0.1)	3 (<0.1)	5 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598) n (%)	mRNA-1273 (N=14550) n (%)	Total (N=29148) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=343) n (%)	Total (N=680) n (%)	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Reason for Discontinuation of Study (Cont.)									
Death	6 (<0.1)	4 (<0.1)	10 (<0.1)	0	0	0	6 (<0.1)	4 (<0.1)	10 (<0.1)
Lost to Follow-Up	34 (0.2)	27 (0.2)	61 (0.2)	1 (0.3)	5 (1.5)	6 (0.9)	35 (0.2)	33 (0.2)	68 (0.2)
Physician Decision	2 (<0.1)	13 (<0.1)	15 (<0.1)	0	0	0	3 (<0.1)	15 (<0.1)	18 (<0.1)
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol Deviation	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	121 (0.8)	76 (0.5)	197 (0.7)	9 (2.7)	2 (0.6)	11 (1.6)	146 (1.0)	85 (0.6)	231 (0.8)
Other	5 (<0.1)	6 (<0.1)	11 (<0.1)	0	0	0	13 (<0.1)	14 (<0.1)	27 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11448) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22887) n (%)	Placebo (N=3762) n (%)	mRNA-1273 (N=3771) n (%)	Total (N=7533) n (%)	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Number of Subjects									
Received First Injection	11418 (99.7)	11413 (99.8)	22831 (99.8)	3752 (99.7)	3768 (>99.9)	7520 (99.8)	15170 (99.7)	15181 (99.8)	30351 (99.8)
Received Second Injection	10950 (95.6)	11009 (96.2)	21959 (95.9)	3667 (97.5)	3702 (98.2)	7369 (97.8)	14617 (96.1)	14711 (96.7)	29328 (96.4)
Discontinued Study Vaccine	239 (2.1)	199 (1.7)	438 (1.9)	51 (1.4)	34 (0.9)	85 (1.1)	290 (1.9)	233 (1.5)	523 (1.7)
Reason for Discontinuation of Study Vaccine									
Adverse Event	18 (0.2)	21 (0.2)	39 (0.2)	7 (0.2)	8 (0.2)	15 (0.2)	25 (0.2)	29 (0.2)	54 (0.2)
Serious Adverse Event	6 (<0.1)	7 (<0.1)	13 (<0.1)	9 (0.2)	2 (<0.1)	11 (0.1)	15 (<0.1)	9 (<0.1)	24 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	24 (0.2)	26 (0.2)	50 (0.2)	0	1 (<0.1)	1 (<0.1)	24 (0.2)	27 (0.2)	51 (0.2)
Physician Decision	8 (<0.1)	14 (0.1)	22 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	9 (<0.1)	15 (<0.1)	24 (<0.1)
Pregnancy	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Protocol Deviation	4 (<0.1)	2 (<0.1)	6 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	3 (<0.1)	8 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11448) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22887) n (%)	Placebo (N=3762) n (%)	mRNA-1273 (N=3771) n (%)	Total (N=7533) n (%)	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	79 (0.7)	44 (0.4)	123 (0.5)	18 (0.5)	12 (0.3)	30 (0.4)	97 (0.6)	56 (0.4)	153 (0.5)
Due to SARS-CoV-2	63 (0.6)	40 (0.3)	103 (0.5)	6 (0.2)	5 (0.1)	11 (0.1)	69 (0.5)	45 (0.3)	114 (0.4)
Other	34 (0.3)	41 (0.4)	75 (0.3)	7 (0.2)	3 (<0.1)	10 (0.1)	41 (0.3)	44 (0.3)	85 (0.3)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	169 (1.5)	138 (1.2)	307 (1.3)	37 (1.0)	21 (0.6)	58 (0.8)	206 (1.4)	159 (1.0)	365 (1.2)
Reason for Discontinuation of Study									
Adverse Event	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	4 (<0.1)	5 (<0.1)
Serious Adverse Event	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	5 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11448) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22887) n (%)	Placebo (N=3762) n (%)	mRNA-1273 (N=3771) n (%)	Total (N=7533) n (%)	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Reason for Discontinuation of Study (Cont.)									
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)	6 (<0.1)	4 (<0.1)	10 (<0.1)
Lost to Follow-Up	35 (0.3)	32 (0.3)	67 (0.3)	0	1 (<0.1)	1 (<0.1)	35 (0.2)	33 (0.2)	68 (0.2)
Physician Decision	2 (<0.1)	14 (0.1)	16 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	15 (<0.1)	18 (<0.1)
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol Deviation	0	1 (<0.1)	1 (<0.1)	0	0	0	0	1 (<0.1)	1 (<0.1)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	120 (1.0)	71 (0.6)	191 (0.8)	26 (0.7)	14 (0.4)	40 (0.5)	146 (1.0)	85 (0.6)	231 (0.8)
Other	8 (<0.1)	13 (0.1)	21 (<0.1)	5 (0.1)	1 (<0.1)	6 (<0.1)	13 (<0.1)	14 (<0.1)	27 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Number of Subjects			
Received First Injection	15170 (99.7)	15181 (99.8)	30351 (99.8)
Received Second Injection	14617 (96.1)	14711 (96.7)	29328 (96.4)
Discontinued Study Vaccine	290 (1.9)	233 (1.5)	523 (1.7)
Reason for Discontinuation of Study Vaccine			
Adverse Event	25 (0.2)	29 (0.2)	54 (0.2)
Serious Adverse Event	15 (<0.1)	9 (<0.1)	24 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	24 (0.2)	27 (0.2)	51 (0.2)
Physician Decision	9 (<0.1)	15 (<0.1)	24 (<0.1)
Pregnancy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Protocol Deviation	5 (<0.1)	3 (<0.1)	8 (<0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	97 (0.6)	56 (0.4)	153 (0.5)
Due to SARS-CoV-2	69 (0.5)	45 (0.3)	114 (0.4)
Other	41 (0.3)	44 (0.3)	85 (0.3)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

	Placebo (N=15210) n (%)	mRNA-1273 (N=15210) n (%)	Total (N=30420) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	206 (1.4)	159 (1.0)	365 (1.2)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)
Serious Adverse Event	2 (<0.1)	3 (<0.1)	5 (<0.1)
Death	6 (<0.1)	4 (<0.1)	10 (<0.1)
Lost to Follow-Up	35 (0.2)	33 (0.2)	68 (0.2)
Physician Decision	3 (<0.1)	15 (<0.1)	18 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	0	1 (<0.1)	1 (<0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	146 (1.0)	85 (0.6)	231 (0.8)
Other	13 (<0.1)	14 (<0.1)	27 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

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

	Placebo (N=8910) n (%)	mRNA-1273 (N=8910) n (%)	Total (N=17820) n (%)
Number of Subjects			
Received First Injection	8886 (99.7)	8888 (99.8)	17774 (99.7)
Received Second Injection	8520 (95.6)	8550 (96.0)	17070 (95.8)
Discontinued Study Vaccine	190 (2.1)	169 (1.9)	359 (2.0)
Reason for Discontinuation of Study Vaccine			
Adverse Event	15 (0.2)	19 (0.2)	34 (0.2)
Serious Adverse Event	5 (<0.1)	4 (<0.1)	9 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lost to Follow-Up	23 (0.3)	24 (0.3)	47 (0.3)
Physician Decision	6 (<0.1)	11 (0.1)	17 (<0.1)
Pregnancy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Protocol Deviation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	59 (0.7)	36 (0.4)	95 (0.5)
Due to SARS-CoV-2	48 (0.5)	33 (0.4)	81 (0.5)
Other	29 (0.3)	36 (0.4)	65 (0.4)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

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

	Placebo (N=8910) n (%)	mRNA-1273 (N=8910) n (%)	Total (N=17820) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	139 (1.6)	101 (1.1)	240 (1.3)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	2 (<0.1)	3 (<0.1)
Serious Adverse Event	0	2 (<0.1)	2 (<0.1)
Death	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lost to Follow-Up	34 (0.4)	29 (0.3)	63 (0.4)
Physician Decision	1 (<0.1)	10 (0.1)	11 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	0	1 (<0.1)	1 (<0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	96 (1.1)	48 (0.5)	144 (0.8)
Other	5 (<0.1)	8 (<0.1)	13 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

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

	Placebo (N=2541) n (%)	mRNA-1273 (N=2534) n (%)	Total (N=5075) n (%)
Number of Subjects			
Received First Injection	2535 (99.8)	2530 (99.8)	5065 (99.8)
Received Second Injection	2433 (95.7)	2464 (97.2)	4897 (96.5)
Discontinued Study Vaccine	49 (1.9)	30 (1.2)	79 (1.6)
Reason for Discontinuation of Study Vaccine			
Adverse Event	3 (0.1)	2 (<0.1)	5 (<0.1)
Serious Adverse Event	1 (<0.1)	3 (0.1)	4 (<0.1)
Death	0	0	0
Lost to Follow-Up	1 (<0.1)	2 (<0.1)	3 (<0.1)
Physician Decision	2 (<0.1)	3 (0.1)	5 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	2 (<0.1)	0	2 (<0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	20 (0.8)	8 (0.3)	28 (0.6)
Due to SARS-CoV-2	15 (0.6)	7 (0.3)	22 (0.4)
Other	5 (0.2)	5 (0.2)	10 (0.2)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

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

	Placebo (N=2541) n (%)	mRNA-1273 (N=2534) n (%)	Total (N=5075) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	30 (1.2)	37 (1.5)	67 (1.3)
Reason for Discontinuation of Study			
Adverse Event	0	1 (<0.1)	1 (<0.1)
Serious Adverse Event	0	0	0
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lost to Follow-Up	1 (<0.1)	3 (0.1)	4 (<0.1)
Physician Decision	1 (<0.1)	4 (0.2)	5 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	24 (0.9)	23 (0.9)	47 (0.9)
Other	3 (0.1)	5 (0.2)	8 (0.2)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

	Placebo (N=3759) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7525) n (%)
Number of Subjects			
Received First Injection	3749 (99.7)	3763 (>99.9)	7512 (99.8)
Received Second Injection	3664 (97.5)	3697 (98.2)	7361 (97.8)
Discontinued Study Vaccine	51 (1.4)	34 (0.9)	85 (1.1)
Reason for Discontinuation of Study Vaccine			
Adverse Event	7 (0.2)	8 (0.2)	15 (0.2)
Serious Adverse Event	9 (0.2)	2 (<0.1)	11 (0.1)
Death	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lost to Follow-Up	0	1 (<0.1)	1 (<0.1)
Physician Decision	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	18 (0.5)	12 (0.3)	30 (0.4)
Due to SARS-CoV-2	6 (0.2)	5 (0.1)	11 (0.1)
Other	7 (0.2)	3 (<0.1)	10 (0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

	Placebo (N=3759) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7525) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	37 (1.0)	21 (0.6)	58 (0.8)
Reason for Discontinuation of Study			
Adverse Event	0	1 (<0.1)	1 (<0.1)
Serious Adverse Event	2 (<0.1)	1 (<0.1)	3 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	0	1 (<0.1)	1 (<0.1)
Physician Decision	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	26 (0.7)	14 (0.4)	40 (0.5)
Other	5 (0.1)	1 (<0.1)	6 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Age at Screening (Years)									
n	14598	14550	29148	337	343	680	15170	15181	30351
Mean	51.5	51.5	51.5	44.8	44.1	44.5	51.3	51.4	51.4
(SD)	(15.58)	(15.48)	(15.53)	(15.42)	(15.34)	(15.37)	(15.60)	(15.50)	(15.55)
Median	52.0	53.0	53.0	46.0	44.0	45.0	52.0	53.0	52.0
Min, Max	18, 95	18, 95	18, 95	18, 83	18, 84	18, 84	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	10944	10890	21834	304	307	611	11418	11413	22831
	(75.0)	(74.8)	(74.9)	(90.2)	(89.5)	(89.9)	(75.3)	(75.2)	(75.2)
Mean	45.0	45.2	45.1	41.9	41.0	41.4	45.0	45.1	45.0
(SD)	(12.27)	(12.33)	(12.30)	(13.16)	(12.87)	(13.01)	(12.30)	(12.35)	(12.32)
Median	46.0	46.0	46.0	43.5	42.0	42.0	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64
>=65 Years	3654	3660	7314	33	36	69	3752	3768	7520
	(25.0)	(25.2)	(25.1)	(9.8)	(10.5)	(10.1)	(24.7)	(24.8)	(24.8)
Mean	70.7	70.4	70.6	71.8	70.8	71.3	70.7	70.4	70.6
(SD)	(4.87)	(4.66)	(4.77)	(4.91)	(5.54)	(5.23)	(4.88)	(4.66)	(4.77)
Median	70.0	69.0	70.0	71.0	69.5	70.0	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95	65, 83	65, 84	65, 84	65, 95	65, 95	65, 95

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	10944 (75.0)	10890 (74.8)	21834 (74.9)	304 (90.2)	307 (89.5)	611 (89.9)	11418 (75.3)	11413 (75.2)	22831 (75.2)
>=65 and <70 Years	1771 (12.1)	1848 (12.7)	3619 (12.4)	12 (3.6)	18 (5.2)	30 (4.4)	1817 (12.0)	1905 (12.5)	3722 (12.3)
>=70 and <75 Years	1168 (8.0)	1171 (8.0)	2339 (8.0)	10 (3.0)	11 (3.2)	21 (3.1)	1194 (7.9)	1205 (7.9)	2399 (7.9)
>=75 and <80 Years	489 (3.3)	456 (3.1)	945 (3.2)	9 (2.7)	3 (0.9)	12 (1.8)	507 (3.3)	467 (3.1)	974 (3.2)
>=80 Years	226 (1.5)	185 (1.3)	411 (1.4)	2 (0.6)	4 (1.2)	6 (0.9)	234 (1.5)	191 (1.3)	425 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	10944 (75.0)	10890 (74.8)	21834 (74.9)	304 (90.2)	307 (89.5)	611 (89.9)	11418 (75.3)	11413 (75.2)	22831 (75.2)
>=65 and <75 Years	2939 (20.1)	3019 (20.7)	5958 (20.4)	22 (6.5)	29 (8.5)	51 (7.5)	3011 (19.8)	3110 (20.5)	6121 (20.2)
>=75 and <85 Years	666 (4.6)	600 (4.1)	1266 (4.3)	11 (3.3)	7 (2.0)	18 (2.6)	692 (4.6)	617 (4.1)	1309 (4.3)
>=85 Years	49 (0.3)	41 (0.3)	90 (0.3)	0	0	0	49 (0.3)	41 (0.3)	90 (0.3)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8532 (58.4)	8468 (58.2)	17000 (58.3)	239 (70.9)	260 (75.8)	499 (73.4)	8886 (58.6)	8888 (58.5)	17774 (58.6)
>=18 and <65 Years and at Risk	2415 (16.5)	2427 (16.7)	4842 (16.6)	65 (19.3)	47 (13.7)	112 (16.5)	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	3651 (25.0)	3655 (25.1)	7306 (25.1)	33 (9.8)	36 (10.5)	69 (10.1)	3749 (24.7)	3763 (24.8)	7512 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	718 (4.9)	695 (4.8)	1413 (4.8)	11 (3.3)	8 (2.3)	19 (2.8)	744 (4.9)	710 (4.7)	1454 (4.8)
Significant Cardiac Disease	720 (4.9)	724 (5.0)	1444 (5.0)	12 (3.6)	12 (3.5)	24 (3.5)	744 (4.9)	752 (5.0)	1496 (4.9)
Severe Obesity	974 (6.7)	983 (6.8)	1957 (6.7)	23 (6.8)	23 (6.7)	46 (6.8)	1021 (6.7)	1025 (6.8)	2046 (6.7)
Diabetes	1394 (9.5)	1389 (9.5)	2783 (9.5)	24 (7.1)	23 (6.7)	47 (6.9)	1440 (9.5)	1435 (9.5)	2875 (9.5)
Liver Disease	93 (0.6)	97 (0.7)	190 (0.7)	1 (0.3)	1 (0.3)	2 (0.3)	96 (0.6)	100 (0.7)	196 (0.6)
Human Immunodeficiency Virus Infection	78 (0.5)	85 (0.6)	163 (0.6)	7 (2.1)	5 (1.5)	12 (1.8)	87 (0.6)	92 (0.6)	179 (0.6)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	3290 (22.5)	3283 (22.6)	6573 (22.6)	68 (20.2)	56 (16.3)	124 (18.2)	3418 (22.5)	3399 (22.4)	6817 (22.5)
One Risk Factor for Severe COVID-19	2693 (18.4)	2678 (18.4)	5371 (18.4)	59 (17.5)	43 (12.5)	102 (15.0)	2798 (18.4)	2775 (18.3)	5573 (18.4)
Two or More Risk Factors for Severe COVID-19	597 (4.1)	605 (4.2)	1202 (4.1)	9 (2.7)	13 (3.8)	22 (3.2)	620 (4.1)	624 (4.1)	1244 (4.1)
No	11308 (77.5)	11267 (77.4)	22575 (77.4)	269 (79.8)	287 (83.7)	556 (81.8)	11752 (77.5)	11782 (77.6)	23534 (77.5)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	8749 (59.9)	8682 (59.7)	17431 (59.8)	243 (72.1)	260 (75.8)	503 (74.0)	9116 (60.1)	9118 (60.1)	18234 (60.1)
>=18 and <65 Years and at Risk	2195 (15.0)	2208 (15.2)	4403 (15.1)	61 (18.1)	47 (13.7)	108 (15.9)	2302 (15.2)	2295 (15.1)	4597 (15.1)
>=65 Years and Not at Risk	2559 (17.5)	2585 (17.8)	5144 (17.6)	26 (7.7)	27 (7.9)	53 (7.8)	2636 (17.4)	2664 (17.5)	5300 (17.5)
>=65 Years and at Risk	1095 (7.5)	1075 (7.4)	2170 (7.4)	7 (2.1)	9 (2.6)	16 (2.4)	1116 (7.4)	1104 (7.3)	2220 (7.3)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Baseline RT-PCR Results, n (%)									
Negative	14598 (100)	14550 (100)	29148 (100)	239 (70.9)	253 (73.8)	492 (72.4)	14923 (98.4)	14917 (98.3)	29840 (98.3)
Positive	0	0	0	95 (28.2)	87 (25.4)	182 (26.8)	95 (0.6)	87 (0.6)	182 (0.6)
Missing	0	0	0	3 (0.9)	3 (0.9)	6 (0.9)	152 (1.0)	177 (1.2)	329 (1.1)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	14598 (100)	14550 (100)	29148 (100)	34 (10.1)	38 (11.1)	72 (10.6)	14726 (97.1)	14690 (96.8)	29416 (96.9)
Positive	0	0	0	303 (89.9)	305 (88.9)	608 (89.4)	303 (2.0)	305 (2.0)	608 (2.0)
Missing	0	0	0	0	0	0	141 (0.9)	186 (1.2)	327 (1.1)
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	14598 (100)	14550 (100)	29148 (100)	0	0	0	14598 (96.2)	14550 (95.8)	29148 (96.0)
Positive	0	0	0	337 (100)	343 (100)	680 (100)	337 (2.2)	343 (2.3)	680 (2.2)
Missing	0	0	0	0	0	0	235 (1.5)	288 (1.9)	523 (1.7)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Sex, n (%)									
Male	7754 (53.1)	7588 (52.2)	15342 (52.6)	182 (54.0)	195 (56.9)	377 (55.4)	8062 (53.1)	7923 (52.2)	15985 (52.7)
Female	6844 (46.9)	6962 (47.8)	13806 (47.4)	155 (46.0)	148 (43.1)	303 (44.6)	7108 (46.9)	7258 (47.8)	14366 (47.3)
Race, n (%)									
White	11573 (79.3)	11570 (79.5)	23143 (79.4)	226 (67.1)	220 (64.1)	446 (65.6)	11995 (79.1)	12029 (79.2)	24024 (79.2)
Black or African American	1416 (9.7)	1443 (9.9)	2859 (9.8)	89 (26.4)	94 (27.4)	183 (26.9)	1527 (10.1)	1563 (10.3)	3090 (10.2)
Asian	716 (4.9)	636 (4.4)	1352 (4.6)	5 (1.5)	10 (2.9)	15 (2.2)	731 (4.8)	651 (4.3)	1382 (4.6)
American Indian or Alaska Native	117 (0.8)	111 (0.8)	228 (0.8)	2 (0.6)	0	2 (0.3)	121 (0.8)	112 (0.7)	233 (0.8)
Native Hawaiian or Other Pacific Islander	31 (0.2)	35 (0.2)	66 (0.2)	1 (0.3)	0	1 (0.1)	32 (0.2)	35 (0.2)	67 (0.2)
Multiracial	317 (2.2)	302 (2.1)	619 (2.1)	2 (0.6)	5 (1.5)	7 (1.0)	321 (2.1)	315 (2.1)	636 (2.1)
Other	305 (2.1)	307 (2.1)	612 (2.1)	8 (2.4)	9 (2.6)	17 (2.5)	316 (2.1)	321 (2.1)	637 (2.1)
Not Reported	69 (0.5)	88 (0.6)	157 (0.5)	4 (1.2)	4 (1.2)	8 (1.2)	73 (0.5)	96 (0.6)	169 (0.6)
Unknown	54 (0.4)	58 (0.4)	112 (0.4)	0	1 (0.3)	1 (0.1)	54 (0.4)	59 (0.4)	113 (0.4)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Ethnicity, n (%)									
Hispanic or Latino	2913 (20.0)	2898 (19.9)	5811 (19.9)	152 (45.1)	145 (42.3)	297 (43.7)	3114 (20.5)	3121 (20.6)	6235 (20.5)
Not Hispanic or Latino	11552 (79.1)	11514 (79.1)	23066 (79.1)	183 (54.3)	196 (57.1)	379 (55.7)	11917 (78.6)	11918 (78.5)	23835 (78.5)
Not Reported	80 (0.5)	100 (0.7)	180 (0.6)	2 (0.6)	2 (0.6)	4 (0.6)	85 (0.6)	104 (0.7)	189 (0.6)
Unknown	53 (0.4)	38 (0.3)	91 (0.3)	0	0	0	54 (0.4)	38 (0.3)	92 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	4337 (29.7)	4329 (29.8)	8666 (29.7)	223 (66.2)	218 (63.6)	441 (64.9)	4632 (30.5)	4650 (30.6)	9282 (30.6)
Non-minority	10235 (70.1)	10197 (70.1)	20432 (70.1)	114 (33.8)	125 (36.4)	239 (35.1)	10512 (69.3)	10505 (69.2)	21017 (69.2)
Missing	26 (0.2)	24 (0.2)	50 (0.2)	0	0	0	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	9205 (63.1)	9248 (63.6)	18453 (63.3)	107 (31.8)	110 (32.1)	217 (31.9)	9461 (62.4)	9529 (62.8)	18990 (62.6)
Communities of Color	5367 (36.8)	5278 (36.3)	10645 (36.5)	230 (68.2)	233 (67.9)	463 (68.1)	5683 (37.5)	5626 (37.1)	11309 (37.3)
Missing	26 (0.2)	24 (0.2)	50 (0.2)	0	0	0	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Weight (kg)									
n	14465	14398	28863	337	339	676	15009	14989	29998
Mean	85.82	85.62	85.72	85.69	87.56	86.62	85.87	85.71	85.79
(SD)	(21.607)	(21.976)	(21.792)	(21.010)	(22.260)	(21.650)	(21.651)	(21.978)	(21.814)
Median	82.95	83.00	83.00	82.10	84.10	83.00	83.00	83.00	83.00
Min, Max	27.1, 223.0	30.3, 236.4	27.1, 236.4	42.7, 182.4	43.2, 179.0	42.7, 182.4	27.1, 223.0	30.3, 236.4	27.1, 236.4
Height (cm)									
n	14464	14398	28862	337	339	676	15008	14989	29997
Mean	170.94	170.74	170.84	169.57	170.08	169.82	170.90	170.73	170.81
(SD)	(10.032)	(9.933)	(9.983)	(10.142)	(9.911)	(10.023)	(10.049)	(9.935)	(9.992)
Median	170.60	170.18	170.20	170.00	170.00	170.00	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5	142.2, 198.1	147.3, 196.0	142.2, 198.1	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	14463	14394	28857	337	339	676	15007	14985	29992
Mean	29.28	29.28	29.28	29.73	30.19	29.96	29.32	29.32	29.32
(SD)	(6.655)	(6.838)	(6.747)	(6.509)	(6.994)	(6.755)	(6.688)	(6.858)	(6.773)
Median	28.10	28.10	28.10	28.64	28.96	28.85	28.13	28.12	28.13
Min, Max	10.3, 72.7	11.2, 82.0	10.3, 82.0	15.7, 59.2	15.8, 60.5	15.7, 60.5	10.3, 72.7	11.2, 86.1	10.3, 86.1

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Occupational Risk, n (%) [2]	12028 (82.4)	11924 (82.0)	23952 (82.2)	307 (91.1)	300 (87.5)	607 (89.3)	12505 (82.4)	12429 (81.9)	24934 (82.2)
Healthcare Workers	3707 (25.4)	3675 (25.3)	7382 (25.3)	70 (20.8)	62 (18.1)	132 (19.4)	3831 (25.3)	3790 (25.0)	7621 (25.1)
Emergency Response	280 (1.9)	291 (2.0)	571 (2.0)	11 (3.3)	6 (1.7)	17 (2.5)	297 (2.0)	302 (2.0)	599 (2.0)
Retail or Restaurant Operations	928 (6.4)	900 (6.2)	1828 (6.3)	38 (11.3)	35 (10.2)	73 (10.7)	974 (6.4)	954 (6.3)	1928 (6.4)
Manufacturing and Production Operations	405 (2.8)	394 (2.7)	799 (2.7)	16 (4.7)	22 (6.4)	32 (4.7)	421 (2.8)	425 (2.8)	846 (2.8)
Warehouse Shipping and Fulfillment Centers	159 (1.1)	178 (1.2)	337 (1.1)	12 (3.6)	8 (2.3)	20 (2.9)	175 (1.2)	191 (1.3)	366 (1.2)
Transportation and Delivery Services	447 (3.1)	447 (3.1)	894 (3.1)	20 (5.9)	28 (8.2)	48 (7.1)	473 (3.1)	482 (3.2)	955 (3.1)
Border Protection and Military Personnel	66 (0.5)	67 (0.5)	133 (0.5)	1 (0.3)	1 (0.3)	2 (0.3)	68 (0.4)	69 (0.5)	137 (0.5)
Personal Care and In-Home Services	434 (3.0)	434 (3.0)	868 (3.0)	25 (7.4)	27 (7.9)	52 (7.6)	469 (3.1)	469 (3.1)	938 (3.1)
Hospitality and Tourism Workers	210 (1.4)	223 (1.5)	433 (1.5)	17 (5.0)	11 (3.2)	28 (4.1)	232 (1.5)	237 (1.6)	469 (1.5)
Pastoral, Social or Public Health Workers	490 (3.4)	509 (3.5)	999 (3.4)	6 (1.8)	11 (3.2)	17 (2.5)	503 (3.3)	533 (3.5)	1036 (3.4)
Educators and Students	1509 (10.3)	1491 (10.2)	3000 (10.3)	25 (7.4)	27 (7.9)	52 (7.6)	1552 (10.2)	1543 (10.2)	3095 (10.2)
Other	4626 (31.7)	4632 (31.8)	9258 (31.8)	104 (30.9)	99 (28.9)	203 (29.9)	4803 (31.7)	4818 (31.7)	9621 (31.7)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14598)	mRNA-1273 (N=14550)	Total (N=29148)	Placebo (N=337)	mRNA-1273 (N=343)	Total (N=680)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Location and Living Circumstances Risk, n (%) [2]	12146 (83.2)	12129 (83.4)	24275 (83.3)	307 (91.1)	307 (89.5)	614 (90.3)	12613 (83.1)	12646 (83.3)	25259 (83.2)
Resides in Nursing Home or Assisted Living Facility	28 (0.2)	31 (0.2)	59 (0.2)	1 (0.3)	0	1 (0.1)	29 (0.2)	33 (0.2)	62 (0.2)
Resides in Multi-Family Dwelling	392 (2.7)	442 (3.0)	834 (2.9)	12 (3.6)	13 (3.8)	25 (3.7)	409 (2.7)	462 (3.0)	871 (2.9)
Resides in High Density Housing	1234 (8.5)	1208 (8.3)	2442 (8.4)	67 (19.9)	60 (17.5)	127 (18.7)	1307 (8.6)	1285 (8.5)	2592 (8.5)
Resides in Low Density, Multi-Family Setting	1406 (9.6)	1389 (9.5)	2795 (9.6)	63 (18.7)	68 (19.8)	131 (19.3)	1482 (9.8)	1479 (9.7)	2961 (9.8)
Resides in a Single Family Home	8084 (55.4)	8042 (55.3)	16126 (55.3)	142 (42.1)	139 (40.5)	281 (41.3)	8350 (55.0)	8329 (54.9)	16679 (55.0)
Other	2089 (14.3)	2109 (14.5)	4198 (14.4)	50 (14.8)	50 (14.6)	100 (14.7)	2165 (14.3)	2189 (14.4)	4354 (14.3)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
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 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Age at Screening (Years)									
n	11418	11413	22831	3752	3768	7520	15170	15181	30351
Mean	45.0	45.1	45.0	70.7	70.4	70.6	51.3	51.4	51.4
(SD)	(12.30)	(12.35)	(12.32)	(4.88)	(4.66)	(4.77)	(15.60)	(15.50)	(15.55)
Median	46.0	46.0	46.0	70.0	69.0	70.0	52.0	53.0	52.0
Min, Max	18, 64	18, 64	18, 64	65, 95	65, 95	65, 95	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	11418 (100)	11413 (100)	22831 (100)	0	0	0	11418 (75.3)	11413 (75.2)	22831 (75.2)
Mean	45.0	45.1	45.0				45.0	45.1	45.0
(SD)	(12.30)	(12.35)	(12.32)				(12.30)	(12.35)	(12.32)
Median	46.0	46.0	46.0				46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64				18, 64	18, 64	18, 64
>=65 Years	0	0	0	3752 (100)	3768 (100)	7520 (100)	3752 (24.7)	3768 (24.8)	7520 (24.8)
Mean				70.7	70.4	70.6	70.7	70.4	70.6
(SD)				(4.88)	(4.66)	(4.77)	(4.88)	(4.66)	(4.77)
Median				70.0	69.0	70.0	70.0	69.0	70.0
Min, Max				65, 95	65, 95	65, 95	65, 95	65, 95	65, 95

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11418 (100)	11413 (100)	22831 (100)	0	0	0	11418 (75.3)	11413 (75.2)	22831 (75.2)
>=65 and <70 Years	0	0	0	1817 (48.4)	1905 (50.6)	3722 (49.5)	1817 (12.0)	1905 (12.5)	3722 (12.3)
>=70 and <75 Years	0	0	0	1194 (31.8)	1205 (32.0)	2399 (31.9)	1194 (7.9)	1205 (7.9)	2399 (7.9)
>=75 and <80 Years	0	0	0	507 (13.5)	467 (12.4)	974 (13.0)	507 (3.3)	467 (3.1)	974 (3.2)
>=80 Years	0	0	0	234 (6.2)	191 (5.1)	425 (5.7)	234 (1.5)	191 (1.3)	425 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11418 (100)	11413 (100)	22831 (100)	0	0	0	11418 (75.3)	11413 (75.2)	22831 (75.2)
>=65 and <75 Years	0	0	0	3011 (80.3)	3110 (82.5)	6121 (81.4)	3011 (19.8)	3110 (20.5)	6121 (20.2)
>=75 and <85 Years	0	0	0	692 (18.4)	617 (16.4)	1309 (17.4)	692 (4.6)	617 (4.1)	1309 (4.3)
>=85 Years	0	0	0	49 (1.3)	41 (1.1)	90 (1.2)	49 (0.3)	41 (0.3)	90 (0.3)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8885 (77.8)	8888 (77.9)	17773 (77.8)	1 (<0.1)	0	1 (<0.1)	8886 (58.6)	8888 (58.5)	17774 (58.6)
>=18 and <65 Years and at Risk	2532 (22.2)	2524 (22.1)	5056 (22.1)	3 (<0.1)	6 (0.2)	9 (0.1)	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)	3748 (99.9)	3762 (99.8)	7510 (99.9)	3749 (24.7)	3763 (24.8)	7512 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	501 (4.4)	473 (4.1)	974 (4.3)	243 (6.5)	237 (6.3)	480 (6.4)	744 (4.9)	710 (4.7)	1454 (4.8)
Significant Cardiac Disease	296 (2.6)	316 (2.8)	612 (2.7)	448 (11.9)	436 (11.6)	884 (11.8)	744 (4.9)	752 (5.0)	1496 (4.9)
Severe Obesity	879 (7.7)	865 (7.6)	1744 (7.6)	142 (3.8)	160 (4.2)	302 (4.0)	1021 (6.7)	1025 (6.8)	2046 (6.7)
Diabetes	902 (7.9)	906 (7.9)	1808 (7.9)	538 (14.3)	529 (14.0)	1067 (14.2)	1440 (9.5)	1435 (9.5)	2875 (9.5)
Liver Disease	70 (0.6)	82 (0.7)	152 (0.7)	26 (0.7)	18 (0.5)	44 (0.6)	96 (0.6)	100 (0.7)	196 (0.6)
Human Immunodeficiency Virus Infection	72 (0.6)	76 (0.7)	148 (0.6)	15 (0.4)	16 (0.4)	31 (0.4)	87 (0.6)	92 (0.6)	179 (0.6)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	2302 (20.2)	2295 (20.1)	4597 (20.1)	1116 (29.7)	1104 (29.3)	2220 (29.5)	3418 (22.5)	3399 (22.4)	6817 (22.5)
One Risk Factor for Severe COVID-19	1935 (16.9)	1925 (16.9)	3860 (16.9)	863 (23.0)	850 (22.6)	1713 (22.8)	2798 (18.4)	2775 (18.3)	5573 (18.4)
Two or More Risk Factors for Severe COVID-19	367 (3.2)	370 (3.2)	737 (3.2)	253 (6.7)	254 (6.7)	507 (6.7)	620 (4.1)	624 (4.1)	1244 (4.1)
No	9116 (79.8)	9118 (79.9)	18234 (79.9)	2636 (70.3)	2664 (70.7)	5300 (70.5)	11752 (77.5)	11782 (77.6)	23534 (77.5)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	9116 (79.8)	9118 (79.9)	18234 (79.9)	0	0	0	9116 (60.1)	9118 (60.1)	18234 (60.1)
>=18 and <65 Years and at Risk	2302 (20.2)	2295 (20.1)	4597 (20.1)	0	0	0	2302 (15.2)	2295 (15.1)	4597 (15.1)
>=65 Years and Not at Risk	0	0	0	2636 (70.3)	2664 (70.7)	5300 (70.5)	2636 (17.4)	2664 (17.5)	5300 (17.5)
>=65 Years and at Risk	0	0	0	1116 (29.7)	1104 (29.3)	2220 (29.5)	1116 (7.4)	1104 (7.3)	2220 (7.3)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Baseline RT-PCR Results, n (%)									
Negative	11226 (98.3)	11201 (98.1)	22427 (98.2)	3697 (98.5)	3716 (98.6)	7413 (98.6)	14923 (98.4)	14917 (98.3)	29840 (98.3)
Positive	85 (0.7)	80 (0.7)	165 (0.7)	10 (0.3)	7 (0.2)	17 (0.2)	95 (0.6)	87 (0.6)	182 (0.6)
Missing	107 (0.9)	132 (1.2)	239 (1.0)	45 (1.2)	45 (1.2)	90 (1.2)	152 (1.0)	177 (1.2)	329 (1.1)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	11041 (96.7)	11001 (96.4)	22042 (96.5)	3685 (98.2)	3689 (97.9)	7374 (98.1)	14726 (97.1)	14690 (96.8)	29416 (96.9)
Positive	275 (2.4)	272 (2.4)	547 (2.4)	28 (0.7)	33 (0.9)	61 (0.8)	303 (2.0)	305 (2.0)	608 (2.0)
Missing	102 (0.9)	140 (1.2)	242 (1.1)	39 (1.0)	46 (1.2)	85 (1.1)	141 (0.9)	186 (1.2)	327 (1.1)
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	10944 (95.8)	10890 (95.4)	21834 (95.6)	3654 (97.4)	3660 (97.1)	7314 (97.3)	14598 (96.2)	14550 (95.8)	29148 (96.0)
Positive	304 (2.7)	307 (2.7)	611 (2.7)	33 (0.9)	36 (1.0)	69 (0.9)	337 (2.2)	343 (2.3)	680 (2.2)
Missing	170 (1.5)	216 (1.9)	386 (1.7)	65 (1.7)	72 (1.9)	137 (1.8)	235 (1.5)	288 (1.9)	523 (1.7)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Sex, n (%)									
Male	5959 (52.2)	5846 (51.2)	11805 (51.7)	2103 (56.1)	2077 (55.1)	4180 (55.6)	8062 (53.1)	7923 (52.2)	15985 (52.7)
Female	5459 (47.8)	5567 (48.8)	11026 (48.3)	1649 (43.9)	1691 (44.9)	3340 (44.4)	7108 (46.9)	7258 (47.8)	14366 (47.3)
Race, n (%)									
White	8655 (75.8)	8652 (75.8)	17307 (75.8)	3340 (89.0)	3377 (89.6)	6717 (89.3)	11995 (79.1)	12029 (79.2)	24024 (79.2)
Black or African American	1313 (11.5)	1342 (11.8)	2655 (11.6)	214 (5.7)	221 (5.9)	435 (5.8)	1527 (10.1)	1563 (10.3)	3090 (10.2)
Asian	654 (5.7)	585 (5.1)	1239 (5.4)	77 (2.1)	66 (1.8)	143 (1.9)	731 (4.8)	651 (4.3)	1382 (4.6)
American Indian or Alaska Native	95 (0.8)	91 (0.8)	186 (0.8)	26 (0.7)	21 (0.6)	47 (0.6)	121 (0.8)	112 (0.7)	233 (0.8)
Native Hawaiian or Other Pacific Islander	29 (0.3)	32 (0.3)	61 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	32 (0.2)	35 (0.2)	67 (0.2)
Multiracial	283 (2.5)	281 (2.5)	564 (2.5)	38 (1.0)	34 (0.9)	72 (1.0)	321 (2.1)	315 (2.1)	636 (2.1)
Other	283 (2.5)	294 (2.6)	577 (2.5)	33 (0.9)	27 (0.7)	60 (0.8)	316 (2.1)	321 (2.1)	637 (2.1)
Not Reported	60 (0.5)	83 (0.7)	143 (0.6)	13 (0.3)	13 (0.3)	26 (0.3)	73 (0.5)	96 (0.6)	169 (0.6)
Unknown	46 (0.4)	53 (0.5)	99 (0.4)	8 (0.2)	6 (0.2)	14 (0.2)	54 (0.4)	59 (0.4)	113 (0.4)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Ethnicity, n (%)									
Hispanic or Latino	2779 (24.3)	2766 (24.2)	5545 (24.3)	335 (8.9)	355 (9.4)	690 (9.2)	3114 (20.5)	3121 (20.6)	6235 (20.5)
Not Hispanic or Latino	8543 (74.8)	8548 (74.9)	17091 (74.9)	3374 (89.9)	3370 (89.4)	6744 (89.7)	11917 (78.6)	11918 (78.5)	23835 (78.5)
Not Reported	58 (0.5)	72 (0.6)	130 (0.6)	27 (0.7)	32 (0.8)	59 (0.8)	85 (0.6)	104 (0.7)	189 (0.6)
Unknown	38 (0.3)	27 (0.2)	65 (0.3)	16 (0.4)	11 (0.3)	27 (0.4)	54 (0.4)	38 (0.3)	92 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	4072 (35.7)	4071 (35.7)	8143 (35.7)	560 (14.9)	579 (15.4)	1139 (15.1)	4632 (30.5)	4650 (30.6)	9282 (30.6)
Non-minority	7333 (64.2)	7322 (64.2)	14655 (64.2)	3179 (84.7)	3183 (84.5)	6362 (84.6)	10512 (69.3)	10505 (69.2)	21017 (69.2)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	6398 (56.0)	6458 (56.6)	12856 (56.3)	3063 (81.6)	3071 (81.5)	6134 (81.6)	9461 (62.4)	9529 (62.8)	18990 (62.6)
Communities of Color	5007 (43.9)	4935 (43.2)	9942 (43.5)	676 (18.0)	691 (18.3)	1367 (18.2)	5683 (37.5)	5626 (37.1)	11309 (37.3)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Weight (kg)									
n	11291	11268	22559	3718	3721	7439	15009	14989	29998
Mean	86.75	86.57	86.66	83.20	83.10	83.15	85.87	85.71	85.79
(SD)	(22.388)	(22.708)	(22.548)	(18.996)	(19.371)	(19.183)	(21.651)	(21.978)	(21.814)
Median	83.64	83.64	83.64	81.60	81.20	81.36	83.00	83.00	83.00
Min, Max	27.1, 223.0	30.3, 236.4	27.1, 236.4	34.8, 184.5	31.5, 165.0	31.5, 184.5	27.1, 223.0	30.3, 236.4	27.1, 236.4
Height (cm)									
n	11291	11267	22558	3717	3722	7439	15008	14989	29997
Mean	171.17	170.98	171.08	170.06	169.96	170.01	170.90	170.73	170.81
(SD)	(9.975)	(9.901)	(9.938)	(10.227)	(10.001)	(10.114)	(10.049)	(9.935)	(9.992)
Median	171.00	170.20	170.50	170.18	170.18	170.18	170.50	170.18	170.20
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0	124.5, 223.5	123.0, 208.3	123.0, 223.5	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	11290	11264	22554	3717	3721	7438	15007	14985	29992
Mean	29.52	29.54	29.53	28.70	28.67	28.68	29.32	29.32	29.32
(SD)	(6.923)	(7.138)	(7.031)	(5.875)	(5.885)	(5.879)	(6.688)	(6.858)	(6.773)
Median	28.27	28.25	28.26	27.71	27.86	27.78	28.13	28.12	28.13
Min, Max	10.3, 72.7	11.2, 86.1	10.3, 86.1	12.1, 71.1	11.2, 62.9	11.2, 71.1	10.3, 72.7	11.2, 86.1	10.3, 86.1

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Occupational Risk, n (%) [2]	10126 (88.7)	10068 (88.2)	20194 (88.4)	2379 (63.4)	2361 (62.7)	4740 (63.0)	12505 (82.4)	12429 (81.9)	24934 (82.2)
Healthcare Workers	3327 (29.1)	3329 (29.2)	6656 (29.2)	504 (13.4)	461 (12.2)	965 (12.8)	3831 (25.3)	3790 (25.0)	7621 (25.1)
Emergency Response	278 (2.4)	281 (2.5)	559 (2.4)	19 (0.5)	21 (0.6)	40 (0.5)	297 (2.0)	302 (2.0)	599 (2.0)
Retail or Restaurant Operations	875 (7.7)	854 (7.5)	1729 (7.6)	99 (2.6)	100 (2.7)	199 (2.6)	974 (6.4)	954 (6.3)	1928 (6.4)
Manufacturing and Production Operations	391 (3.4)	391 (3.4)	782 (3.4)	30 (0.8)	34 (0.9)	64 (0.9)	421 (2.8)	425 (2.8)	846 (2.8)
Warehouse Shipping and Fulfillment Centers	163 (1.4)	182 (1.6)	345 (1.5)	12 (0.3)	9 (0.2)	21 (0.3)	175 (1.2)	191 (1.3)	366 (1.2)
Transportation and Delivery Services	412 (3.6)	432 (3.8)	844 (3.7)	61 (1.6)	50 (1.3)	111 (1.5)	473 (3.1)	482 (3.2)	955 (3.1)
Border Protection and Military Personnel	62 (0.5)	66 (0.6)	128 (0.6)	6 (0.2)	3 (<0.1)	9 (0.1)	68 (0.4)	69 (0.5)	137 (0.5)
Personal Care and In-Home Services	408 (3.6)	402 (3.5)	810 (3.5)	61 (1.6)	67 (1.8)	128 (1.7)	469 (3.1)	469 (3.1)	938 (3.1)
Hospitality and Tourism Workers	189 (1.7)	201 (1.8)	390 (1.7)	43 (1.1)	36 (1.0)	79 (1.1)	232 (1.5)	237 (1.6)	469 (1.5)
Pastoral, Social or Public Health Workers	364 (3.2)	385 (3.4)	749 (3.3)	139 (3.7)	148 (3.9)	287 (3.8)	503 (3.3)	533 (3.5)	1036 (3.4)
Educators and Students	1383 (12.1)	1358 (11.9)	2741 (12.0)	169 (4.5)	185 (4.9)	354 (4.7)	1552 (10.2)	1543 (10.2)	3095 (10.2)
Other	3379 (29.6)	3389 (29.7)	6768 (29.6)	1424 (38.0)	1429 (37.9)	2853 (37.9)	4803 (31.7)	4818 (31.7)	9621 (31.7)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11418)	mRNA-1273 (N=11413)	Total (N=22831)	Placebo (N=3752)	mRNA-1273 (N=3768)	Total (N=7520)	Placebo (N=15170)	mRNA-1273 (N=15181)	Total (N=30351)
Location and Living Circumstances Risk, n (%) [2]	9520 (83.4)	9524 (83.4)	19044 (83.4)	3093 (82.4)	3122 (82.9)	6215 (82.6)	12613 (83.1)	12646 (83.3)	25259 (83.2)
Resides in Nursing Home or Assisted Living Facility	9 (<0.1)	22 (0.2)	31 (0.1)	20 (0.5)	11 (0.3)	31 (0.4)	29 (0.2)	33 (0.2)	62 (0.2)
Resides in Multi-Family Dwelling	346 (3.0)	396 (3.5)	742 (3.2)	63 (1.7)	66 (1.8)	129 (1.7)	409 (2.7)	462 (3.0)	871 (2.9)
Resides in High Density Housing	1068 (9.4)	1034 (9.1)	2102 (9.2)	239 (6.4)	251 (6.7)	490 (6.5)	1307 (8.6)	1285 (8.5)	2592 (8.5)
Resides in Low Density, Multi-Family Setting	1227 (10.7)	1235 (10.8)	2462 (10.8)	255 (6.8)	244 (6.5)	499 (6.6)	1482 (9.8)	1479 (9.7)	2961 (9.8)
Resides in a Single Family Home	6101 (53.4)	6057 (53.1)	12158 (53.3)	2249 (59.9)	2272 (60.3)	4521 (60.1)	8350 (55.0)	8329 (54.9)	16679 (55.0)
Other	1637 (14.3)	1643 (14.4)	3280 (14.4)	528 (14.1)	546 (14.5)	1074 (14.3)	2165 (14.3)	2189 (14.4)	4354 (14.3)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
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 14.1.6.2.1
Summary of Study Duration
Safety Set

	Placebo (N=15166)	mRNA-1273 (N=15185)	Total (N=30351)
Number of Subjects, n (%)			
Received First Injection	15166 (100)	15185 (100)	30351 (100)
Received Second Injection	14613 (96.4)	14715 (96.9)	29328 (96.6)
>= 49 Days Since First Injection	14095 (92.9)	14095 (92.8)	28190 (92.9)
>= 56 Days Since First Injection	13743 (90.6)	13767 (90.7)	27510 (90.6)
>= 2 Months Since First Injection	13454 (88.7)	13498 (88.9)	26952 (88.8)
>= 28 Days Since Second Injection	13397 (87.7)	13386 (88.2)	26683 (87.9)
>= 56 Days Since Second Injection	9299 (61.3)	9406 (61.9)	18705 (61.6)
>= 2 Months Since Second Injection	8111 (53.5)	8163 (53.8)	16274 (53.6)
< 28 Days Since Second Injection	1316 (8.7)	1329 (8.8)	2645 (8.7)
>= 28 and < 56 Days Since Second Injection	3998 (26.4)	3980 (26.2)	7978 (26.3)
>= 56 Days Since Second Injection	9299 (61.3)	9406 (61.9)	18705 (61.6)
Study Duration from Randomization (Days)			
Mean (SD)	88.7 (21.05)	88.8 (21.00)	88.7 (21.03)
Median	92.0	92.0	92.0
Q1, Q3	77.0, 105.0	77.0, 105.0	77.0, 105.0
Min, Max	1, 122	1, 122	1, 122
Study Duration from First Injection (Days)			
Mean (SD)	88.7 (21.06)	88.8 (21.01)	88.7 (21.03)
Median	92.0	92.0	92.0
Q1, Q3	77.0, 105.0	77.0, 105.0	77.0, 105.0
Min, Max	1, 122	1, 122	1, 122

1 month = 30.4375 days.
Percentages are based on the number of safety subjects.
[1] Study duration from second injection is 0 day for subjects who did not receive second injection.
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Table 14.1.6.2.1
Summary of Study Duration
Safety Set

	Placebo (N=15166)	mRNA-1273 (N=15185)	Total (N=30351)
Study Duration from Second Injection (Days) [1]			
Mean (SD)	57.7 (22.93)	58.1 (22.67)	57.9 (22.80)
Median	63.0	63.0	63.0
Q1, Q3	45.0, 73.0	48.0, 75.0	47.0, 75.0
Min, Max	0, 97	0, 97	0, 97
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	14613	14715	29328
Mean (SD)	59.9 (20.36)	60.0 (20.47)	60.0 (20.42)
Median	63.0	63.0	63.0
Q1, Q3	49.0, 76.0	49.0, 76.0	49.0, 76.0
Min, Max	1, 97	1, 97	1, 97

1 month = 30.4375 days.
Percentages are based on the number of safety subjects.
[1] Study duration from second injection is 0 day for subjects who did not receive second injection.
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Table 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Solicited Adverse Reactions - N1	15155	15168	30323
Any Solicited Adverse Reactions	7284 (48.1)	13319 (87.8)	20603 (67.9)
95% CI	47.3, 48.9	87.3, 88.3	67.4, 68.5
Grade 1	5147 (34.0)	9342 (61.6)	14489 (47.8)
Grade 2	1770 (11.7)	3124 (20.6)	4894 (16.1)
Grade 3	361 (2.4)	848 (5.6)	1209 (4.0)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Solicited Local Adverse Reactions - N1	15151	15164	30315
Any Solicited Local Adverse Reactions	2997 (19.8)	12765 (84.2)	15762 (52.0)
95% CI	19.1, 20.4	83.6, 84.8	51.4, 52.6
Grade 1	2837 (18.7)	10731 (70.8)	13568 (44.8)
Grade 2	82 (0.5)	1505 (9.9)	1587 (5.2)
Grade 3	78 (0.5)	529 (3.5)	607 (2.0)
Grade 4	0	0	0
Pain - N1	15151	15164	30315
Any	2658 (17.5)	12690 (83.7)	15348 (50.6)
Grade 1	2549 (16.8)	10990 (72.5)	13539 (44.7)
Grade 2	54 (0.4)	1284 (8.5)	1338 (4.4)
Grade 3	55 (0.4)	416 (2.7)	471 (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 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15155) n	(%)	mRNA-1273 (N=15168) n	(%)	Total (N=30323) n	(%)
Erythema (Redness) - N1	15151		15163		30314	
Any	67	(0.4)	430	(2.8)	497	(1.6)
Grade 1	47	(0.3)	267	(1.8)	314	(1.0)
Grade 2	7	(<0.1)	121	(0.8)	128	(0.4)
Grade 3	13	(<0.1)	42	(0.3)	55	(0.2)
Grade 4	0		0		0	
Swelling (Hardness) - N1	15151		15163		30314	
Any	52	(0.3)	932	(6.1)	984	(3.2)
Grade 1	39	(0.3)	605	(4.0)	644	(2.1)
Grade 2	7	(<0.1)	245	(1.6)	252	(0.8)
Grade 3	6	(<0.1)	82	(0.5)	88	(0.3)
Grade 4	0		0		0	
Lymphadenopathy - N1 [1]	15151		15163		30314	
Any	722	(4.8)	1553	(10.2)	2275	(7.5)
Grade 1	668	(4.4)	1395	(9.2)	2063	(6.8)
Grade 2	27	(0.2)	109	(0.7)	136	(0.4)
Grade 3	27	(0.2)	49	(0.3)	76	(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 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Solicited Systemic Adverse Reactions - N1	15155	15167	30322
Any Solicited Systemic Adverse Reactions	6399 (42.2)	8320 (54.9)	14719 (48.5)
95% CI	41.4, 43.0	54.1, 55.7	48.0, 49.1
Grade 1	4346 (28.7)	5372 (35.4)	9718 (32.0)
Grade 2	1739 (11.5)	2496 (16.5)	4235 (14.0)
Grade 3	308 (2.0)	447 (2.9)	755 (2.5)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Fever - N1	15153	15164	30317
Any	44 (0.3)	115 (0.8)	159 (0.5)
Grade 1	29 (0.2)	74 (0.5)	103 (0.3)
Grade 2	7 (<0.1)	26 (0.2)	33 (0.1)
Grade 3	2 (<0.1)	11 (<0.1)	13 (<0.1)
Grade 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Headache - N1	15150	15163	30313
Any	4027 (26.6)	4951 (32.7)	8978 (29.6)
Grade 1	3306 (21.8)	3953 (26.1)	7259 (23.9)
Grade 2	525 (3.5)	727 (4.8)	1252 (4.1)
Grade 3	196 (1.3)	271 (1.8)	467 (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 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Fatigue - N1	15150	15163	30313
Any	4133 (27.3)	5635 (37.2)	9768 (32.2)
Grade 1	2709 (17.9)	3599 (23.7)	6308 (20.8)
Grade 2	1319 (8.7)	1885 (12.4)	3204 (10.6)
Grade 3	105 (0.7)	150 (1.0)	255 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Myalgia - N1	15150	15163	30313
Any	2071 (13.7)	3441 (22.7)	5512 (18.2)
Grade 1	1567 (10.3)	2445 (16.1)	4012 (13.2)
Grade 2	457 (3.0)	906 (6.0)	1363 (4.5)
Grade 3	47 (0.3)	90 (0.6)	137 (0.5)
Grade 4	0	0	0
Arthralgia - N1	15150	15163	30313
Any	1783 (11.8)	2511 (16.6)	4294 (14.2)
Grade 1	1341 (8.9)	1846 (12.2)	3187 (10.5)
Grade 2	405 (2.7)	604 (4.0)	1009 (3.3)
Grade 3	37 (0.2)	60 (0.4)	97 (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 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Nausea/Vomiting - N1	15150	15163	30313
Any	1074 (7.1)	1262 (8.3)	2336 (7.7)
Grade 1	890 (5.9)	1048 (6.9)	1938 (6.4)
Grade 2	172 (1.1)	204 (1.3)	376 (1.2)
Grade 3	12 (<0.1)	10 (<0.1)	22 (<0.1)
Grade 4	0	0	0
Chills - N1	15150	15163	30313
Any	878 (5.8)	1253 (8.3)	2131 (7.0)
Grade 1	706 (4.7)	940 (6.2)	1646 (5.4)
Grade 2	158 (1.0)	289 (1.9)	447 (1.5)
Grade 3	14 (<0.1)	24 (0.2)	38 (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 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Solicited Adverse Reactions - N1	14566	14677	29243
Any Solicited Adverse Reactions	6232 (42.8)	13534 (92.2)	19766 (67.6)
95% CI	42.0, 43.6	91.8, 92.6	67.1, 68.1
Grade 1	4354 (29.9)	4855 (33.1)	9209 (31.5)
Grade 2	1534 (10.5)	5781 (39.4)	7315 (25.0)
Grade 3	341 (2.3)	2884 (19.6)	3225 (11.0)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Solicited Local Adverse Reactions - N1	14562	14673	29235
Any Solicited Local Adverse Reactions	2735 (18.8)	13006 (88.6)	15741 (53.8)
95% CI	18.2, 19.4	88.1, 89.1	53.3, 54.4
Grade 1	2581 (17.7)	8778 (59.8)	11359 (38.9)
Grade 2	82 (0.6)	3208 (21.9)	3290 (11.3)
Grade 3	72 (0.5)	1020 (7.0)	1092 (3.7)
Grade 4	0	0	0
Pain - N1	14562	14673	29235
Any	2477 (17.0)	12943 (88.2)	15420 (52.7)
Grade 1	2378 (16.3)	9498 (64.7)	11876 (40.6)
Grade 2	59 (0.4)	2841 (19.4)	2900 (9.9)
Grade 3	40 (0.3)	604 (4.1)	644 (2.2)
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 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Erythema (Redness) - N1	14562	14673	29235
Any	56 (0.4)	1257 (8.6)	1313 (4.5)
Grade 1	38 (0.3)	442 (3.0)	480 (1.6)
Grade 2	3 (<0.1)	528 (3.6)	531 (1.8)
Grade 3	15 (0.1)	287 (2.0)	302 (1.0)
Grade 4	0	0	0
Swelling (Hardness) - N1	14562	14673	29235
Any	49 (0.3)	1789 (12.2)	1838 (6.3)
Grade 1	29 (0.2)	890 (6.1)	919 (3.1)
Grade 2	9 (<0.1)	645 (4.4)	654 (2.2)
Grade 3	11 (<0.1)	254 (1.7)	265 (0.9)
Grade 4	0	0	0
Lymphadenopathy - N1 [1]	14562	14673	29235
Any	567 (3.9)	2090 (14.2)	2657 (9.1)
Grade 1	521 (3.6)	1737 (11.8)	2258 (7.7)
Grade 2	27 (0.2)	286 (1.9)	313 (1.1)
Grade 3	19 (0.1)	67 (0.5)	86 (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 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Solicited Systemic Adverse Reactions - N1	14565	14677	29242
Any Solicited Systemic Adverse Reactions	5323 (36.5)	11652 (79.4)	16975 (58.1)
95% CI	35.8, 37.3	78.7, 80.0	57.5, 58.6
Grade 1	3526 (24.2)	3723 (25.4)	7249 (24.8)
Grade 2	1512 (10.4)	5590 (38.1)	7102 (24.3)
Grade 3	282 (1.9)	2325 (15.8)	2607 (8.9)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Fever - N1	14559	14669	29228
Any	43 (0.3)	2278 (15.5)	2321 (7.9)
Grade 1	33 (0.2)	1364 (9.3)	1397 (4.8)
Grade 2	5 (<0.1)	699 (4.8)	704 (2.4)
Grade 3	2 (<0.1)	202 (1.4)	204 (0.7)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)
Headache - N1	14562	14673	29235
Any	3410 (23.4)	8602 (58.6)	12012 (41.1)
Grade 1	2739 (18.8)	4804 (32.7)	7543 (25.8)
Grade 2	509 (3.5)	3139 (21.4)	3648 (12.5)
Grade 3	162 (1.1)	659 (4.5)	821 (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 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Fatigue - N1	14560	14673	29233
Any	3403 (23.4)	9582 (65.3)	12985 (44.4)
Grade 1	2182 (15.0)	3432 (23.4)	5614 (19.2)
Grade 2	1115 (7.7)	4728 (32.2)	5837 (20.0)
Grade 3	106 (0.7)	1428 (9.7)	1534 (5.2)
Grade 4	0	0	0
Myalgia - N1	14560	14673	29233
Any	1809 (12.4)	8508 (58.0)	10317 (35.3)
Grade 1	1300 (8.9)	3239 (22.1)	4539 (15.5)
Grade 2	457 (3.1)	3951 (26.9)	4408 (15.1)
Grade 3	52 (0.4)	1318 (9.0)	1370 (4.7)
Grade 4	0	0	0
Arthralgia - N1	14560	14673	29233
Any	1569 (10.8)	6284 (42.8)	7853 (26.9)
Grade 1	1142 (7.8)	2802 (19.1)	3944 (13.5)
Grade 2	383 (2.6)	2712 (18.5)	3095 (10.6)
Grade 3	44 (0.3)	770 (5.2)	814 (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 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Nausea/Vomiting - N1	14560	14673	29233
Any	934 (6.4)	2785 (19.0)	3719 (12.7)
Grade 1	756 (5.2)	2090 (14.2)	2846 (9.7)
Grade 2	167 (1.1)	674 (4.6)	841 (2.9)
Grade 3	11 (<0.1)	20 (0.1)	31 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Chills - N1	14560	14673	29233
Any	809 (5.6)	6482 (44.2)	7291 (24.9)
Grade 1	626 (4.3)	2899 (19.8)	3525 (12.1)
Grade 2	166 (1.1)	3392 (23.1)	3558 (12.2)
Grade 3	17 (0.1)	191 (1.3)	208 (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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	5738 (50.3)	10261 (90.0)	15999 (70.1)
95% CI	49.4, 51.2	89.4, 90.5	69.5, 70.7
Grade 1	4003 (35.1)	6959 (61.0)	10962 (48.1)
Grade 2	1459 (12.8)	2593 (22.7)	4052 (17.8)
Grade 3	272 (2.4)	704 (6.2)	976 (4.3)
Grade 4	4 (<0.1)	5 (<0.1)	9 (<0.1)
Solicited Local Adverse Reactions - N1	11405	11402	22807
Any Solicited Local Adverse Reactions	2430 (21.3)	9960 (87.4)	12390 (54.3)
95% CI	20.6, 22.1	86.7, 88.0	53.7, 55.0
Grade 1	2333 (20.5)	8154 (71.5)	10487 (46.0)
Grade 2	58 (0.5)	1354 (11.9)	1412 (6.2)
Grade 3	39 (0.3)	452 (4.0)	491 (2.2)
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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	2177 (19.1)	9903 (86.9)	12085 (53.0)
Grade 1	2114 (18.5)	8362 (73.3)	10476 (45.9)
Grade 2	40 (0.4)	1180 (10.3)	1220 (5.3)
Grade 3	23 (0.2)	366 (3.2)	389 (1.7)
Grade 4	0	0	0
Erythema (Redness) - N1	11405	11402	22807
Any	47 (0.4)	344 (3.0)	391 (1.7)
Grade 1	32 (0.3)	212 (1.9)	244 (1.1)
Grade 2	4 (<0.1)	98 (0.9)	102 (0.4)
Grade 3	11 (<0.1)	34 (0.3)	45 (0.2)
Grade 4	0	0	0
Swelling (Hardness) - N1	11405	11402	22807
Any	34 (0.3)	767 (6.7)	801 (3.5)
Grade 1	28 (0.2)	500 (4.4)	528 (2.3)
Grade 2	3 (<0.1)	205 (1.8)	208 (0.9)
Grade 3	3 (<0.1)	62 (0.5)	65 (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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	567 (5.0)	1322 (11.6)	1889 (8.3)
Grade 1	534 (4.7)	1181 (10.4)	1715 (7.5)
Grade 2	20 (0.2)	104 (0.9)	124 (0.5)
Grade 3	13 (0.1)	37 (0.3)	50 (0.2)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	11407	11406	22813
Any Solicited Systemic Adverse Reactions	5065 (44.4)	6503 (57.0)	11568 (50.7)
95% CI	43.5, 45.3	56.1, 57.9	50.1, 51.4
Grade 1	3375 (29.6)	4092 (35.9)	7467 (32.7)
Grade 2	1438 (12.6)	2043 (17.9)	3481 (15.3)
Grade 3	248 (2.2)	363 (3.2)	611 (2.7)
Grade 4	4 (<0.1)	5 (<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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	37 (0.3)	105 (0.9)	142 (0.6)
Grade 1	26 (0.2)	67 (0.6)	93 (0.4)
Grade 2	6 (<0.1)	24 (0.2)	30 (0.1)
Grade 3	1 (<0.1)	10 (<0.1)	11 (<0.1)
Grade 4	4 (<0.1)	4 (<0.1)	8 (<0.1)
Headache - N1	11405	11402	22807
Any	3304 (29.0)	4030 (35.3)	7334 (32.2)
Grade 1	2676 (23.5)	3174 (27.8)	5850 (25.7)
Grade 2	466 (4.1)	637 (5.6)	1103 (4.8)
Grade 3	162 (1.4)	219 (1.9)	381 (1.7)
Grade 4	0	0	0
Fatigue - N1	11405	11402	22807
Any	3282 (28.8)	4384 (38.4)	7666 (33.6)
Grade 1	2104 (18.4)	2744 (24.1)	4848 (21.3)
Grade 2	1095 (9.6)	1519 (13.3)	2614 (11.5)
Grade 3	83 (0.7)	120 (1.1)	203 (0.9)
Grade 4	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.
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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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 (%)
Myalgia - N1	11405	11402	22807
Any	1628 (14.3)	2699 (23.7)	4327 (19.0)
Grade 1	1205 (10.6)	1876 (16.5)	3081 (13.5)
Grade 2	385 (3.4)	750 (6.6)	1135 (5.0)
Grade 3	38 (0.3)	73 (0.6)	111 (0.5)
Grade 4	0	0	0
Arthralgia - N1	11405	11402	22807
Any	1327 (11.6)	1893 (16.6)	3220 (14.1)
Grade 1	970 (8.5)	1371 (12.0)	2341 (10.3)
Grade 2	328 (2.9)	474 (4.2)	802 (3.5)
Grade 3	29 (0.3)	47 (0.4)	76 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Nausea/Vomiting - N1	11405	11402	22807
Any	908 (8.0)	1068 (9.4)	1976 (8.7)
Grade 1	752 (6.6)	889 (7.8)	1641 (7.2)
Grade 2	148 (1.3)	173 (1.5)	321 (1.4)
Grade 3	8 (<0.1)	6 (<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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	730 (6.4)	1051 (9.2)	1781 (7.8)
Grade 1	584 (5.1)	781 (6.8)	1365 (6.0)
Grade 2	138 (1.2)	253 (2.2)	391 (1.7)
Grade 3	8 (<0.1)	17 (0.1)	25 (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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	1546 (41.2)	3058 (81.3)	4604 (61.3)
95% CI	39.7, 42.8	80.0, 82.5	60.2, 62.4
Grade 1	1144 (30.5)	2383 (63.3)	3527 (47.0)
Grade 2	311 (8.3)	531 (14.1)	842 (11.2)
Grade 3	89 (2.4)	144 (3.8)	233 (3.1)
Grade 4	2 (<0.1)	0	2 (<0.1)
Solicited Local Adverse Reactions - N1	3746	3762	7508
Any Solicited Local Adverse Reactions	567 (15.1)	2805 (74.6)	3372 (44.9)
95% CI	14.0, 16.3	73.1, 75.9	43.8, 46.0
Grade 1	504 (13.5)	2577 (68.5)	3081 (41.0)
Grade 2	24 (0.6)	151 (4.0)	175 (2.3)
Grade 3	39 (1.0)	77 (2.0)	116 (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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	481 (12.8)	2782 (74.0)	3263 (43.5)
Grade 1	435 (11.6)	2628 (69.9)	3063 (40.8)
Grade 2	14 (0.4)	104 (2.8)	118 (1.6)
Grade 3	32 (0.9)	50 (1.3)	82 (1.1)
Grade 4	0	0	0
Erythema (Redness) - N1	3746	3761	7507
Any	20 (0.5)	86 (2.3)	106 (1.4)
Grade 1	15 (0.4)	55 (1.5)	70 (0.9)
Grade 2	3 (<0.1)	23 (0.6)	26 (0.3)
Grade 3	2 (<0.1)	8 (0.2)	10 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	3746	3761	7507
Any	18 (0.5)	165 (4.4)	183 (2.4)
Grade 1	11 (0.3)	105 (2.8)	116 (1.5)
Grade 2	4 (0.1)	40 (1.1)	44 (0.6)
Grade 3	3 (<0.1)	20 (0.5)	23 (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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	155 (4.1)	231 (6.1)	386 (5.1)
Grade 1	134 (3.6)	214 (5.7)	348 (4.6)
Grade 2	7 (0.2)	5 (0.1)	12 (0.2)
Grade 3	14 (0.4)	12 (0.3)	26 (0.3)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	3748	3761	7509
Any Solicited Systemic Adverse Reactions	1334 (35.6)	1817 (48.3)	3151 (42.0)
95% CI	34.1, 37.1	46.7, 49.9	40.8, 43.1
Grade 1	971 (25.9)	1280 (34.0)	2251 (30.0)
Grade 2	301 (8.0)	453 (12.0)	754 (10.0)
Grade 3	60 (1.6)	84 (2.2)	144 (1.9)
Grade 4	2 (<0.1)	0	2 (<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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	7 (0.2)	10 (0.3)	17 (0.2)
Grade 1	3 (<0.1)	7 (0.2)	10 (0.1)
Grade 2	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	2 (<0.1)	0	2 (<0.1)
Headache - N1	3745	3761	7506
Any	723 (19.3)	921 (24.5)	1644 (21.9)
Grade 1	630 (16.8)	779 (20.7)	1409 (18.8)
Grade 2	59 (1.6)	90 (2.4)	149 (2.0)
Grade 3	34 (0.9)	52 (1.4)	86 (1.1)
Grade 4	0	0	0
Fatigue - N1	3745	3761	7506
Any	851 (22.7)	1251 (33.3)	2102 (28.0)
Grade 1	605 (16.2)	855 (22.7)	1460 (19.5)
Grade 2	224 (6.0)	366 (9.7)	590 (7.9)
Grade 3	22 (0.6)	30 (0.8)	52 (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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	443 (11.8)	742 (19.7)	1185 (15.8)
Grade 1	362 (9.7)	569 (15.1)	931 (12.4)
Grade 2	72 (1.9)	156 (4.1)	228 (3.0)
Grade 3	9 (0.2)	17 (0.5)	26 (0.3)
Grade 4	0	0	0
Arthralgia - N1	3745	3761	7506
Any	456 (12.2)	618 (16.4)	1074 (14.3)
Grade 1	371 (9.9)	475 (12.6)	846 (11.3)
Grade 2	77 (2.1)	130 (3.5)	207 (2.8)
Grade 3	8 (0.2)	13 (0.3)	21 (0.3)
Grade 4	0	0	0
Nausea/Vomiting - N1	3745	3761	7506
Any	166 (4.4)	194 (5.2)	360 (4.8)
Grade 1	138 (3.7)	159 (4.2)	297 (4.0)
Grade 2	24 (0.6)	31 (0.8)	55 (0.7)
Grade 3	4 (0.1)	4 (0.1)	8 (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 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 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	148 (4.0)	202 (5.4)	350 (4.7)
Grade 1	122 (3.3)	159 (4.2)	281 (3.7)
Grade 2	20 (0.5)	36 (1.0)	56 (0.7)
Grade 3	6 (0.2)	7 (0.2)	13 (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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	4902 (44.9)	10231 (93.1)	15133 (69.1)
95% CI	44.0, 45.8	92.6, 93.6	68.5, 69.7
Grade 1	3397 (31.1)	3294 (30.0)	6691 (30.5)
Grade 2	1248 (11.4)	4576 (41.7)	5824 (26.6)
Grade 3	255 (2.3)	2349 (21.4)	2604 (11.9)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Solicited Local Adverse Reactions - N1	10914	10984	21898
Any Solicited Local Adverse Reactions	2244 (20.6)	9915 (90.3)	12159 (55.5)
95% CI	19.8, 21.3	89.7, 90.8	54.9, 56.2
Grade 1	2135 (19.6)	6410 (58.4)	8545 (39.0)
Grade 2	67 (0.6)	2703 (24.6)	2770 (12.6)
Grade 3	42 (0.4)	802 (7.3)	844 (3.9)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.
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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	2040 (18.7)	9873 (89.9)	11913 (54.4)
Grade 1	1972 (18.1)	6923 (63.0)	8895 (40.6)
Grade 2	46 (0.4)	2444 (22.3)	2490 (11.4)
Grade 3	22 (0.2)	506 (4.6)	528 (2.4)
Grade 4	0	0	0
Erythema (Redness) - N1	10914	10984	21898
Any	43 (0.4)	982 (8.9)	1025 (4.7)
Grade 1	28 (0.3)	352 (3.2)	380 (1.7)
Grade 2	3 (<0.1)	420 (3.8)	423 (1.9)
Grade 3	12 (0.1)	210 (1.9)	222 (1.0)
Grade 4	0	0	0
Swelling (Hardness) - N1	10914	10984	21898
Any	36 (0.3)	1389 (12.6)	1425 (6.5)
Grade 1	24 (0.2)	700 (6.4)	724 (3.3)
Grade 2	8 (<0.1)	507 (4.6)	515 (2.4)
Grade 3	4 (<0.1)	182 (1.7)	186 (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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	470 (4.3)	1779 (16.2)	2245 (10.3)
Grade 1	433 (4.0)	1469 (13.4)	1902 (8.7)
Grade 2	26 (0.2)	260 (2.4)	286 (1.3)
Grade 3	11 (0.1)	46 (0.4)	57 (0.3)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	10917	10985	21902
Any Solicited Systemic Adverse Reactions	4192 (38.4)	8999 (81.9)	13191 (60.2)
95% CI	37.5, 39.3	81.2, 82.6	59.6, 60.9
Grade 1	2734 (25.0)	2618 (23.8)	5352 (24.4)
Grade 2	1233 (11.3)	4441 (40.4)	5674 (25.9)
Grade 3	223 (2.0)	1928 (17.6)	2151 (9.8)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.
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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	39 (0.4)	1908 (17.4)	1947 (8.9)
Grade 1	31 (0.3)	1111 (10.1)	1142 (5.2)
Grade 2	4 (<0.1)	601 (5.5)	605 (2.8)
Grade 3	2 (<0.1)	184 (1.7)	186 (0.8)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Headache - N1	10914	10984	21898
Any	2760 (25.3)	6898 (62.8)	9658 (44.1)
Grade 1	2180 (20.0)	3658 (33.3)	5838 (26.7)
Grade 2	451 (4.1)	2687 (24.5)	3138 (14.3)
Grade 3	129 (1.2)	553 (5.0)	682 (3.1)
Grade 4	0	0	0
Fatigue - N1	10912	10984	21896
Any	2687 (24.6)	7430 (67.6)	10117 (46.2)
Grade 1	1700 (15.6)	2525 (23.0)	4225 (19.3)
Grade 2	901 (8.3)	3731 (34.0)	4632 (21.2)
Grade 3	86 (0.8)	1174 (10.7)	1260 (5.8)
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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	1411 (12.9)	6769 (61.6)	8180 (37.4)
Grade 1	994 (9.1)	2411 (22.0)	3405 (15.6)
Grade 2	375 (3.4)	3245 (29.5)	3620 (16.5)
Grade 3	42 (0.4)	1113 (10.1)	1155 (5.3)
Grade 4	0	0	0
Arthralgia - N1	10912	10984	21896
Any	1172 (10.7)	4993 (45.5)	6165 (28.2)
Grade 1	837 (7.7)	2105 (19.2)	2942 (13.4)
Grade 2	298 (2.7)	2241 (20.4)	2539 (11.6)
Grade 3	37 (0.3)	647 (5.9)	684 (3.1)
Grade 4	0	0	0
Nausea/Vomiting - N1	10912	10984	21896
Any	801 (7.3)	2348 (21.4)	3149 (14.4)
Grade 1	646 (5.9)	1752 (16.0)	2398 (11.0)
Grade 2	147 (1.3)	586 (5.3)	733 (3.3)
Grade 3	8 (<0.1)	10 (<0.1)	18 (<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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	658 (6.0)	5341 (48.6)	5999 (27.4)
Grade 1	502 (4.6)	2307 (21.0)	2809 (12.8)
Grade 2	141 (1.3)	2870 (26.1)	3011 (13.8)
Grade 3	15 (0.1)	164 (1.5)	179 (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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	1330 (36.5)	3303 (89.5)	4633 (63.1)
95% CI	34.9, 38.0	88.4, 90.4	62.0, 64.2
Grade 1	957 (26.2)	1561 (42.3)	2518 (34.3)
Grade 2	286 (7.8)	1205 (32.6)	1491 (20.3)
Grade 3	86 (2.4)	535 (14.5)	621 (8.5)
Grade 4	1 (<0.1)	2 (<0.1)	3 (<0.1)
Solicited Local Adverse Reactions - N1	3648	3689	7337
Any Solicited Local Adverse Reactions	491 (13.5)	3091 (83.8)	3582 (48.8)
95% CI	12.4, 14.6	82.6, 85.0	47.7, 50.0
Grade 1	446 (12.2)	2368 (64.2)	2814 (38.4)
Grade 2	15 (0.4)	505 (13.7)	520 (7.1)
Grade 3	30 (0.8)	218 (5.9)	248 (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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	437 (12.0)	3070 (83.2)	3507 (47.8)
Grade 1	406 (11.1)	2575 (69.8)	2981 (40.6)
Grade 2	13 (0.4)	397 (10.8)	410 (5.6)
Grade 3	18 (0.5)	98 (2.7)	116 (1.6)
Grade 4	0	0	0
Erythema (Redness) - N1	3648	3689	7337
Any	13 (0.4)	275 (7.5)	288 (3.9)
Grade 1	10 (0.3)	90 (2.4)	100 (1.4)
Grade 2	0	108 (2.9)	108 (1.5)
Grade 3	3 (<0.1)	77 (2.1)	80 (1.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	3648	3689	7337
Any	13 (0.4)	400 (10.8)	413 (5.6)
Grade 1	5 (0.1)	190 (5.2)	195 (2.7)
Grade 2	1 (<0.1)	138 (3.7)	139 (1.9)
Grade 3	7 (0.2)	72 (2.0)	79 (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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	97 (2.7)	319 (8.5)	412 (5.6)
Grade 1	88 (2.4)	268 (7.3)	356 (4.9)
Grade 2	1 (<0.1)	26 (0.7)	27 (0.4)
Grade 3	8 (0.2)	21 (0.6)	29 (0.4)
Grade 4	0	0	0
Solicited Systemic Adverse Reactions - N1	3648	3692	7340
Any Solicited Systemic Adverse Reactions	1131 (31.0)	2653 (71.9)	3784 (51.6)
95% CI	29.5, 32.5	70.4, 73.3	50.4, 52.7
Grade 1	792 (21.7)	1105 (29.9)	1897 (25.8)
Grade 2	279 (7.6)	1149 (31.1)	1428 (19.5)
Grade 3	59 (1.6)	397 (10.8)	456 (6.2)
Grade 4	1 (<0.1)	2 (<0.1)	3 (<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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	4 (0.1)	370 (10.0)	374 (5.1)
Grade 1	2 (<0.1)	253 (6.9)	255 (3.5)
Grade 2	1 (<0.1)	98 (2.7)	99 (1.3)
Grade 3	0	18 (0.5)	18 (0.2)
Grade 4	1 (<0.1)	1 (<0.1)	2 (<0.1)
Headache - N1	3648	3689	7337
Any	650 (17.8)	1704 (46.2)	2354 (32.1)
Grade 1	559 (15.3)	1146 (31.1)	1705 (23.2)
Grade 2	58 (1.6)	452 (12.3)	510 (7.0)
Grade 3	33 (0.9)	106 (2.9)	139 (1.9)
Grade 4	0	0	0
Fatigue - N1	3648	3689	7337
Any	716 (19.6)	2152 (58.3)	2868 (39.1)
Grade 1	482 (13.2)	907 (24.6)	1389 (18.9)
Grade 2	214 (5.9)	991 (26.9)	1205 (16.4)
Grade 3	20 (0.5)	254 (6.9)	274 (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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	398 (10.9)	1739 (47.1)	2137 (29.1)
Grade 1	306 (8.4)	828 (22.4)	1134 (15.5)
Grade 2	82 (2.2)	706 (19.1)	788 (10.7)
Grade 3	10 (0.3)	205 (5.6)	215 (2.9)
Grade 4	0	0	0
Arthralgia - N1	3648	3689	7337
Any	397 (10.9)	1291 (35.0)	1688 (23.0)
Grade 1	305 (8.4)	697 (18.9)	1002 (13.7)
Grade 2	85 (2.3)	471 (12.8)	556 (7.6)
Grade 3	7 (0.2)	123 (3.3)	130 (1.8)
Grade 4	0	0	0
Nausea/Vomiting - N1	3648	3689	7337
Any	133 (3.6)	437 (11.8)	570 (7.8)
Grade 1	110 (3.0)	338 (9.2)	448 (6.1)
Grade 2	20 (0.5)	88 (2.4)	108 (1.5)
Grade 3	3 (<0.1)	10 (0.3)	13 (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 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 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	151 (4.1)	1141 (30.9)	1292 (17.6)
Grade 1	124 (3.4)	592 (16.0)	716 (9.8)
Grade 2	25 (0.7)	522 (14.2)	547 (7.5)
Grade 3	2 (<0.1)	27 (0.7)	29 (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 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15155)	mRNA-1273 (N=15168)	Total (N=30323)
Solicited Adverse Reactions			
n	7284	13319	20603
Mean (SD)	3.2 (4.16)	3.4 (3.27)	3.3 (3.61)
Median	2.0	3.0	3.0
Min, Max	1, 88	1, 84	1, 88
Solicited Local Adverse Reactions			
n	2997	12765	15762
Mean (SD)	1.9 (2.58)	2.6 (1.93)	2.5 (2.08)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 45	1, 51
Pain			
n	2658	12690	15348
Mean (SD)	1.7 (2.07)	2.4 (1.37)	2.3 (1.54)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 34	1, 51
Erythema (Redness)			
n	67	430	497
Mean (SD)	3.2 (5.63)	2.5 (4.12)	2.6 (4.36)
Median	1.0	2.0	1.0
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 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15155)	mRNA-1273 (N=15168)	Total (N=30323)
Swelling (Hardness)			
n	52	932	984
Mean (SD)	5.1 (7.78)	2.1 (2.15)	2.2 (2.82)
Median	2.0	1.0	1.0
Min, Max	1, 28	1, 29	1, 29
Lymphadenopathy [1]			
n	722	1553	2275
Mean (SD)	2.1 (2.83)	2.3 (2.89)	2.2 (2.87)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 31	1, 33
Solicited Systemic Adverse Reactions			
n	6399	8320	14719
Mean (SD)	3.1 (4.18)	2.9 (3.67)	3.0 (3.90)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Fever			
n	44	115	159
Mean (SD)	1.4 (0.62)	1.3 (0.71)	1.3 (0.69)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 6	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.
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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15155)	mRNA-1273 (N=15168)	Total (N=30323)
Headache			
n	4027	4951	8978
Mean (SD)	2.1 (2.38)	2.1 (2.17)	2.1 (2.27)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 42	1, 42
Fatigue			
n	4133	5635	9768
Mean (SD)	2.8 (3.74)	2.7 (3.57)	2.7 (3.64)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Myalgia			
n	2071	3441	5512
Mean (SD)	2.7 (3.72)	2.3 (3.24)	2.4 (3.43)
Median	1.0	1.0	1.0
Min, Max	1, 44	1, 75	1, 75
Arthralgia			
n	1783	2511	4294
Mean (SD)	3.2 (5.02)	2.6 (4.10)	2.9 (4.51)
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 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15155)	mRNA-1273 (N=15168)	Total (N=30323)
Nausea/Vomiting			
n	1074	1262	2336
Mean (SD)	1.8 (2.20)	1.7 (1.54)	1.7 (1.88)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 28	1, 33
Chills			
n	878	1253	2131
Mean (SD)	1.7 (1.71)	1.5 (1.69)	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 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14566)	mRNA-1273 (N=14677)	Total (N=29243)
Solicited Adverse Reactions			
n	6232	13534	19766
Mean (SD)	3.4 (5.72)	4.0 (6.82)	3.8 (5.13)
Median	2.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Solicited Local Adverse Reactions			
n	2735	13006	15741
Mean (SD)	2.1 (4.04)	3.2 (2.90)	3.0 (3.15)
Median	1.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Pain			
n	2477	12943	15420
Mean (SD)	1.8 (3.26)	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	56	1257	1313
Mean (SD)	3.8 (10.62)	2.7 (3.89)	2.7 (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 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14566)	mRNA-1273 (N=14677)	Total (N=29243)
Swelling (Hardness)			
n	49	1789	1838
Mean (SD)	2.7 (4.90)	2.6 (4.13)	2.6 (4.15)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 93	1, 93
Lymphadenopathy [1]			
n	567	2090	2657
Mean (SD)	2.6 (5.28)	2.4 (3.20)	2.4 (3.74)
Median	1.0	2.0	2.0
Min, Max	1, 90	1, 68	1, 90
Solicited Systemic Adverse Reactions			
n	5323	11652	16975
Mean (SD)	3.4 (5.63)	3.1 (4.58)	3.2 (4.93)
Median	2.0	2.0	2.0
Min, Max	1, 90	1, 84	1, 90
Fever			
n	43	2278	2321
Mean (SD)	1.2 (0.51)	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 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 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14566)	mRNA-1273 (N=14677)	Total (N=29243)
Headache			
n	3410	8602	12012
Mean (SD)	2.3 (3.29)	2.3 (2.94)	2.3 (3.04)
Median	1.0	2.0	2.0
Min, Max	1, 72	1, 78	1, 78
Fatigue			
n	3403	9582	12985
Mean (SD)	3.0 (5.07)	2.6 (3.74)	2.7 (4.13)
Median	2.0	2.0	2.0
Min, Max	1, 83	1, 78	1, 83
Myalgia			
n	1809	8508	10317
Mean (SD)	3.2 (6.10)	2.1 (3.12)	2.3 (3.83)
Median	2.0	1.0	2.0
Min, Max	1, 72	1, 79	1, 79
Arthralgia			
n	1569	6284	7853
Mean (SD)	3.7 (6.97)	2.3 (3.53)	2.5 (4.47)
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 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14566)	mRNA-1273 (N=14677)	Total (N=29243)
Nausea/Vomiting			
n	934	2785	3719
Mean (SD)	1.9 (3.82)	1.7 (2.36)	1.8 (2.80)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 78	1, 78
Chills			
n	809	6482	7291
Mean (SD)	1.9 (3.21)	1.5 (1.56)	1.5 (1.82)
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 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15163)	mRNA-1273 (N=15179)	Total (N=30342)
Solicited Adverse Reactions			
n	9108	14400	23508
Mean (SD)	3.7 (5.68)	4.5 (5.22)	4.2 (5.42)
Median	2.0	4.0	3.0
Min, Max	1, 90	1, 93	1, 93
Solicited Local Adverse Reactions			
n	4450	14027	18477
Mean (SD)	2.1 (3.67)	3.4 (3.08)	3.1 (3.28)
Median	1.0	3.0	3.0
Min, Max	1, 90	1, 93	1, 93
Pain			
n	4037	13965	18002
Mean (SD)	1.8 (2.93)	3.2 (2.23)	2.9 (2.46)
Median	1.0	3.0	3.0
Min, Max	1, 72	1, 78	1, 78
Erythema (Redness)			
n	117	1522	1639
Mean (SD)	3.5 (8.43)	2.7 (4.13)	2.8 (4.57)
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 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15163)	mRNA-1273 (N=15179)	Total (N=30342)
Swelling (Hardness)			
n	95	2232	2327
Mean (SD)	3.9 (6.67)	2.5 (3.92)	2.6 (4.07)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 93	1, 93
Lymphadenopathy [1]			
n	1098	3011	4109
Mean (SD)	2.3 (4.23)	2.4 (3.21)	2.4 (3.51)
Median	1.0	1.0	1.0
Min, Max	1, 90	1, 68	1, 90
Solicited Systemic Adverse Reactions			
n	8112	12770	20882
Mean (SD)	3.6 (5.55)	3.5 (4.98)	3.5 (5.21)
Median	2.0	2.0	2.0
Min, Max	1, 90	1, 84	1, 90
Fever			
n	86	2353	2439
Mean (SD)	1.3 (0.58)	1.2 (1.67)	1.2 (1.64)
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 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15163)	mRNA-1273 (N=15179)	Total (N=30342)
Headache			
n	5603	9825	15428
Mean (SD)	2.4 (3.13)	2.4 (3.02)	2.4 (3.06)
Median	2.0	2.0	2.0
Min, Max	1, 72	1, 78	1, 78
Fatigue			
n	5544	10627	16171
Mean (SD)	3.1 (4.87)	2.9 (4.18)	3.0 (4.43)
Median	2.0	2.0	2.0
Min, Max	1, 88	1, 83	1, 88
Myalgia			
n	3113	9334	12447
Mean (SD)	3.0 (5.25)	2.3 (3.45)	2.5 (3.99)
Median	2.0	2.0	2.0
Min, Max	1, 72	1, 79	1, 79
Arthralgia			
n	2666	7044	9710
Mean (SD)	3.6 (6.43)	2.4 (3.94)	2.8 (4.78)
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 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15163)	mRNA-1273 (N=15179)	Total (N=30342)
Nausea/Vomiting			
n	1716	3484	5200
Mean (SD)	1.9 (3.18)	1.7 (2.26)	1.8 (2.60)
Median	1.0	1.0	1.0
Min, Max	1, 72	1, 78	1, 78
Chills			
n	1470	6891	8361
Mean (SD)	1.8 (2.55)	1.5 (1.63)	1.5 (1.83)
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 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Solicited Adverse Reactions - N1	15155	15168	30323
Any Solicited Adverse Reactions	930 (6.1)	1113 (7.3)	2043 (6.7)
95% CI	5.8, 6.5	6.9, 7.8	6.5, 7.0
Grade 1	411 (2.7)	509 (3.4)	920 (3.0)
Grade 2	421 (2.8)	494 (3.3)	915 (3.0)
Grade 3	98 (0.6)	110 (0.7)	208 (0.7)
Grade 4	0	0	0
Solicited Local Adverse Reactions - N1	15151	15164	30315
Any Solicited Local Adverse Reactions	113 (0.7)	331 (2.2)	444 (1.5)
95% CI	0.6, 0.9	2.0, 2.4	1.3, 1.6
Grade 1	86 (0.6)	230 (1.5)	316 (1.0)
Grade 2	23 (0.2)	80 (0.5)	103 (0.3)
Grade 3	4 (<0.1)	21 (0.1)	25 (<0.1)
Grade 4	0	0	0
Pain - N1	15151	15164	30315
Any	51 (0.3)	86 (0.6)	137 (0.5)
Grade 1	41 (0.3)	45 (0.3)	86 (0.3)
Grade 2	8 (<0.1)	32 (0.2)	40 (0.1)
Grade 3	2 (<0.1)	9 (<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 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Erythema (Redness) - N1	15151	15163	30314
Any	10 (<0.1)	21 (0.1)	31 (0.1)
Grade 1	8 (<0.1)	10 (<0.1)	18 (<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	15151	15163	30314
Any	12 (<0.1)	24 (0.2)	36 (0.1)
Grade 1	8 (<0.1)	15 (<0.1)	23 (<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
Lymphadenopathy - N1 [1]	15151	15163	30314
Any	57 (0.4)	235 (1.5)	292 (1.0)
Grade 1	43 (0.3)	181 (1.2)	224 (0.7)
Grade 2	14 (<0.1)	44 (0.3)	58 (0.2)
Grade 3	0	10 (<0.1)	10 (<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 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Solicited Systemic Adverse Reactions - N1	15155	15167	30322
Any Solicited Systemic Adverse Reactions	857 (5.7)	877 (5.8)	1734 (5.7)
95% CI	5.3, 6.0	5.4, 6.2	5.5, 6.0
Grade 1	354 (2.3)	335 (2.2)	689 (2.3)
Grade 2	408 (2.7)	446 (2.9)	854 (2.8)
Grade 3	95 (0.6)	96 (0.6)	191 (0.6)
Grade 4	0	0	0
Fever - N1	15153	15164	30317
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	15150	15163	30313
Any	313 (2.1)	337 (2.2)	650 (2.1)
Grade 1	156 (1.0)	177 (1.2)	333 (1.1)
Grade 2	112 (0.7)	125 (0.8)	237 (0.8)
Grade 3	45 (0.3)	35 (0.2)	80 (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 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=15155) n	(%)	mRNA-1273 (N=15168) n	(%)	Total (N=30323) n	(%)
Fatigue - N1	15150		15163		30313	
Any	474	(3.1)	523	(3.4)	997	(3.3)
Grade 1	158	(1.0)	154	(1.0)	312	(1.0)
Grade 2	269	(1.8)	315	(2.1)	584	(1.9)
Grade 3	47	(0.3)	54	(0.4)	101	(0.3)
Grade 4	0		0		0	
Myalgia - N1	15150		15163		30313	
Any	247	(1.6)	227	(1.5)	474	(1.6)
Grade 1	102	(0.7)	84	(0.6)	186	(0.6)
Grade 2	123	(0.8)	111	(0.7)	234	(0.8)
Grade 3	22	(0.1)	32	(0.2)	54	(0.2)
Grade 4	0		0		0	
Arthralgia - N1	15150		15163		30313	
Any	282	(1.9)	249	(1.6)	531	(1.8)
Grade 1	137	(0.9)	105	(0.7)	242	(0.8)
Grade 2	126	(0.8)	118	(0.8)	244	(0.8)
Grade 3	19	(0.1)	26	(0.2)	45	(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 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=15155) n (%)	mRNA-1273 (N=15168) n (%)	Total (N=30323) n (%)
Nausea/Vomiting - N1	15150	15163	30313
Any	67 (0.4)	62 (0.4)	129 (0.4)
Grade 1	40 (0.3)	33 (0.2)	73 (0.2)
Grade 2	26 (0.2)	27 (0.2)	53 (0.2)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Chills - N1	15150	15163	30313
Any	46 (0.3)	35 (0.2)	81 (0.3)
Grade 1	26 (0.2)	12 (<0.1)	38 (0.1)
Grade 2	19 (0.1)	18 (0.1)	37 (0.1)
Grade 3	1 (<0.1)	5 (<0.1)	6 (<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 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Solicited Adverse Reactions - N1	14566	14677	29243
Any Solicited Adverse Reactions	768 (5.3)	1019 (6.9)	1787 (6.1)
95% CI	4.9, 5.6	6.5, 7.4	5.8, 6.4
Grade 1	326 (2.2)	230 (1.6)	562 (1.9)
Grade 2	348 (2.4)	503 (3.4)	851 (2.9)
Grade 3	94 (0.6)	279 (1.9)	373 (1.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	14562	14673	29235
Any Solicited Local Adverse Reactions	109 (0.7)	301 (2.1)	410 (1.4)
95% CI	0.6, 0.9	1.8, 2.3	1.3, 1.5
Grade 1	87 (0.6)	116 (0.8)	203 (0.7)
Grade 2	14 (<0.1)	119 (0.8)	133 (0.5)
Grade 3	8 (<0.1)	66 (0.4)	74 (0.3)
Grade 4	0	0	0
Pain - N1	14562	14673	29235
Any	58 (0.4)	159 (1.1)	217 (0.7)
Grade 1	41 (0.3)	58 (0.4)	99 (0.3)
Grade 2	11 (<0.1)	76 (0.5)	87 (0.3)
Grade 3	6 (<0.1)	25 (0.2)	31 (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 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Erythema (Redness) - N1	14562	14673	29235
Any	4 (<0.1)	60 (0.4)	64 (0.2)
Grade 1	4 (<0.1)	10 (<0.1)	14 (<0.1)
Grade 2	0	20 (0.1)	20 (<0.1)
Grade 3	0	30 (0.2)	30 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	14562	14673	29235
Any	6 (<0.1)	48 (0.3)	54 (0.2)
Grade 1	6 (<0.1)	18 (0.1)	24 (<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
Lymphadenopathy - N1 [1]	14562	14673	29235
Any	48 (0.3)	91 (0.6)	139 (0.5)
Grade 1	42 (0.3)	60 (0.4)	102 (0.3)
Grade 2	4 (<0.1)	24 (0.2)	28 (<0.1)
Grade 3	2 (<0.1)	7 (<0.1)	9 (<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 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Solicited Systemic Adverse Reactions - N1	14565	14677	29242
Any Solicited Systemic Adverse Reactions	709 (4.9)	836 (5.7)	1545 (5.3)
95% CI	4.5, 5.2	5.3, 6.1	5.0, 5.5
Grade 1	279 (1.9)	162 (1.1)	441 (1.5)
Grade 2	343 (2.4)	449 (3.1)	792 (2.7)
Grade 3	87 (0.6)	224 (1.5)	311 (1.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Fever - N1	14559	14669	29228
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	14562	14673	29235
Any	304 (2.1)	381 (2.6)	685 (2.3)
Grade 1	152 (1.0)	100 (0.7)	252 (0.9)
Grade 2	119 (0.8)	225 (1.5)	344 (1.2)
Grade 3	33 (0.2)	56 (0.4)	89 (0.3)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.
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Table 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=14566) n	(%)	mRNA-1273 (N=14677) n	(%)	Total (N=29243) n	(%)
Fatigue - N1	14560		14673		29233	
Any	389	(2.7)	485	(3.3)	874	(3.0)
Grade 1	117	(0.8)	71	(0.5)	188	(0.6)
Grade 2	222	(1.5)	262	(1.8)	484	(1.7)
Grade 3	50	(0.3)	152	(1.0)	202	(0.7)
Grade 4	0		0		0	
Myalgia - N1	14560		14673		29233	
Any	223	(1.5)	235	(1.6)	458	(1.6)
Grade 1	84	(0.6)	45	(0.3)	129	(0.4)
Grade 2	111	(0.8)	130	(0.9)	241	(0.8)
Grade 3	28	(0.2)	60	(0.4)	88	(0.3)
Grade 4	0		0		0	
Arthralgia - N1	14560		14673		29233	
Any	260	(1.8)	267	(1.8)	527	(1.8)
Grade 1	105	(0.7)	60	(0.4)	165	(0.6)
Grade 2	133	(0.9)	155	(1.1)	288	(1.0)
Grade 3	22	(0.2)	52	(0.4)	74	(0.3)
Grade 4	0		0		0	

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.
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Table 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14566) n (%)	mRNA-1273 (N=14677) n (%)	Total (N=29243) n (%)
Nausea/Vomiting - N1	14560	14673	29233
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)
Chills - N1	14560	14673	29233
Any	51 (0.4)	53 (0.4)	104 (0.4)
Grade 1	24 (0.2)	11 (<0.1)	35 (0.1)
Grade 2	22 (0.2)	34 (0.2)	56 (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 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 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	1463 (9.6)	1851 (12.2)	3314 (10.9)
95% CI	9.2, 10.1	11.7, 12.7	10.6, 11.3
Grade 1	615 (4.1)	613 (4.0)	1228 (4.0)
Grade 2	666 (4.4)	866 (5.7)	1532 (5.0)
Grade 3	182 (1.2)	371 (2.4)	553 (1.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Solicited Local Adverse Reactions - N1	15162	15179	30341
Any Solicited Local Adverse Reactions	204 (1.3)	579 (3.8)	783 (2.6)
95% CI	1.2, 1.5	3.5, 4.1	2.4, 2.8
Grade 1	155 (1.0)	312 (2.1)	467 (1.5)
Grade 2	37 (0.2)	181 (1.2)	218 (0.7)
Grade 3	12 (<0.1)	86 (0.6)	98 (0.3)
Grade 4	0	0	0
Pain - N1	15162	15179	30341
Any	103 (0.7)	227 (1.5)	330 (1.1)
Grade 1	76 (0.5)	94 (0.6)	170 (0.6)
Grade 2	19 (0.1)	100 (0.7)	119 (0.4)
Grade 3	8 (<0.1)	33 (0.2)	41 (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 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 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	13 (<0.1)	79 (0.5)	92 (0.3)
Grade 1	11 (<0.1)	19 (0.1)	30 (<0.1)
Grade 2	1 (<0.1)	27 (0.2)	28 (<0.1)
Grade 3	1 (<0.1)	33 (0.2)	34 (0.1)
Grade 4	0	0	0
Swelling (Hardness) - N1	15162	15179	30341
Any	17 (0.1)	71 (0.5)	88 (0.3)
Grade 1	13 (<0.1)	32 (0.2)	45 (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
Lymphadenopathy - N1 [1]	15162	15179	30341
Any	95 (0.6)	301 (2.0)	396 (1.3)
Grade 1	75 (0.5)	222 (1.5)	297 (1.0)
Grade 2	18 (0.1)	62 (0.4)	80 (0.3)
Grade 3	2 (<0.1)	17 (0.1)	19 (<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 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 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	1348 (8.9)	1498 (9.9)	2846 (9.4)
95% CI	8.4, 9.4	9.4, 10.4	9.1, 9.7
Grade 1	527 (3.5)	415 (2.7)	942 (3.1)
Grade 2	649 (4.3)	777 (5.1)	1426 (4.7)
Grade 3	172 (1.1)	305 (2.0)	477 (1.6)
Grade 4	0	1 (<0.1)	1 (<0.1)
Fever - N1	15162	15178	30340
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	15162	15179	30341
Any	568 (3.7)	661 (4.4)	1229 (4.1)
Grade 1	278 (1.8)	244 (1.6)	522 (1.7)
Grade 2	216 (1.4)	326 (2.1)	542 (1.8)
Grade 3	74 (0.5)	91 (0.6)	165 (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 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 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	755 (5.0)	894 (5.9)	1649 (5.4)
Grade 1	235 (1.5)	190 (1.3)	425 (1.4)
Grade 2	428 (2.8)	506 (3.3)	934 (3.1)
Grade 3	92 (0.6)	198 (1.3)	290 (1.0)
Grade 4	0	0	0
Myalgia - N1	15162	15179	30341
Any	421 (2.8)	423 (2.8)	844 (2.8)
Grade 1	158 (1.0)	111 (0.7)	269 (0.9)
Grade 2	213 (1.4)	224 (1.5)	437 (1.4)
Grade 3	50 (0.3)	88 (0.6)	138 (0.5)
Grade 4	0	0	0
Arthralgia - N1	15162	15179	30341
Any	476 (3.1)	454 (3.0)	930 (3.1)
Grade 1	201 (1.3)	132 (0.9)	333 (1.1)
Grade 2	235 (1.5)	251 (1.7)	486 (1.6)
Grade 3	40 (0.3)	71 (0.5)	111 (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 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 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	107 (0.7)	118 (0.8)	225 (0.7)
Grade 1	55 (0.4)	45 (0.3)	100 (0.3)
Grade 2	50 (0.3)	60 (0.4)	115 (0.4)
Grade 3	2 (<0.1)	7 (<0.1)	9 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Chills - N1	15162	15179	30341
Any	92 (0.6)	84 (0.6)	176 (0.6)
Grade 1	48 (0.3)	22 (0.1)	70 (0.2)
Grade 2	38 (0.3)	51 (0.3)	89 (0.3)
Grade 3	6 (<0.1)	11 (<0.1)	17 (<0.1)
Grade 4	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.
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Table 14.3.1.7.1
Summary of Unsolicited 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	3277 (21.6)	3632 (23.9)	6909 (22.8)
Serious	89 (0.6)	93 (0.6)	182 (0.6)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Medically-Attended	1465 (9.7)	1372 (9.0)	2837 (9.3)
Leading to Discontinuation from Study Vaccine	80 (0.5)	50 (0.3)	130 (0.4)
Leading to Discontinuation from Participation in the Study	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	202 (1.3)	234 (1.5)	436 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	686 (4.5)	1242 (8.2)	1928 (6.4)
Serious	4 (<0.1)	6 (<0.1)	10 (<0.1)
Fatal	0	0	0
Medically-Attended	83 (0.5)	140 (0.9)	223 (0.7)
Leading to Discontinuation from Study Vaccine	15 (<0.1)	18 (0.1)	33 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	28 (0.2)	71 (0.5)	99 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.3
Summary of Unsolicited 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	3888 (25.6)	4058 (26.7)	7946 (26.2)
Serious	153 (1.0)	147 (1.0)	300 (1.0)
Fatal	6 (<0.1)	4 (<0.1)	10 (<0.1)
Medically-Attended	1958 (12.9)	1745 (11.5)	3703 (12.2)
Leading to Discontinuation from Study Vaccine	93 (0.6)	59 (0.4)	152 (0.5)
Leading to Discontinuation from Participation in the Study	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	267 (1.8)	300 (2.0)	567 (1.9)
Unsolicited TEAEs Related to Study Vaccination			
All	702 (4.6)	1256 (8.3)	1958 (6.5)
Serious	5 (<0.1)	7 (<0.1)	12 (<0.1)
Fatal	0	0	0
Medically-Attended	88 (0.6)	143 (0.9)	231 (0.8)
Leading to Discontinuation from Study Vaccine	16 (0.1)	18 (0.1)	34 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	30 (0.2)	73 (0.5)	103 (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 14.3.1.7.4
Summary of Unsolicited TEAE by Age Group up to 28 Days After Any Injection
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	2463 (21.6)	2674 (23.4)	5137 (22.5)
Serious	46 (0.4)	54 (0.5)	100 (0.4)
Fatal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Medically-Attended	1051 (9.2)	991 (8.7)	2042 (8.9)
Leading to Discontinuation from Study Vaccine	62 (0.5)	37 (0.3)	99 (0.4)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	132 (1.2)	156 (1.4)	288 (1.3)
Unsolicited TEAEs Related to Study Vaccination			
All	526 (4.6)	938 (8.2)	1464 (6.4)
Serious	3 (<0.1)	4 (<0.1)	7 (<0.1)
Fatal	0	0	0
Medically-Attended	68 (0.6)	110 (1.0)	178 (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	19 (0.2)	49 (0.4)	68 (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 14.3.1.7.4
Summary of Unsolicited TEAE by Age Group up to 28 Days After Any Injection
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	814 (21.7)	958 (25.4)	1772 (23.6)
Serious	43 (1.1)	39 (1.0)	82 (1.1)
Fatal	2 (<0.1)	1 (<0.1)	3 (<0.1)
Medically-Attended	414 (11.0)	381 (10.1)	795 (10.6)
Leading to Discontinuation from Study Vaccine	18 (0.5)	13 (0.3)	31 (0.4)
Leading to Discontinuation from Participation in the Study	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	70 (1.9)	78 (2.1)	148 (2.0)
Unsolicited TEAEs Related to Study Vaccination			
All	160 (4.3)	304 (8.1)	464 (6.2)
Serious	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fatal	0	0	0
Medically-Attended	15 (0.4)	30 (0.8)	45 (0.6)
Leading to Discontinuation from Study Vaccine	5 (0.1)	4 (0.1)	9 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	9 (0.2)	22 (0.6)	31 (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 14.3.1.8.1
Subject Incidence of Unsolicited 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	3277 (21.6)	3632 (23.9)	6909 (22.8)
Number of Unsolicited Adverse Events	6085	6798	12883
Infections and infestations	734 (4.8)	611 (4.0)	1345 (4.4)
Urinary tract infection	101 (0.7)	83 (0.5)	184 (0.6)
Sinusitis	32 (0.2)	54 (0.4)	86 (0.3)
Upper respiratory tract infection	74 (0.5)	49 (0.3)	123 (0.4)
Viral infection	29 (0.2)	25 (0.2)	54 (0.2)
COVID-19	125 (0.8)	24 (0.2)	149 (0.5)
Rhinovirus infection	15 (<0.1)	20 (0.1)	35 (0.1)
Herpes zoster	13 (<0.1)	19 (0.1)	32 (0.1)
Tooth infection	13 (<0.1)	19 (0.1)	32 (0.1)
Tooth abscess	22 (0.1)	18 (0.1)	40 (0.1)
Gastroenteritis	16 (0.1)	17 (0.1)	33 (0.1)
Ear infection	10 (<0.1)	16 (0.1)	26 (<0.1)
Pharyngitis	20 (0.1)	16 (0.1)	36 (0.1)
Conjunctivitis	9 (<0.1)	13 (<0.1)	22 (<0.1)
Cellulitis	12 (<0.1)	12 (<0.1)	24 (<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)
Hordeolum	9 (<0.1)	8 (<0.1)	17 (<0.1)
Viral upper respiratory tract infection	11 (<0.1)	8 (<0.1)	19 (<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 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
Diverticulitis	8 (<0.1)	7 (<0.1)	15 (<0.1)
Herpes simplex	3 (<0.1)	7 (<0.1)	10 (<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)
Folliculitis	6 (<0.1)	6 (<0.1)	12 (<0.1)
Fungal infection	6 (<0.1)	6 (<0.1)	12 (<0.1)
Otitis externa	11 (<0.1)	6 (<0.1)	17 (<0.1)
Paronychia	4 (<0.1)	6 (<0.1)	10 (<0.1)
Acute sinusitis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Onychomycosis	1 (<0.1)	5 (<0.1)	6 (<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)
Asymptomatic COVID-19	3 (<0.1)	4 (<0.1)	7 (<0.1)
Bronchitis	6 (<0.1)	4 (<0.1)	10 (<0.1)
Skin infection	3 (<0.1)	4 (<0.1)	7 (<0.1)
Staphylococcal infection	1 (<0.1)	4 (<0.1)	5 (<0.1)
Subcutaneous abscess	1 (<0.1)	4 (<0.1)	5 (<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)
Clostridium difficile infection	0	3 (<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 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
Cystitis	6 (<0.1)	3 (<0.1)	9 (<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)
Laryngitis	2 (<0.1)	3 (<0.1)	5 (<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)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gonorrhoea	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)
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
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)
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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	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)
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)
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 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	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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
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)
Septic shock	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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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) (Cont.)			
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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) (Cont.)			
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)
Blood and lymphatic system disorders	89 (0.6)	154 (1.0)	243 (0.8)
Lymphadenopathy	74 (0.5)	129 (0.8)	203 (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)	28 (0.2)	71 (0.2)
Seasonal allergy	28 (0.2)	19 (0.1)	47 (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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (Cont.)			
Food allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to chemicals	1 (<0.1)	0	1 (<0.1)
Allergy to 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)
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	80 (0.5)	80 (0.5)	160 (0.5)
Hyperlipidaemia	12 (<0.1)	16 (0.1)	28 (<0.1)
Type 2 diabetes mellitus	3 (<0.1)	11 (<0.1)	14 (<0.1)
Decreased appetite	7 (<0.1)	10 (<0.1)	17 (<0.1)
Dehydration	4 (<0.1)	7 (<0.1)	11 (<0.1)
Hypercholesterolaemia	13 (<0.1)	7 (<0.1)	20 (<0.1)
Vitamin D deficiency	9 (<0.1)	7 (<0.1)	16 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Metabolism and nutrition disorders (Cont.)			
Diabetes mellitus	2 (<0.1)	3 (<0.1)	5 (<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)
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)
Hypoglycaemia	2 (<0.1)	1 (<0.1)	3 (<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)
Increased appetite	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Metabolism and nutrition disorders (Cont.)			
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	74 (0.5)	104 (0.7)	178 (0.6)
Anxiety	25 (0.2)	30 (0.2)	55 (0.2)
Depression	16 (0.1)	27 (0.2)	43 (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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (Cont.)			
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)
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	622 (4.1)	684 (4.5)	1306 (4.3)
Headache	458 (3.0)	466 (3.1)	924 (3.0)
Dizziness	51 (0.3)	66 (0.4)	117 (0.4)
Paraesthesia	24 (0.2)	28 (0.2)	52 (0.2)
Sinus headache	6 (<0.1)	13 (<0.1)	19 (<0.1)
Dysgeusia	6 (<0.1)	12 (<0.1)	18 (<0.1)
Sciatica	9 (<0.1)	12 (<0.1)	21 (<0.1)
Syncope	14 (<0.1)	12 (<0.1)	26 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
Hypoaesthesia	7 (<0.1)	11 (<0.1)	18 (<0.1)
Migraine	18 (0.1)	11 (<0.1)	29 (<0.1)
Ageusia	7 (<0.1)	10 (<0.1)	17 (<0.1)
Tension headache	3 (<0.1)	7 (<0.1)	10 (<0.1)
Anosmia	6 (<0.1)	6 (<0.1)	12 (<0.1)
Hyperaesthesia	0	6 (<0.1)	6 (<0.1)
Presyncope	12 (<0.1)	6 (<0.1)	18 (<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	1 (<0.1)	2 (<0.1)	3 (<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	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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Essential tremor	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	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	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)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
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)
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 (0.3)	51 (0.3)	103 (0.3)
Eye pruritus	5 (<0.1)	7 (<0.1)	12 (<0.1)
Eye irritation	0	5 (<0.1)	5 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Eye disorders (Cont.)			
Vision blurred	3 (<0.1)	3 (<0.1)	6 (<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)
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Eye disorders (Cont.)			
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)
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	70 (0.5)	60 (0.4)	130 (0.4)
Vertigo	16 (0.1)	17 (0.1)	33 (0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Ear and labyrinth disorders (Cont.)			
Ear pain	16 (0.1)	13 (<0.1)	29 (<0.1)
Tinnitus	11 (<0.1)	9 (<0.1)	20 (<0.1)
Vertigo positional	1 (<0.1)	6 (<0.1)	7 (<0.1)
Cerumen impaction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Ear canal erythema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ear discomfort	6 (<0.1)	2 (<0.1)	8 (<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)
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	5 (<0.1)	0	5 (<0.1)
Cardiac disorders	63 (0.4)	59 (0.4)	122 (0.4)
Bradycardia	18 (0.1)	12 (<0.1)	30 (<0.1)
Tachycardia	10 (<0.1)	12 (<0.1)	22 (<0.1)

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Subject Incidence of Unsolicited 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 (%)
Cardiac disorders (Cont.)			
Atrial fibrillation	9 (<0.1)	9 (<0.1)	18 (<0.1)
Palpitations	6 (<0.1)	5 (<0.1)	11 (<0.1)
Angina pectoris	2 (<0.1)	4 (<0.1)	6 (<0.1)
Cardiac failure congestive	3 (<0.1)	4 (<0.1)	7 (<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	1 (<0.1)	1 (<0.1)	2 (<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)
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)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Vascular disorders	152 (1.0)	163 (1.1)	315 (1.0)
Hypertension	117 (0.8)	123 (0.8)	240 (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)
Haematoma	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypotension	2 (<0.1)	3 (<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)
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)

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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	583 (3.8)	536 (3.5)	1119 (3.7)
Cough	156 (1.0)	164 (1.1)	320 (1.1)
Oropharyngeal pain	203 (1.3)	147 (1.0)	350 (1.2)
Nasal congestion	144 (0.9)	138 (0.9)	282 (0.9)
Rhinorrhoea	136 (0.9)	130 (0.9)	266 (0.9)
Dyspnoea	38 (0.3)	47 (0.3)	85 (0.3)
Tachypnoea	32 (0.2)	32 (0.2)	64 (0.2)
Sinus congestion	26 (0.2)	16 (0.1)	42 (0.1)
Throat irritation	13 (<0.1)	16 (0.1)	29 (<0.1)
Epistaxis	9 (<0.1)	14 (<0.1)	23 (<0.1)
Upper-airway cough syndrome	10 (<0.1)	13 (<0.1)	23 (<0.1)
Asthma	11 (<0.1)	11 (<0.1)	22 (<0.1)
Respiratory tract congestion	9 (<0.1)	11 (<0.1)	20 (<0.1)
Sneezing	9 (<0.1)	9 (<0.1)	18 (<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)
Pharyngeal erythema	4 (<0.1)	5 (<0.1)	9 (<0.1)
Productive cough	7 (<0.1)	5 (<0.1)	12 (<0.1)
Dry throat	2 (<0.1)	4 (<0.1)	6 (<0.1)
Dysphonia	8 (<0.1)	4 (<0.1)	12 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)	7 (<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)

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Subject Incidence of Unsolicited 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 (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
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)
Acute respiratory failure	1 (<0.1)	1 (<0.1)	2 (<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	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)
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)

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Subject Incidence of Unsolicited 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 (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
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)
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	440 (2.9)	478 (3.1)	918 (3.0)
Diarrhoea	162 (1.1)	189 (1.2)	351 (1.2)
Nausea	125 (0.8)	117 (0.8)	242 (0.8)
Vomiting	38 (0.3)	42 (0.3)	80 (0.3)
Gastrooesophageal reflux disease	13 (<0.1)	33 (0.2)	46 (0.2)
Toothache	23 (0.2)	30 (0.2)	53 (0.2)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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	18 (0.1)	20 (0.1)	38 (0.1)
Dental caries	8 (<0.1)	12 (<0.1)	20 (<0.1)
Constipation	12 (<0.1)	11 (<0.1)	23 (<0.1)
Abdominal pain upper	17 (0.1)	10 (<0.1)	27 (<0.1)
Dyspepsia	15 (<0.1)	10 (<0.1)	25 (<0.1)
Food poisoning	8 (<0.1)	10 (<0.1)	18 (<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)
Gastric ulcer	2 (<0.1)	4 (<0.1)	6 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)	6 (<0.1)
Inguinal hernia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)	6 (<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)
Umbilical 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)
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 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Paraesthesia oral	4 (<0.1)	2 (<0.1)	6 (<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)
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)
Oesophageal ulcer	0	1 (<0.1)	1 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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	2 (<0.1)	12 (<0.1)	14 (<0.1)
Cholelithiasis	1 (<0.1)	6 (<0.1)	7 (<0.1)
Cholecystitis	0	2 (<0.1)	2 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Hepatic steatosis	0	1 (<0.1)	1 (<0.1)
Hepatic cyst	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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	193 (1.3)	264 (1.7)	457 (1.5)
Rash	29 (0.2)	42 (0.3)	71 (0.2)
Urticaria	19 (0.1)	25 (0.2)	44 (0.1)
Pruritus	18 (0.1)	23 (0.2)	41 (0.1)
Dermatitis contact	26 (0.2)	20 (0.1)	46 (0.2)
Erythema	6 (<0.1)	16 (0.1)	22 (<0.1)
Hyperhidrosis	14 (<0.1)	12 (<0.1)	26 (<0.1)
Rash maculo-papular	1 (<0.1)	11 (<0.1)	12 (<0.1)
Night sweats	7 (<0.1)	9 (<0.1)	16 (<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)	7 (<0.1)	12 (<0.1)
Alopecia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Rash erythematous	2 (<0.1)	6 (<0.1)	8 (<0.1)
Rash macular	3 (<0.1)	6 (<0.1)	9 (<0.1)
Actinic keratosis	0	5 (<0.1)	5 (<0.1)
Ecchymosis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Rash pruritic	2 (<0.1)	5 (<0.1)	7 (<0.1)
Dermatitis atopic	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	2 (<0.1)	3 (<0.1)	5 (<0.1)
Eczema	3 (<0.1)	3 (<0.1)	6 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (Cont.)			
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)
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (Cont.)			
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)
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	617 (4.1)	671 (4.4)	1288 (4.2)
Myalgia	167 (1.1)	207 (1.4)	374 (1.2)
Arthralgia	181 (1.2)	200 (1.3)	381 (1.3)
Back pain	109 (0.7)	82 (0.5)	191 (0.6)
Pain in extremity	71 (0.5)	61 (0.4)	132 (0.4)
Neck pain	30 (0.2)	38 (0.3)	68 (0.2)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (Cont.)			
Muscle spasms	15 (<0.1)	32 (0.2)	47 (0.2)
Musculoskeletal pain	29 (0.2)	31 (0.2)	60 (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	13 (<0.1)	13 (<0.1)	26 (<0.1)
Arthritis	2 (<0.1)	8 (<0.1)	10 (<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)
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)	6 (<0.1)	7 (<0.1)
Joint swelling	7 (<0.1)	5 (<0.1)	12 (<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)
Limb discomfort	3 (<0.1)	4 (<0.1)	7 (<0.1)
Osteoporosis	1 (<0.1)	4 (<0.1)	5 (<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)
Flank pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Neck mass	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (Cont.)			
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	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	3 (<0.1)	2 (<0.1)	5 (<0.1)
Osteopenia	0	2 (<0.1)	2 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)	5 (<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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (Cont.)			
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)
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	42 (0.3)	40 (0.3)	82 (0.3)
Nephrolithiasis	21 (0.1)	12 (<0.1)	33 (0.1)
Dysuria	3 (<0.1)	6 (<0.1)	9 (<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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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	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)
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	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)
Reproductive system and breast disorders	39 (0.3)	50 (0.3)	89 (0.3)
Benign prostatic hyperplasia	6 (<0.1)	5 (<0.1)	11 (<0.1)
Dysmenorrhoea	3 (<0.1)	4 (<0.1)	7 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Reproductive system and breast disorders (Cont.)			
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)
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)
Adenomyosis	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 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 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Congenital, familial and genetic disorders (Cont.)			
Hydrocele	2 (<0.1)	0	2 (<0.1)
General disorders and administration site conditions	622 (4.1)	1006 (6.6)	1628 (5.4)
Fatigue	336 (2.2)	372 (2.4)	708 (2.3)
Injection site pain	54 (0.4)	151 (1.0)	205 (0.7)
Injection site erythema	20 (0.1)	127 (0.8)	147 (0.5)
Injection site swelling	15 (<0.1)	83 (0.5)	98 (0.3)
Chills	72 (0.5)	82 (0.5)	154 (0.5)
Pyrexia	46 (0.3)	82 (0.5)	128 (0.4)
Injection site pruritus	12 (<0.1)	76 (0.5)	88 (0.3)
Pain	51 (0.3)	60 (0.4)	111 (0.4)
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	12 (<0.1)	25 (0.2)	37 (0.1)
Injection site macule	2 (<0.1)	21 (0.1)	23 (<0.1)
Injection site lymphadenopathy	4 (<0.1)	17 (0.1)	21 (<0.1)
Injection site urticaria	0	15 (<0.1)	15 (<0.1)
Chest pain	8 (<0.1)	14 (<0.1)	22 (<0.1)
Chest discomfort	12 (<0.1)	13 (<0.1)	25 (<0.1)
Injection site bruising	19 (0.1)	12 (<0.1)	31 (0.1)
Malaise	9 (<0.1)	12 (<0.1)	21 (<0.1)
Swelling	1 (<0.1)	10 (<0.1)	11 (<0.1)
Injection site warmth	1 (<0.1)	8 (<0.1)	9 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 haemorrhage	2 (<0.1)	6 (<0.1)	8 (<0.1)
Oedema peripheral	4 (<0.1)	6 (<0.1)	10 (<0.1)
Peripheral swelling	10 (<0.1)	6 (<0.1)	16 (<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)
Non-cardiac chest pain	5 (<0.1)	4 (<0.1)	9 (<0.1)
Tenderness	0	4 (<0.1)	4 (<0.1)
Feeling abnormal	3 (<0.1)	3 (<0.1)	6 (<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	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)
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)
Asthenia	4 (<0.1)	1 (<0.1)	5 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
Hangover	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	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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Investigations	66 (0.4)	88 (0.6)	154 (0.5)
Blood pressure increased	24 (0.2)	24 (0.2)	48 (0.2)
Blood pressure systolic increased	11 (<0.1)	15 (0.1)	26 (<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)
Heart rate increased	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hepatic enzyme increased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Blood glucose increased	3 (<0.1)	3 (<0.1)	6 (<0.1)
Transaminases increased	0	3 (<0.1)	3 (<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)
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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Investigations (Cont.)			
Glycosylated haemoglobin increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Heart rate irregular	2 (<0.1)	1 (<0.1)	3 (<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)
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)
International normalised ratio 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)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Investigations (Cont.)			
Weight increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	318 (2.1)	280 (1.8)	598 (2.0)
Muscle strain	29 (0.2)	34 (0.2)	63 (0.2)
Ligament sprain	26 (0.2)	25 (0.2)	51 (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	27 (0.2)	18 (0.1)	45 (0.1)
Fall	17 (0.1)	14 (<0.1)	31 (0.1)
Tooth fracture	14 (<0.1)	13 (<0.1)	27 (<0.1)
Limb injury	9 (<0.1)	12 (<0.1)	21 (<0.1)
Procedural pain	20 (0.1)	12 (<0.1)	32 (0.1)
Foot fracture	10 (<0.1)	11 (<0.1)	21 (<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)	7 (<0.1)	12 (<0.1)
Animal bite	7 (<0.1)	5 (<0.1)	12 (<0.1)
Concussion	4 (<0.1)	5 (<0.1)	9 (<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)
Joint injury	5 (<0.1)	3 (<0.1)	8 (<0.1)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
Facial bones fracture	0	2 (<0.1)	2 (<0.1)
Head injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Heat exhaustion	0	2 (<0.1)	2 (<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	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 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
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)

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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\t1403010801.sas 01DEC2020 05:26

Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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 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.
MedDRA version 23.0.
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Table 14.3.1.8.1
Subject Incidence of Unsolicited 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.)			
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)
Cataract operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cholecystectomy	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 14.3.1.8.1
Subject Incidence of Unsolicited 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 (%)
Surgical and medical procedures (Cont.)			
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)
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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	2463 (21.6)	2674 (23.4)	5137 (22.5)
Number of Unsolicited Adverse Events	4603	5014	9617
Infections and infestations	579 (5.1)	475 (4.2)	1054 (4.6)
Urinary tract infection	66 (0.6)	60 (0.5)	126 (0.6)
Upper respiratory tract infection	67 (0.6)	45 (0.4)	112 (0.5)
Sinusitis	27 (0.2)	43 (0.4)	70 (0.3)
Viral infection	26 (0.2)	22 (0.2)	48 (0.2)
COVID-19	113 (1.0)	19 (0.2)	132 (0.6)
Rhinovirus infection	15 (0.1)	16 (0.1)	31 (0.1)
Tooth infection	11 (<0.1)	15 (0.1)	26 (0.1)
Pharyngitis	19 (0.2)	14 (0.1)	33 (0.1)
Tooth abscess	12 (0.1)	14 (0.1)	26 (0.1)
Ear infection	8 (<0.1)	13 (0.1)	21 (<0.1)
Herpes zoster	9 (<0.1)	13 (0.1)	22 (<0.1)
Gastroenteritis	13 (0.1)	12 (0.1)	25 (0.1)
Pharyngitis streptococcal	15 (0.1)	12 (0.1)	27 (0.1)
Conjunctivitis	6 (<0.1)	10 (<0.1)	16 (<0.1)
Cellulitis	7 (<0.1)	8 (<0.1)	15 (<0.1)
Oral herpes	5 (<0.1)	8 (<0.1)	13 (<0.1)
Otitis media	7 (<0.1)	7 (<0.1)	14 (<0.1)
Viral upper respiratory tract infection	10 (<0.1)	7 (<0.1)	17 (<0.1)
Bacterial vaginosis	5 (<0.1)	6 (<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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Folliculitis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Hordeolum	7 (<0.1)	5 (<0.1)	12 (<0.1)
Vulvovaginal mycotic infection	12 (0.1)	5 (<0.1)	17 (<0.1)
Acute sinusitis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	4 (<0.1)	6 (<0.1)
Bronchitis	6 (<0.1)	4 (<0.1)	10 (<0.1)
Diverticulitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Fungal infection	4 (<0.1)	4 (<0.1)	8 (<0.1)
Gingivitis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Herpes simplex	3 (<0.1)	4 (<0.1)	7 (<0.1)
Localised infection	5 (<0.1)	4 (<0.1)	9 (<0.1)
Otitis externa	8 (<0.1)	4 (<0.1)	12 (<0.1)
Paronychia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Pneumonia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Respiratory tract infection	3 (<0.1)	4 (<0.1)	7 (<0.1)
Vulvovaginal candidiasis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Enterovirus infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Furuncle	0	3 (<0.1)	3 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Onychomycosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Suspected COVID-19	10 (<0.1)	3 (<0.1)	13 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Impetigo	0	2 (<0.1)	2 (<0.1)
Kidney infection	0	2 (<0.1)	2 (<0.1)
Lyme disease	0	2 (<0.1)	2 (<0.1)
Nasopharyngitis	6 (<0.1)	2 (<0.1)	8 (<0.1)
Oral candidiasis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory tract infection viral	5 (<0.1)	2 (<0.1)	7 (<0.1)
Rhinitis	4 (<0.1)	2 (<0.1)	6 (<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)
Viral rhinitis	0	2 (<0.1)	2 (<0.1)
Abscess	0	1 (<0.1)	1 (<0.1)
Abscess jaw	0	1 (<0.1)	1 (<0.1)
Bacterial infection	0	1 (<0.1)	1 (<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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cystitis	5 (<0.1)	1 (<0.1)	6 (<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)
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Nail infection	0	1 (<0.1)	1 (<0.1)
Osteomyelitis	0	1 (<0.1)	1 (<0.1)
Otitis media acute	2 (<0.1)	1 (<0.1)	3 (<0.1)
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)
Proctitis chlamydial	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)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Staphylococcal infection	0	1 (<0.1)	1 (<0.1)
Tinea pedis	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Uterine infection	0	1 (<0.1)	1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
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	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)
Gastrointestinal viral infection	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)
Laryngitis	2 (<0.1)	0	2 (<0.1)
Latent tuberculosis	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Nasal abscess	1 (<0.1)	0	1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0	1 (<0.1)
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Pustule	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Pyelonephritis acute	1 (<0.1)	0	1 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Septic shock	1 (<0.1)	0	1 (<0.1)
Sialoadenitis	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)
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)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (0.1)	24 (0.2)	37 (0.2)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Squamous cell carcinoma	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 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)
Haemangioma of liver	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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Lung cancer metastatic	0	1 (<0.1)	1 (<0.1)
Malignant melanoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)	1 (<0.1)
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)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	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)
Hepatic cancer	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Squamous cell carcinoma of skin	1 (<0.1)	0	1 (<0.1)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	78 (0.7)	130 (1.1)	208 (0.9)
Lymphadenopathy	65 (0.6)	108 (0.9)	173 (0.8)
Anaemia	1 (<0.1)	9 (<0.1)	10 (<0.1)
Lymphadenitis	2 (<0.1)	8 (<0.1)	10 (<0.1)
Lymph node pain	4 (<0.1)	3 (<0.1)	7 (<0.1)
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 (%)
Blood and lymphatic system disorders (Cont.)			
Iron deficiency anaemia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Increased tendency to bruise	1 (<0.1)	0	1 (<0.1)
Leukocytosis	1 (<0.1)	0	1 (<0.1)
Immune system disorders	33 (0.3)	22 (0.2)	55 (0.2)
Seasonal allergy	20 (0.2)	17 (0.1)	37 (0.2)
Hypersensitivity	3 (<0.1)	3 (<0.1)	6 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)	2 (<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)
Drug hypersensitivity	3 (<0.1)	0	3 (<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)	7 (<0.1)	13 (<0.1)
Hypothyroidism	3 (<0.1)	6 (<0.1)	9 (<0.1)
Thyroid cyst	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	62 (0.5)	49 (0.4)	111 (0.5)
Decreased appetite	6 (<0.1)	8 (<0.1)	14 (<0.1)
Type 2 diabetes mellitus	2 (<0.1)	8 (<0.1)	10 (<0.1)
Hyperlipidaemia	10 (<0.1)	7 (<0.1)	17 (<0.1)
Vitamin D deficiency	9 (<0.1)	5 (<0.1)	14 (<0.1)
Dehydration	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypercholesterolaemia	12 (0.1)	3 (<0.1)	15 (<0.1)
Hypertriglyceridaemia	0	3 (<0.1)	3 (<0.1)
Abnormal loss of weight	0	2 (<0.1)	2 (<0.1)
Diabetes mellitus	0	2 (<0.1)	2 (<0.1)
Glucose tolerance impaired	4 (<0.1)	2 (<0.1)	6 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)	4 (<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	2 (<0.1)	1 (<0.1)	3 (<0.1)
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Abnormal weight gain	1 (<0.1)	0	1 (<0.1)
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Dyslipidaemia	3 (<0.1)	0	3 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Hyponatraemia	1 (<0.1)	0	1 (<0.1)
Increased appetite	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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	64 (0.6)	81 (0.7)	145 (0.6)
Depression	16 (0.1)	24 (0.2)	40 (0.2)
Anxiety	22 (0.2)	23 (0.2)	45 (0.2)
Insomnia	11 (<0.1)	13 (0.1)	24 (0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)	6 (<0.1)
Attention deficit hyperactivity disorder	5 (<0.1)	4 (<0.1)	9 (<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 withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	0	1 (<0.1)	1 (<0.1)
Claustrophobia	0	1 (<0.1)	1 (<0.1)
Completed suicide	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Stress	1 (<0.1)	1 (<0.1)	2 (<0.1)
Substance abuse	0	1 (<0.1)	1 (<0.1)
Alcohol abuse	1 (<0.1)	0	1 (<0.1)
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)
Nightmare	1 (<0.1)	0	1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Suicidal ideation	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	493 (4.3)	537 (4.7)	1030 (4.5)
Headache	374 (3.3)	370 (3.2)	744 (3.3)
Dizziness	34 (0.3)	49 (0.4)	83 (0.4)
Paraesthesia	22 (0.2)	23 (0.2)	45 (0.2)
Dysgeusia	3 (<0.1)	10 (<0.1)	13 (<0.1)
Migraine	15 (0.1)	10 (<0.1)	25 (0.1)
Syncope	10 (<0.1)	10 (<0.1)	20 (<0.1)
Ageusia	7 (<0.1)	9 (<0.1)	16 (<0.1)
Hypoaesthesia	5 (<0.1)	8 (<0.1)	13 (<0.1)
Sciatica	5 (<0.1)	8 (<0.1)	13 (<0.1)
Sinus headache	5 (<0.1)	7 (<0.1)	12 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Anosmia	6 (<0.1)	6 (<0.1)	12 (<0.1)
Presyncope	9 (<0.1)	6 (<0.1)	15 (<0.1)
Tension headache	3 (<0.1)	6 (<0.1)	9 (<0.1)
Hyperaesthesia	0	4 (<0.1)	4 (<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)
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)
Seizure	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)
Cerebrovascular accident	0	1 (<0.1)	1 (<0.1)
Cervical radiculopathy	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)
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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Migraine with aura	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
Neuralgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
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)
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	2 (<0.1)	0	2 (<0.1)
Dyskinesia	1 (<0.1)	0	1 (<0.1)
Facial paralysis	1 (<0.1)	0	1 (<0.1)
Head discomfort	1 (<0.1)	0	1 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Hyposmia	1 (<0.1)	0	1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	0	2 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0	1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Eye disorders	29 (0.3)	34 (0.3)	63 (0.3)
Eye pruritus	4 (<0.1)	5 (<0.1)	9 (<0.1)
Conjunctival haemorrhage	0	3 (<0.1)	3 (<0.1)
Eye irritation	0	3 (<0.1)	3 (<0.1)
Vision blurred	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lacrimation increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Blepharitis	1 (<0.1)	1 (<0.1)	2 (<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)
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)
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Ocular hyperaemia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)	2 (<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)
Eyelid ptosis	1 (<0.1)	0	1 (<0.1)
Macular degeneration	1 (<0.1)	0	1 (<0.1)
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Retinal haemorrhage	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	50 (0.4)	42 (0.4)	92 (0.4)
Ear pain	14 (0.1)	11 (<0.1)	25 (0.1)
Vertigo	9 (<0.1)	11 (<0.1)	20 (<0.1)
Tinnitus	8 (<0.1)	7 (<0.1)	15 (<0.1)
Vertigo positional	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Cerumen impaction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ear canal erythema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ear discomfort	4 (<0.1)	2 (<0.1)	6 (<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)
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	3 (<0.1)	0	3 (<0.1)
Cardiac disorders	39 (0.3)	33 (0.3)	72 (0.3)
Bradycardia	12 (0.1)	11 (<0.1)	23 (0.1)
Tachycardia	9 (<0.1)	10 (<0.1)	19 (<0.1)
Myocardial infarction	0	3 (<0.1)	3 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)	4 (<0.1)
Palpitations	5 (<0.1)	2 (<0.1)	7 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Angina pectoris	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atrial fibrillation	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Cardiac failure	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)
Arrhythmia	2 (<0.1)	0	2 (<0.1)
Atrial tachycardia	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	0	1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0	1 (<0.1)
Cardiomyopathy	1 (<0.1)	0	1 (<0.1)
Pericarditis	1 (<0.1)	0	1 (<0.1)
Vascular disorders	97 (0.8)	108 (0.9)	205 (0.9)
Hypertension	77 (0.7)	88 (0.8)	165 (0.7)
Flushing	2 (<0.1)	5 (<0.1)	7 (<0.1)
Hot flush	3 (<0.1)	4 (<0.1)	7 (<0.1)
Haematoma	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)	3 (<0.1)
Systolic hypertension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Deep vein thrombosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypotension	0	1 (<0.1)	1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)	1 (<0.1)
Peripheral coldness	0	1 (<0.1)	1 (<0.1)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Aortic aneurysm	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 stenosis	1 (<0.1)	0	1 (<0.1)
Blood pressure inadequately controlled	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	2 (<0.1)	0	2 (<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	466 (4.1)	417 (3.7)	883 (3.9)
Cough	135 (1.2)	135 (1.2)	270 (1.2)
Oropharyngeal pain	172 (1.5)	120 (1.1)	292 (1.3)
Nasal congestion	118 (1.0)	112 (1.0)	230 (1.0)
Rhinorrhoea	105 (0.9)	94 (0.8)	199 (0.9)
Dyspnoea	30 (0.3)	37 (0.3)	67 (0.3)
Tachypnoea	29 (0.3)	29 (0.3)	58 (0.3)
Sinus congestion	22 (0.2)	14 (0.1)	36 (0.2)
Throat irritation	10 (<0.1)	14 (0.1)	24 (0.1)
Epistaxis	4 (<0.1)	11 (<0.1)	15 (<0.1)
Respiratory tract congestion	8 (<0.1)	8 (<0.1)	16 (<0.1)
Upper-airway cough syndrome	8 (<0.1)	7 (<0.1)	15 (<0.1)
Asthma	10 (<0.1)	6 (<0.1)	16 (<0.1)
Rhinitis allergic	6 (<0.1)	6 (<0.1)	12 (<0.1)
Chronic obstructive pulmonary disease	5 (<0.1)	4 (<0.1)	9 (<0.1)
Productive cough	5 (<0.1)	4 (<0.1)	9 (<0.1)
Sneezing	8 (<0.1)	4 (<0.1)	12 (<0.1)
Dry throat	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Paranasal sinus discomfort	3 (<0.1)	3 (<0.1)	6 (<0.1)
Pharyngeal erythema	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dyspnoea exertional	1 (<0.1)	2 (<0.1)	3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sinus pain	3 (<0.1)	2 (<0.1)	5 (<0.1)
Wheezing	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute respiratory failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchiectasis	0	1 (<0.1)	1 (<0.1)
Dysphonia	6 (<0.1)	1 (<0.1)	7 (<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)
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 disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Respiratory failure	0	1 (<0.1)	1 (<0.1)
Respiratory symptom	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sputum increased	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Tonsillolith	3 (<0.1)	1 (<0.1)	4 (<0.1)
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
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)
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)
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)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	325 (2.8)	351 (3.1)	676 (3.0)
Diarrhoea	114 (1.0)	147 (1.3)	261 (1.1)
Nausea	103 (0.9)	83 (0.7)	186 (0.8)
Vomiting	30 (0.3)	29 (0.3)	59 (0.3)
Toothache	18 (0.2)	22 (0.2)	40 (0.2)
Gastrooesophageal reflux disease	11 (<0.1)	20 (0.2)	31 (0.1)
Abdominal pain	16 (0.1)	16 (0.1)	32 (0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Food poisoning	6 (<0.1)	9 (<0.1)	15 (<0.1)
Constipation	8 (<0.1)	8 (<0.1)	16 (<0.1)
Dental caries	6 (<0.1)	8 (<0.1)	14 (<0.1)
Abdominal pain upper	14 (0.1)	6 (<0.1)	20 (<0.1)
Dyspepsia	11 (<0.1)	5 (<0.1)	16 (<0.1)
Abdominal discomfort	4 (<0.1)	4 (<0.1)	8 (<0.1)
Abdominal pain lower	5 (<0.1)	4 (<0.1)	9 (<0.1)
Gastric ulcer	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)
Haematochezia	0	3 (<0.1)	3 (<0.1)
Haemorrhoids	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)
Hiatus hernia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hyperaesthesia teeth	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mouth ulceration	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Proctalgia	0	2 (<0.1)	2 (<0.1)
Tongue discolouration	0	2 (<0.1)	2 (<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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Diverticulum	0	1 (<0.1)	1 (<0.1)
Dry mouth	2 (<0.1)	1 (<0.1)	3 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Flatulence	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)	1 (<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)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)	1 (<0.1)
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Paraesthesia oral	3 (<0.1)	1 (<0.1)	4 (<0.1)
Peptic ulcer	0	1 (<0.1)	1 (<0.1)
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)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stomatitis	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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Tooth impacted	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dysphagia	2 (<0.1)	0	2 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Gastritis	1 (<0.1)	0	1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0	1 (<0.1)
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Gingival pain	1 (<0.1)	0	1 (<0.1)
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)
Oral pain	2 (<0.1)	0	2 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Regurgitation	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	2 (<0.1)	7 (<0.1)	9 (<0.1)
Cholelithiasis	1 (<0.1)	5 (<0.1)	6 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 (Cont.)			
Cholecystitis	0	1 (<0.1)	1 (<0.1)
Hepatic mass	0	1 (<0.1)	1 (<0.1)
Hepatic cyst	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	137 (1.2)	183 (1.6)	320 (1.4)
Rash	24 (0.2)	30 (0.3)	54 (0.2)
Pruritus	10 (<0.1)	16 (0.1)	26 (0.1)
Urticaria	14 (0.1)	16 (0.1)	30 (0.1)
Dermatitis contact	15 (0.1)	15 (0.1)	30 (0.1)
Hyperhidrosis	12 (0.1)	9 (<0.1)	21 (<0.1)
Rash maculo-papular	1 (<0.1)	9 (<0.1)	10 (<0.1)
Acne	5 (<0.1)	7 (<0.1)	12 (<0.1)
Night sweats	5 (<0.1)	7 (<0.1)	12 (<0.1)
Rash papular	3 (<0.1)	7 (<0.1)	10 (<0.1)
Alopecia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Dermatitis	3 (<0.1)	6 (<0.1)	9 (<0.1)
Erythema	3 (<0.1)	6 (<0.1)	9 (<0.1)
Ecchymosis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Rash erythematous	2 (<0.1)	5 (<0.1)	7 (<0.1)
Blister	2 (<0.1)	3 (<0.1)	5 (<0.1)
Eczema	3 (<0.1)	3 (<0.1)	6 (<0.1)
Pityriasis rosea	0	3 (<0.1)	3 (<0.1)
Psoriasis	0	3 (<0.1)	3 (<0.1)
Rash pruritic	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<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)
Rosacea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Skin lesion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Actinic keratosis	0	1 (<0.1)	1 (<0.1)
Angioedema	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cold sweat	0	1 (<0.1)	1 (<0.1)
Dermal cyst	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dermatitis atopic	5 (<0.1)	1 (<0.1)	6 (<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)
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)
Rash vesicular	0	1 (<0.1)	1 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)	1 (<0.1)
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
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)
Musculoskeletal and connective tissue disorders	439 (3.8)	482 (4.2)	921 (4.0)
Myalgia	129 (1.1)	155 (1.4)	284 (1.2)
Arthralgia	132 (1.2)	139 (1.2)	271 (1.2)
Back pain	76 (0.7)	58 (0.5)	134 (0.6)
Pain in extremity	49 (0.4)	45 (0.4)	94 (0.4)
Neck pain	21 (0.2)	29 (0.3)	50 (0.2)
Muscle spasms	9 (<0.1)	24 (0.2)	33 (0.1)
Musculoskeletal pain	22 (0.2)	23 (0.2)	45 (0.2)
Musculoskeletal chest pain	9 (<0.1)	10 (<0.1)	19 (<0.1)
Tendonitis	5 (<0.1)	10 (<0.1)	15 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Groin pain	0	6 (<0.1)	6 (<0.1)
Musculoskeletal stiffness	12 (0.1)	6 (<0.1)	18 (<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)
Osteoarthritis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Rotator cuff syndrome	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bone pain	0	4 (<0.1)	4 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	4 (<0.1)	5 (<0.1)
Pain in jaw	3 (<0.1)	4 (<0.1)	7 (<0.1)
Arthritis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Axillary mass	3 (<0.1)	3 (<0.1)	6 (<0.1)
Bursitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Costochondritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Joint swelling	7 (<0.1)	3 (<0.1)	10 (<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)
Flank pain	0	2 (<0.1)	2 (<0.1)
Muscular weakness	2 (<0.1)	2 (<0.1)	4 (<0.1)
Neck mass	0	2 (<0.1)	2 (<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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Bone lesion	0	1 (<0.1)	1 (<0.1)
Bone swelling	0	1 (<0.1)	1 (<0.1)
Floating patella	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint stiffness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Limb mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle twitching	3 (<0.1)	1 (<0.1)	4 (<0.1)
Osteopenia	0	1 (<0.1)	1 (<0.1)
Osteoporosis	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)
Temporomandibular joint syndrome	1 (<0.1)	1 (<0.1)	2 (<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	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)
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)
Spinal stenosis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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	23 (0.2)	20 (0.2)	43 (0.2)
Nephrolithiasis	14 (0.1)	6 (<0.1)	20 (<0.1)
Dysuria	2 (<0.1)	5 (<0.1)	7 (<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 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)
Bladder prolapse	1 (<0.1)	0	1 (<0.1)
Chromaturia	1 (<0.1)	0	1 (<0.1)
Haematuria	5 (<0.1)	0	5 (<0.1)
Micturition urgency	1 (<0.1)	0	1 (<0.1)
Renal colic	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 (Cont.)			
Urinary retention	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	34 (0.3)	37 (0.3)	71 (0.3)
Dysmenorrhoea	3 (<0.1)	4 (<0.1)	7 (<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)
Vaginal haemorrhage	0	2 (<0.1)	2 (<0.1)
Adnexal torsion	0	1 (<0.1)	1 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast disorder	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 mass	0	1 (<0.1)	1 (<0.1)
Perineal rash	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Benign prostatic hyperplasia	4 (<0.1)	0	4 (<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)
Oligomenorrhoea	1 (<0.1)	0	1 (<0.1)
Ovarian cyst	2 (<0.1)	0	2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)
Polycystic ovaries	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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	473 (4.1)	752 (6.6)	1225 (5.4)
Fatigue	271 (2.4)	266 (2.3)	537 (2.4)
Injection site pain	40 (0.4)	117 (1.0)	157 (0.7)
Injection site erythema	11 (<0.1)	89 (0.8)	100 (0.4)
Injection site swelling	9 (<0.1)	66 (0.6)	75 (0.3)
Pyrexia	37 (0.3)	64 (0.6)	101 (0.4)
Chills	55 (0.5)	62 (0.5)	117 (0.5)
Injection site pruritus	10 (<0.1)	55 (0.5)	65 (0.3)
Pain	39 (0.3)	49 (0.4)	88 (0.4)
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	10 (<0.1)	23 (0.2)	33 (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)
Chest pain	5 (<0.1)	12 (0.1)	17 (<0.1)
Chest discomfort	9 (<0.1)	11 (<0.1)	20 (<0.1)
Injection site urticaria	0	11 (<0.1)	11 (<0.1)
Malaise	4 (<0.1)	11 (<0.1)	15 (<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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Non-cardiac chest pain	4 (<0.1)	4 (<0.1)	8 (<0.1)
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)
Oedema peripheral	1 (<0.1)	3 (<0.1)	4 (<0.1)
Peripheral swelling	5 (<0.1)	3 (<0.1)	8 (<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	0	3 (<0.1)	3 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)	4 (<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)
Crying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)	3 (<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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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)
Asthenia	3 (<0.1)	0	3 (<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)
Medical device site inflammation	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
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	48 (0.4)	59 (0.5)	107 (0.5)
Blood pressure increased	17 (0.1)	15 (0.1)	32 (0.1)
Blood pressure systolic increased	6 (<0.1)	10 (<0.1)	16 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	7 (<0.1)	9 (<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	1 (<0.1)	2 (<0.1)	3 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 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)
Heart rate irregular	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Mammogram abnormal	0	1 (<0.1)	1 (<0.1)
Oxygen saturation decreased	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)
White blood cell count increased	0	1 (<0.1)	1 (<0.1)
Alanine aminotransferase increased	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)
C-reactive protein increased	1 (<0.1)	0	1 (<0.1)
Cardiac murmur	2 (<0.1)	0	2 (<0.1)
Glycosylated haemoglobin 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	2 (<0.1)	0	2 (<0.1)
Weight increased	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	223 (2.0)	184 (1.6)	407 (1.8)
Muscle strain	23 (0.2)	26 (0.2)	49 (0.2)
Ligament sprain	22 (0.2)	18 (0.2)	40 (0.2)
Skin laceration	23 (0.2)	15 (0.1)	38 (0.2)
Arthropod bite	20 (0.2)	12 (0.1)	32 (0.1)
Foot fracture	8 (<0.1)	8 (<0.1)	16 (<0.1)
Limb injury	6 (<0.1)	8 (<0.1)	14 (<0.1)
Contusion	19 (0.2)	7 (<0.1)	26 (0.1)
Tooth fracture	8 (<0.1)	7 (<0.1)	15 (<0.1)
Arthropod sting	7 (<0.1)	6 (<0.1)	13 (<0.1)
Skin abrasion	15 (0.1)	6 (<0.1)	21 (<0.1)
Procedural pain	13 (0.1)	5 (<0.1)	18 (<0.1)
Animal bite	5 (<0.1)	4 (<0.1)	9 (<0.1)
Concussion	3 (<0.1)	4 (<0.1)	7 (<0.1)
Road traffic accident	3 (<0.1)	4 (<0.1)	7 (<0.1)
Fall	9 (<0.1)	3 (<0.1)	12 (<0.1)
Hand fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Joint injury	4 (<0.1)	3 (<0.1)	7 (<0.1)
Meniscus injury	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)	3 (<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)
Post-traumatic pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tendon injury	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Tendon rupture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Thermal burn	1 (<0.1)	2 (<0.1)	3 (<0.1)
Upper limb fracture	0	2 (<0.1)	2 (<0.1)
Wrist fracture	0	2 (<0.1)	2 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Ankle fracture	3 (<0.1)	1 (<0.1)	4 (<0.1)
Back injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bone contusion	0	1 (<0.1)	1 (<0.1)
Bone fragmentation	0	1 (<0.1)	1 (<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	3 (<0.1)	1 (<0.1)	4 (<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)
Head injury	0	1 (<0.1)	1 (<0.1)
Hypobarism	0	1 (<0.1)	1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	0	1 (<0.1)	1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)	1 (<0.1)
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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Stab wound	0	1 (<0.1)	1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)	6 (<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)
Vaccination complication	2 (<0.1)	1 (<0.1)	3 (<0.1)
Wound	1 (<0.1)	1 (<0.1)	2 (<0.1)
Burns first degree	1 (<0.1)	0	1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0	1 (<0.1)
Eyelid contusion	1 (<0.1)	0	1 (<0.1)
Fibula fracture	1 (<0.1)	0	1 (<0.1)
Foreign body	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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	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)
Venomous sting	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	8 (<0.1)	8 (<0.1)	16 (<0.1)
Endodontic procedure	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cholecystectomy	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)
Tendon sheath incision	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 (%)
Surgical and medical procedures (Cont.)			
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)
Tooth repair	2 (<0.1)	0	2 (<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	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	814 (21.7)	958 (25.4)	1772 (23.6)
Number of Unsolicited Adverse Events	1482	1784	3266
Infections and infestations	155 (4.1)	136 (3.6)	291 (3.9)
Urinary tract infection	35 (0.9)	23 (0.6)	58 (0.8)
Sinusitis	5 (0.1)	11 (0.3)	16 (0.2)
Gingivitis	1 (<0.1)	6 (0.2)	7 (<0.1)
Herpes zoster	4 (0.1)	6 (0.2)	10 (0.1)
COVID-19	12 (0.3)	5 (0.1)	17 (0.2)
Gastroenteritis	3 (<0.1)	5 (0.1)	8 (0.1)
Cellulitis	5 (0.1)	4 (0.1)	9 (0.1)
Rhinovirus infection	0	4 (0.1)	4 (<0.1)
Tooth abscess	10 (0.3)	4 (0.1)	14 (0.2)
Tooth infection	2 (<0.1)	4 (0.1)	6 (<0.1)
Upper respiratory tract infection	7 (0.2)	4 (0.1)	11 (0.1)
Conjunctivitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Diverticulitis	4 (0.1)	3 (<0.1)	7 (<0.1)
Ear infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Enterovirus infection	0	3 (<0.1)	3 (<0.1)
Herpes simplex	0	3 (<0.1)	3 (<0.1)
Hordeolum	2 (<0.1)	3 (<0.1)	5 (<0.1)
Laryngitis	0	3 (<0.1)	3 (<0.1)
Localised infection	3 (<0.1)	3 (<0.1)	6 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Pneumonia	6 (0.2)	3 (<0.1)	9 (0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Viral infection	3 (<0.1)	3 (<0.1)	6 (<0.1)
Cystitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fungal infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Onychomycosis	0	2 (<0.1)	2 (<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)
Pharyngitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Subcutaneous abscess	0	2 (<0.1)	2 (<0.1)
Acute sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Chronic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	1 (<0.1)	1 (<0.1)
Dermatophytosis of nail	0	1 (<0.1)	1 (<0.1)
Folliculitis	3 (<0.1)	1 (<0.1)	4 (<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)
Otitis media acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Rhinitis	4 (0.1)	1 (<0.1)	5 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sialoadenitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Suspected COVID-19	0	1 (<0.1)	1 (<0.1)
Tinea pedis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Urosepsis	0	1 (<0.1)	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Viral upper respiratory tract infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	0	1 (<0.1)
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Body tinea	1 (<0.1)	0	1 (<0.1)
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
Candida 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)
Genital herpes simplex	1 (<0.1)	0	1 (<0.1)
Kidney infection	1 (<0.1)	0	1 (<0.1)
Labyrinthitis	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Nasopharyngitis	2 (<0.1)	0	2 (<0.1)
Oral candidiasis	1 (<0.1)	0	1 (<0.1)
Osteomyelitis	1 (<0.1)	0	1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	0	2 (<0.1)
Postoperative wound infection	1 (<0.1)	0	1 (<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)
Vulvovaginal mycotic infection	1 (<0.1)	0	1 (<0.1)
Wound infection	2 (<0.1)	0	2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	25 (0.7)	24 (0.6)	49 (0.7)
Basal cell carcinoma	9 (0.2)	5 (0.1)	14 (0.2)
Lipoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)	5 (<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)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	0	1 (<0.1)	1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Malignant melanoma	1 (<0.1)	1 (<0.1)	2 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Squamous cell carcinoma	6 (0.2)	1 (<0.1)	7 (<0.1)
Squamous cell carcinoma of skin	1 (<0.1)	1 (<0.1)	2 (<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)
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	11 (0.3)	24 (0.6)	35 (0.5)
Lymphadenopathy	9 (0.2)	21 (0.6)	30 (0.4)
Anaemia	0	1 (<0.1)	1 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Leukocytosis	0	1 (<0.1)	1 (<0.1)
Lymph node pain	1 (<0.1)	0	1 (<0.1)
Lymphadenitis	1 (<0.1)	0	1 (<0.1)
Immune system disorders	10 (0.3)	6 (0.2)	16 (0.2)
Hypersensitivity	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Immune system disorders (Cont.)			
Seasonal allergy	8 (0.2)	2 (<0.1)	10 (0.1)
Drug hypersensitivity	1 (<0.1)	1 (<0.1)	2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to chemicals	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	4 (0.1)	0	4 (<0.1)
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Hypothyroidism	3 (<0.1)	0	3 (<0.1)
Metabolism and nutrition disorders	18 (0.5)	31 (0.8)	49 (0.7)
Hyperlipidaemia	2 (<0.1)	9 (0.2)	11 (0.1)
Dehydration	1 (<0.1)	4 (0.1)	5 (<0.1)
Hypercholesterolaemia	1 (<0.1)	4 (0.1)	5 (<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)
Gout	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hyponatraemia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vitamin D deficiency	0	2 (<0.1)	2 (<0.1)
Diabetes mellitus	2 (<0.1)	1 (<0.1)	3 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)	2 (<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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Hyperkalaemia	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)
Psychiatric disorders	10 (0.3)	23 (0.6)	33 (0.4)
Anxiety	3 (<0.1)	7 (0.2)	10 (0.1)
Insomnia	3 (<0.1)	4 (0.1)	7 (<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)
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	129 (3.4)	147 (3.9)	276 (3.7)
Headache	84 (2.2)	96 (2.5)	180 (2.4)
Dizziness	17 (0.5)	17 (0.5)	34 (0.5)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Sinus headache	1 (<0.1)	6 (0.2)	7 (<0.1)
Paraesthesia	2 (<0.1)	5 (0.1)	7 (<0.1)
Sciatica	4 (0.1)	4 (0.1)	8 (0.1)
Cervical radiculopathy	0	3 (<0.1)	3 (<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)
Hyperaesthesia	0	2 (<0.1)	2 (<0.1)
Syncope	4 (0.1)	2 (<0.1)	6 (<0.1)
Ageusia	0	1 (<0.1)	1 (<0.1)
Amnesia	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)
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Essential tremor	0	1 (<0.1)	1 (<0.1)
Facial paralysis	0	1 (<0.1)	1 (<0.1)
Hyposmia	0	1 (<0.1)	1 (<0.1)
Migraine	3 (<0.1)	1 (<0.1)	4 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)	1 (<0.1)
Piriformis syndrome	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Tension headache	0	1 (<0.1)	1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Lumbar radiculopathy	1 (<0.1)	0	1 (<0.1)
Nerve compression	1 (<0.1)	0	1 (<0.1)
Neuralgia	2 (<0.1)	0	2 (<0.1)
Post-traumatic headache	1 (<0.1)	0	1 (<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	23 (0.6)	17 (0.5)	40 (0.5)
Eye irritation	0	2 (<0.1)	2 (<0.1)
Eye pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Eye pruritus	1 (<0.1)	2 (<0.1)	3 (<0.1)
Accommodation disorder	0	1 (<0.1)	1 (<0.1)
Cataract	0	1 (<0.1)	1 (<0.1)
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)
Glaucoma	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Eye disorders (Cont.)			
Retinal detachment	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)
Blepharitis	1 (<0.1)	0	1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0	1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Eye discharge	1 (<0.1)	0	1 (<0.1)
Macular hole	1 (<0.1)	0	1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0	1 (<0.1)
Ocular rosacea	1 (<0.1)	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Strabismus	1 (<0.1)	0	1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)
Vision blurred	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	20 (0.5)	18 (0.5)	38 (0.5)
Vertigo	7 (0.2)	6 (0.2)	13 (0.2)
Vertigo positional	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Ear and labyrinth disorders (Cont.)			
Ear pain	2 (<0.1)	2 (<0.1)	4 (<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	2 (<0.1)	0	2 (<0.1)
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Otorrhoea	1 (<0.1)	0	1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	0	2 (<0.1)
Cardiac disorders	24 (0.6)	26 (0.7)	50 (0.7)
Atrial fibrillation	6 (0.2)	8 (0.2)	14 (0.2)
Angina pectoris	1 (<0.1)	3 (<0.1)	4 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)	6 (<0.1)
Palpitations	1 (<0.1)	3 (<0.1)	4 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arrhythmia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cardiac failure congestive	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tachycardia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Bradycardia	6 (0.2)	1 (<0.1)	7 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Sinus tachycardia	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)
Extrasystoles	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	55 (1.5)	55 (1.5)	110 (1.5)
Hypertension	40 (1.1)	35 (0.9)	75 (1.0)
Hot flush	3 (<0.1)	8 (0.2)	11 (0.1)
Flushing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Systolic hypertension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Aortic aneurysm	3 (<0.1)	1 (<0.1)	4 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Haematoma	0	1 (<0.1)	1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)	1 (<0.1)
Peripheral artery occlusion	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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	117 (3.1)	119 (3.2)	236 (3.1)
Rhinorrhoea	31 (0.8)	36 (1.0)	67 (0.9)
Cough	21 (0.6)	29 (0.8)	50 (0.7)
Oropharyngeal pain	31 (0.8)	27 (0.7)	58 (0.8)
Nasal congestion	26 (0.7)	26 (0.7)	52 (0.7)
Dyspnoea	8 (0.2)	10 (0.3)	18 (0.2)
Upper-airway cough syndrome	2 (<0.1)	6 (0.2)	8 (0.1)
Asthma	1 (<0.1)	5 (0.1)	6 (<0.1)
Sneezing	1 (<0.1)	5 (0.1)	6 (<0.1)
Dysphonia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Epistaxis	5 (0.1)	3 (<0.1)	8 (0.1)
Respiratory tract congestion	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tachypnoea	3 (<0.1)	3 (<0.1)	6 (<0.1)
Chronic obstructive pulmonary disease	5 (0.1)	2 (<0.1)	7 (<0.1)
Pharyngeal erythema	2 (<0.1)	2 (<0.1)	4 (<0.1)
Sinus congestion	4 (0.1)	2 (<0.1)	6 (<0.1)
Throat irritation	3 (<0.1)	2 (<0.1)	5 (<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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Dyspnoea exertional	0	1 (<0.1)	1 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)	1 (<0.1)
Productive cough	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pulmonary embolism	0	1 (<0.1)	1 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory failure	0	1 (<0.1)	1 (<0.1)
Rhinitis allergic	4 (0.1)	1 (<0.1)	5 (<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)
Emphysema	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)
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	115 (3.1)	127 (3.4)	242 (3.2)
Diarrhoea	48 (1.3)	42 (1.1)	90 (1.2)
Nausea	22 (0.6)	34 (0.9)	56 (0.7)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Gastrooesophageal reflux disease	2 (<0.1)	13 (0.3)	15 (0.2)
Vomiting	8 (0.2)	13 (0.3)	21 (0.3)
Toothache	5 (0.1)	8 (0.2)	13 (0.2)
Dyspepsia	4 (0.1)	5 (0.1)	9 (0.1)
Abdominal pain	2 (<0.1)	4 (0.1)	6 (<0.1)
Abdominal pain upper	3 (<0.1)	4 (0.1)	7 (<0.1)
Dental caries	2 (<0.1)	4 (0.1)	6 (<0.1)
Constipation	4 (0.1)	3 (<0.1)	7 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)	2 (<0.1)
Abdominal discomfort	4 (0.1)	1 (<0.1)	5 (<0.1)
Abdominal pain lower	2 (<0.1)	1 (<0.1)	3 (<0.1)
Colitis	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)
Food poisoning	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastrointestinal haemorrhage	0	1 (<0.1)	1 (<0.1)
Haemorrhoids	0	1 (<0.1)	1 (<0.1)
Hiatus hernia	0	1 (<0.1)	1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	1 (<0.1)
Large intestine polyp	3 (<0.1)	1 (<0.1)	4 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oesophageal pain	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Paraesthesia oral	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Salivary hypersecretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stomatitis	0	1 (<0.1)	1 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Umbilical hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Volvulus	0	1 (<0.1)	1 (<0.1)
Aphthous ulcer	1 (<0.1)	0	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Gastric perforation	1 (<0.1)	0	1 (<0.1)
Gastritis	1 (<0.1)	0	1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0	1 (<0.1)
Gingival pain	2 (<0.1)	0	2 (<0.1)
Intestinal obstruction	1 (<0.1)	0	1 (<0.1)
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)
Hepatobiliary disorders	0	5 (0.1)	5 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Cholecystitis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 (Cont.)			
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Cholelithiasis	0	1 (<0.1)	1 (<0.1)
Hepatic steatosis	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	56 (1.5)	81 (2.1)	137 (1.8)
Rash	5 (0.1)	12 (0.3)	17 (0.2)
Erythema	3 (<0.1)	10 (0.3)	13 (0.2)
Urticaria	5 (0.1)	9 (0.2)	14 (0.2)
Pruritus	8 (0.2)	7 (0.2)	15 (0.2)
Dermatitis contact	11 (0.3)	5 (0.1)	16 (0.2)
Actinic keratosis	0	4 (0.1)	4 (<0.1)
Rash macular	2 (<0.1)	4 (0.1)	6 (<0.1)
Dermatitis atopic	0	3 (<0.1)	3 (<0.1)
Hyperhidrosis	2 (<0.1)	3 (<0.1)	5 (<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)
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)
Skin lesion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Ingrowing nail	0	1 (<0.1)	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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 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)
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Urticaria papular	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	178 (4.7)	189 (5.0)	367 (4.9)
Arthralgia	49 (1.3)	61 (1.6)	110 (1.5)
Myalgia	38 (1.0)	52 (1.4)	90 (1.2)
Back pain	33 (0.9)	24 (0.6)	57 (0.8)
Pain in extremity	22 (0.6)	16 (0.4)	38 (0.5)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Neck pain	9 (0.2)	9 (0.2)	18 (0.2)
Muscle spasms	6 (0.2)	8 (0.2)	14 (0.2)
Musculoskeletal pain	7 (0.2)	8 (0.2)	15 (0.2)
Musculoskeletal stiffness	1 (<0.1)	7 (0.2)	8 (0.1)
Arthritis	0	5 (0.1)	5 (<0.1)
Bursitis	1 (<0.1)	5 (0.1)	6 (<0.1)
Tendonitis	5 (0.1)	4 (0.1)	9 (0.1)
Muscular weakness	0	3 (<0.1)	3 (<0.1)
Musculoskeletal chest pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Osteoporosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Spinal stenosis	0	3 (<0.1)	3 (<0.1)
Joint swelling	0	2 (<0.1)	2 (<0.1)
Osteoarthritis	8 (0.2)	2 (<0.1)	10 (0.1)
Rotator cuff syndrome	4 (0.1)	2 (<0.1)	6 (<0.1)
Trigger finger	1 (<0.1)	2 (<0.1)	3 (<0.1)
Costochondritis	0	1 (<0.1)	1 (<0.1)
Flank pain	1 (<0.1)	1 (<0.1)	2 (<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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Muscle twitching	0	1 (<0.1)	1 (<0.1)
Neck mass	0	1 (<0.1)	1 (<0.1)
Osteopenia	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
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)
Bone lesion	1 (<0.1)	0	1 (<0.1)
Fibromyalgia	1 (<0.1)	0	1 (<0.1)
Foot deformity	2 (<0.1)	0	2 (<0.1)
Groin pain	1 (<0.1)	0	1 (<0.1)
Limb mass	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	19 (0.5)	20 (0.5)	39 (0.5)
Nephrolithiasis	7 (0.2)	6 (0.2)	13 (0.2)
Pollakiuria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematuria	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bladder diverticulum	0	1 (<0.1)	1 (<0.1)
Chronic kidney disease	0	1 (<0.1)	1 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
Dysuria	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Urinary incontinence	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urinary retention	1 (<0.1)	1 (<0.1)	2 (<0.1)
Acute kidney injury	2 (<0.1)	0	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)	13 (0.3)	18 (0.2)
Benign prostatic hyperplasia	2 (<0.1)	5 (0.1)	7 (<0.1)
Erectile dysfunction	0	2 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Breast discharge	0	1 (<0.1)	1 (<0.1)
Breast mass	0	1 (<0.1)	1 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Ovarian cyst	0	1 (<0.1)	1 (<0.1)
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Prostatitis	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)			
Prostatomegaly	2 (<0.1)	0	2 (<0.1)
General disorders and administration site conditions	149 (4.0)	254 (6.7)	403 (5.4)
Fatigue	65 (1.7)	106 (2.8)	171 (2.3)
Injection site erythema	9 (0.2)	38 (1.0)	47 (0.6)
Injection site pain	14 (0.4)	34 (0.9)	48 (0.6)
Injection site pruritus	2 (<0.1)	21 (0.6)	23 (0.3)
Chills	17 (0.5)	20 (0.5)	37 (0.5)
Pyrexia	9 (0.2)	18 (0.5)	27 (0.4)
Injection site swelling	6 (0.2)	17 (0.5)	23 (0.3)
Pain	12 (0.3)	11 (0.3)	23 (0.3)
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)
Injection site urticaria	0	4 (0.1)	4 (<0.1)
Injection site bruising	8 (0.2)	3 (<0.1)	11 (0.1)
Oedema peripheral	3 (<0.1)	3 (<0.1)	6 (<0.1)
Peripheral swelling	5 (0.1)	3 (<0.1)	8 (0.1)
Axillary pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Chest discomfort	3 (<0.1)	2 (<0.1)	5 (<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 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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)
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)
Swelling	0	1 (<0.1)	1 (<0.1)
Temperature intolerance	0	1 (<0.1)	1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Vaccination site pain	0	1 (<0.1)	1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)	1 (<0.1)
Facial pain	1 (<0.1)	0	1 (<0.1)
Gait disturbance	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)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3750) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)			
Injection site haematoma	1 (<0.1)	0	1 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	0	1 (<0.1)
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Thirst	1 (<0.1)	0	1 (<0.1)
Vaccination site inflammation	1 (<0.1)	0	1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	0	1 (<0.1)
Investigations	18 (0.5)	29 (0.8)	47 (0.6)
Blood pressure increased	7 (0.2)	9 (0.2)	16 (0.2)
Blood pressure systolic increased	5 (0.1)	5 (0.1)	10 (0.1)
Blood pressure diastolic increased	0	2 (<0.1)	2 (<0.1)
Blood creatine increased	0	1 (<0.1)	1 (<0.1)
Blood creatinine increased	0	1 (<0.1)	1 (<0.1)
Blood glucose decreased	0	1 (<0.1)	1 (<0.1)
Blood glucose increased	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)
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	0	1 (<0.1)	1 (<0.1)
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)
Heart rate increased	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Weight decreased	0	1 (<0.1)	1 (<0.1)
Blood cholesterol increased	1 (<0.1)	0	1 (<0.1)
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	95 (2.5)	96 (2.5)	191 (2.5)
Contusion	8 (0.2)	11 (0.3)	19 (0.3)
Fall	8 (0.2)	11 (0.3)	19 (0.3)
Arthropod bite	6 (0.2)	9 (0.2)	15 (0.2)
Muscle strain	6 (0.2)	8 (0.2)	14 (0.2)
Skin laceration	5 (0.1)	8 (0.2)	13 (0.2)
Ligament sprain	4 (0.1)	7 (0.2)	11 (0.1)
Procedural pain	7 (0.2)	7 (0.2)	14 (0.2)
Tooth fracture	6 (0.2)	6 (0.2)	12 (0.2)
Limb injury	3 (<0.1)	4 (0.1)	7 (<0.1)
Foot fracture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Rib fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Road traffic accident	2 (<0.1)	3 (<0.1)	5 (<0.1)
Skin abrasion	6 (0.2)	3 (<0.1)	9 (0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Facial bones fracture	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Hand fracture	0	2 (<0.1)	2 (<0.1)
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Animal bite	2 (<0.1)	1 (<0.1)	3 (<0.1)
Animal scratch	0	1 (<0.1)	1 (<0.1)
Arthropod sting	8 (0.2)	1 (<0.1)	9 (0.1)
Back injury	0	1 (<0.1)	1 (<0.1)
Bone contusion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Burns first degree	0	1 (<0.1)	1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Craniocerebral injury	0	1 (<0.1)	1 (<0.1)
Epicondylitis	0	1 (<0.1)	1 (<0.1)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
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)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Muscle rupture	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Post-traumatic pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Scratch	0	1 (<0.1)	1 (<0.1)
Spinal compression fracture	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thermal burn	0	1 (<0.1)	1 (<0.1)
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Ankle fracture	1 (<0.1)	0	1 (<0.1)
Buttock 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	1 (<0.1)	0	1 (<0.1)
Foreign body in ear	1 (<0.1)	0	1 (<0.1)
Humerus fracture	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)
Lip injury	1 (<0.1)	0	1 (<0.1)
Lumbar vertebral fracture	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)
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)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Wound	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	4 (0.1)	4 (0.1)	8 (0.1)
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)
Skin operation	0	1 (<0.1)	1 (<0.1)
Carpal tunnel decompression	1 (<0.1)	0	1 (<0.1)
Hip arthroplasty	1 (<0.1)	0	1 (<0.1)
Tooth extraction	1 (<0.1)	0	1 (<0.1)
Tooth repair	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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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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	686 (4.5)	1242 (8.2)	1928 (6.4)
Number of Unsolicited Adverse Events	1137	2063	3200
Infections and infestations	17 (0.1)	14 (<0.1)	31 (0.1)
Conjunctivitis	0	2 (<0.1)	2 (<0.1)
Injection site cellulitis	0	2 (<0.1)	2 (<0.1)
Viral infection	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)
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)
Tinea pedis	1 (<0.1)	0	1 (<0.1)
Upper respiratory tract infection	7 (<0.1)	0	7 (<0.1)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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.)			
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	54 (0.4)	99 (0.7)	153 (0.5)
Lymphadenopathy	48 (0.3)	91 (0.6)	139 (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)
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)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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 (Cont.)			
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	182 (1.2)	286 (1.9)	468 (1.5)
Headache	143 (0.9)	211 (1.4)	354 (1.2)
Dizziness	13 (<0.1)	27 (0.2)	40 (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)
Ageusia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Disturbance in attention	1 (<0.1)	2 (<0.1)	3 (<0.1)
Somnolence	0	2 (<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)
Burning sensation	0	1 (<0.1)	1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	1 (<0.1)
Essential tremor	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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.)			
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Mental impairment	0	1 (<0.1)	1 (<0.1)
Migraine	6 (<0.1)	1 (<0.1)	7 (<0.1)
Movement disorder	0	1 (<0.1)	1 (<0.1)
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)
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)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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 (%)
Eye disorders (Cont.)			
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)	7 (<0.1)	12 (<0.1)
Tachycardia	0	4 (<0.1)	4 (<0.1)
Sinus tachycardia	0	2 (<0.1)	2 (<0.1)
Angina pectoris	0	1 (<0.1)	1 (<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)
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)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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.)			
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)	54 (0.4)	96 (0.3)
Nasal congestion	9 (<0.1)	20 (0.1)	29 (<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)
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)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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	83 (0.5)	87 (0.6)	170 (0.6)
Diarrhoea	30 (0.2)	40 (0.3)	70 (0.2)
Nausea	40 (0.3)	31 (0.2)	71 (0.2)
Vomiting	5 (<0.1)	7 (<0.1)	12 (<0.1)
Abdominal pain	2 (<0.1)	6 (<0.1)	8 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Dyspepsia	2 (<0.1)	2 (<0.1)	4 (<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)
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	4 (<0.1)	0	4 (<0.1)
Salivary hypersecretion	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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	35 (0.2)	88 (0.6)	123 (0.4)
Urticaria	5 (<0.1)	18 (0.1)	23 (<0.1)
Rash	4 (<0.1)	15 (<0.1)	19 (<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)
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)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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 (Cont.)			
Skin discolouration	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	161 (1.1)	231 (1.5)	392 (1.3)
Myalgia	77 (0.5)	121 (0.8)	198 (0.7)
Arthralgia	90 (0.6)	97 (0.6)	187 (0.6)
Pain in extremity	12 (<0.1)	17 (0.1)	29 (<0.1)
Back pain	4 (<0.1)	9 (<0.1)	13 (<0.1)
Neck pain	1 (<0.1)	9 (<0.1)	10 (<0.1)
Musculoskeletal pain	6 (<0.1)	6 (<0.1)	12 (<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)
Limb discomfort	1 (<0.1)	3 (<0.1)	4 (<0.1)
Musculoskeletal stiffness	3 (<0.1)	3 (<0.1)	6 (<0.1)
Axillary mass	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bone pain	0	2 (<0.1)	2 (<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)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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 (Cont.)			
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)
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	313 (2.1)	681 (4.5)	994 (3.3)
Fatigue	178 (1.2)	222 (1.5)	400 (1.3)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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 pain	38 (0.3)	120 (0.8)	158 (0.5)
Injection site erythema	18 (0.1)	116 (0.8)	134 (0.4)
Injection site swelling	15 (<0.1)	75 (0.5)	90 (0.3)
Injection site pruritus	11 (<0.1)	63 (0.4)	74 (0.2)
Chills	18 (0.1)	46 (0.3)	64 (0.2)
Pyrexia	12 (<0.1)	44 (0.3)	56 (0.2)
Injection site rash	1 (<0.1)	32 (0.2)	33 (0.1)
Injection site induration	7 (<0.1)	30 (0.2)	37 (0.1)
Pain	8 (<0.1)	24 (0.2)	32 (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)	16 (0.1)	19 (<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)
Vaccination site lymphadenopathy	0	6 (<0.1)	6 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)	6 (<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)
Injection site haemorrhage	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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.)			
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)
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)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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.)			
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)
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)

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related 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.)			
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)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	526 (4.6)	938 (8.2)	1464 (6.4)
Number of Unsolicited Adverse Events	859	1562	2421
Infections and infestations	13 (0.1)	9 (<0.1)	22 (<0.1)
Injection site cellulitis	0	2 (<0.1)	2 (<0.1)
Viral infection	0	2 (<0.1)	2 (<0.1)
Conjunctivitis	0	1 (<0.1)	1 (<0.1)
Ear infection	0	1 (<0.1)	1 (<0.1)
Oral herpes	0	1 (<0.1)	1 (<0.1)
Respiratory tract infection viral	0	1 (<0.1)	1 (<0.1)
Sinusitis	0	1 (<0.1)	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	1 (<0.1)	0	1 (<0.1)
Tinea pedis	1 (<0.1)	0	1 (<0.1)
Upper respiratory tract infection	6 (<0.1)	0	6 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 (%)
Blood and lymphatic system disorders	49 (0.4)	88 (0.8)	137 (0.6)
Lymphadenopathy	44 (0.4)	80 (0.7)	124 (0.5)
Lymphadenitis	2 (<0.1)	7 (<0.1)	9 (<0.1)
Lymph node pain	4 (<0.1)	2 (<0.1)	6 (<0.1)
Anaemia	0	1 (<0.1)	1 (<0.1)
Immune system disorders	2 (<0.1)	1 (<0.1)	3 (<0.1)
Seasonal allergy	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)
Psychiatric disorders	0	9 (<0.1)	9 (<0.1)
Insomnia	0	4 (<0.1)	4 (<0.1)
Abnormal dreams	0	3 (<0.1)	3 (<0.1)
Affect lability	0	1 (<0.1)	1 (<0.1)
Anxiety	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Sleep disorder	0	1 (<0.1)	1 (<0.1)
Nervous system disorders	144 (1.3)	223 (2.0)	367 (1.6)
Headache	115 (1.0)	163 (1.4)	278 (1.2)
Dizziness	9 (<0.1)	18 (0.2)	27 (0.1)
Paraesthesia	7 (<0.1)	11 (<0.1)	18 (<0.1)
Dysgeusia	3 (<0.1)	9 (<0.1)	12 (<0.1)
Hyperaesthesia	0	4 (<0.1)	4 (<0.1)
Syncope	0	3 (<0.1)	3 (<0.1)
Ageusia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Disturbance in attention	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypoaesthesia	0	2 (<0.1)	2 (<0.1)
Somnolence	0	2 (<0.1)	2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Burning sensation	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)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Presyncope	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sciatica	1 (<0.1)	1 (<0.1)	2 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anosmia	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)
Eye disorders	3 (<0.1)	4 (<0.1)	7 (<0.1)
Blepharospasm	0	1 (<0.1)	1 (<0.1)
Vision blurred	0	1 (<0.1)	1 (<0.1)
Visual impairment	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	2 (<0.1)	6 (<0.1)	8 (<0.1)
Tinnitus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vertigo	0	2 (<0.1)	2 (<0.1)
Ear discomfort	0	1 (<0.1)	1 (<0.1)
Ear pain	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	2 (<0.1)	6 (<0.1)	8 (<0.1)
Tachycardia	0	4 (<0.1)	4 (<0.1)
Angina pectoris	0	1 (<0.1)	1 (<0.1)
Sinus tachycardia	0	1 (<0.1)	1 (<0.1)
Arrhythmia	1 (<0.1)	0	1 (<0.1)
Palpitations	1 (<0.1)	0	1 (<0.1)
Vascular disorders	8 (<0.1)	12 (0.1)	20 (<0.1)
Flushing	1 (<0.1)	4 (<0.1)	5 (<0.1)
Hot flush	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hypertension	6 (<0.1)	3 (<0.1)	9 (<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	30 (0.3)	47 (0.4)	77 (0.3)
Nasal congestion	5 (<0.1)	18 (0.2)	23 (0.1)
Cough	4 (<0.1)	12 (0.1)	16 (<0.1)
Rhinorrhoea	4 (<0.1)	9 (<0.1)	13 (<0.1)
Oropharyngeal pain	12 (0.1)	7 (<0.1)	19 (<0.1)
Dyspnoea	2 (<0.1)	5 (<0.1)	7 (<0.1)
Throat irritation	2 (<0.1)	4 (<0.1)	6 (<0.1)
Sinus congestion	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asthma	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Dysphonia	1 (<0.1)	0	1 (<0.1)
Pleurisy	1 (<0.1)	0	1 (<0.1)
Pleuritic pain	1 (<0.1)	0	1 (<0.1)
Productive cough	1 (<0.1)	0	1 (<0.1)
Pulmonary embolism	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	60 (0.5)	66 (0.6)	126 (0.6)
Diarrhoea	18 (0.2)	31 (0.3)	49 (0.2)
Nausea	32 (0.3)	24 (0.2)	56 (0.2)
Vomiting	5 (<0.1)	5 (<0.1)	10 (<0.1)
Abdominal pain	2 (<0.1)	4 (<0.1)	6 (<0.1)
Chapped lips	0	2 (<0.1)	2 (<0.1)
Gastrooesophageal reflux disease	0	2 (<0.1)	2 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	2 (<0.1)	3 (<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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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Aphthous ulcer	0	1 (<0.1)	1 (<0.1)
Dry mouth	0	1 (<0.1)	1 (<0.1)
Dyspepsia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lip swelling	0	1 (<0.1)	1 (<0.1)
Mouth ulceration	0	1 (<0.1)	1 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Abdominal pain upper	2 (<0.1)	0	2 (<0.1)
Dysphagia	1 (<0.1)	0	1 (<0.1)
Gingival discomfort	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)
Skin and subcutaneous tissue disorders	27 (0.2)	62 (0.5)	89 (0.4)
Rash	4 (<0.1)	12 (0.1)	16 (<0.1)
Urticaria	4 (<0.1)	12 (0.1)	16 (<0.1)
Erythema	0	5 (<0.1)	5 (<0.1)
Night sweats	2 (<0.1)	5 (<0.1)	7 (<0.1)
Pruritus	6 (<0.1)	5 (<0.1)	11 (<0.1)
Rash maculo-papular	0	5 (<0.1)	5 (<0.1)
Hyperhidrosis	7 (<0.1)	4 (<0.1)	11 (<0.1)
Skin burning sensation	0	3 (<0.1)	3 (<0.1)
Alopecia	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Ecchymosis	0	1 (<0.1)	1 (<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)
Rash macular	0	1 (<0.1)	1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin warm	0	1 (<0.1)	1 (<0.1)
Dermatitis bullous	1 (<0.1)	0	1 (<0.1)
Dermatitis contact	1 (<0.1)	0	1 (<0.1)
Skin discolouration	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	120 (1.1)	169 (1.5)	289 (1.3)
Myalgia	57 (0.5)	87 (0.8)	144 (0.6)
Arthralgia	70 (0.6)	70 (0.6)	140 (0.6)
Pain in extremity	7 (<0.1)	13 (0.1)	20 (<0.1)
Neck pain	1 (<0.1)	8 (<0.1)	9 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Back pain	3 (<0.1)	6 (<0.1)	9 (<0.1)
Musculoskeletal pain	5 (<0.1)	6 (<0.1)	11 (<0.1)
Joint range of motion decreased	0	4 (<0.1)	4 (<0.1)
Limb discomfort	1 (<0.1)	3 (<0.1)	4 (<0.1)
Muscle spasms	3 (<0.1)	3 (<0.1)	6 (<0.1)
Musculoskeletal stiffness	2 (<0.1)	3 (<0.1)	5 (<0.1)
Axillary mass	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bone pain	0	2 (<0.1)	2 (<0.1)
Tendonitis	0	2 (<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)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neck mass	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)
Temporomandibular joint syndrome	0	1 (<0.1)	1 (<0.1)
Arthritis	1 (<0.1)	0	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)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Muscular weakness	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	4 (<0.1)	3 (<0.1)	7 (<0.1)
Menorrhagia	0	2 (<0.1)	2 (<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	240 (2.1)	511 (4.5)	751 (3.3)
Fatigue	144 (1.3)	157 (1.4)	301 (1.3)
Injection site pain	29 (0.3)	95 (0.8)	124 (0.5)
Injection site erythema	10 (<0.1)	80 (0.7)	90 (0.4)
Injection site swelling	9 (<0.1)	60 (0.5)	69 (0.3)
Injection site pruritus	9 (<0.1)	45 (0.4)	54 (0.2)
Chills	12 (0.1)	37 (0.3)	49 (0.2)
Pyrexia	9 (<0.1)	33 (0.3)	42 (0.2)
Injection site induration	4 (<0.1)	25 (0.2)	29 (0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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 rash	1 (<0.1)	24 (0.2)	25 (0.1)
Pain	6 (<0.1)	18 (0.2)	24 (0.1)
Axillary pain	3 (<0.1)	17 (0.1)	20 (<0.1)
Injection site lymphadenopathy	3 (<0.1)	15 (0.1)	18 (<0.1)
Injection site macule	2 (<0.1)	11 (<0.1)	13 (<0.1)
Injection site urticaria	0	8 (<0.1)	8 (<0.1)
Malaise	2 (<0.1)	7 (<0.1)	9 (<0.1)
Swelling	1 (<0.1)	7 (<0.1)	8 (<0.1)
Vaccination site lymphadenopathy	0	5 (<0.1)	5 (<0.1)
Chest discomfort	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)
Injection site warmth	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)
Chest pain	0	2 (<0.1)	2 (<0.1)
Induration	0	2 (<0.1)	2 (<0.1)
Injection site bruising	6 (<0.1)	2 (<0.1)	8 (<0.1)
Injection site haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Peripheral swelling	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
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)
Injection site haematoma	0	1 (<0.1)	1 (<0.1)
Injection site joint pain	0	1 (<0.1)	1 (<0.1)
Injection site mass	0	1 (<0.1)	1 (<0.1)
Injection site papule	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site paraesthesia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injection site scab	0	1 (<0.1)	1 (<0.1)
Non-cardiac chest pain	0	1 (<0.1)	1 (<0.1)
Reactogenicity event	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vaccination site induration	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	3 (<0.1)	0	3 (<0.1)
Discomfort	1 (<0.1)	0	1 (<0.1)
Feeling hot	2 (<0.1)	0	2 (<0.1)
Injection site discomfort	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)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	3 (<0.1)	10 (<0.1)	13 (<0.1)
Blood pressure increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Body temperature increased	0	3 (<0.1)	3 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)	1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)	1 (<0.1)
Heart rate increased	0	1 (<0.1)	1 (<0.1)
Heart rate irregular	0	1 (<0.1)	1 (<0.1)
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	6 (<0.1)	4 (<0.1)	10 (<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)
Vaccination complication	1 (<0.1)	1 (<0.1)	2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Tooth fracture	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	160 (4.3)	304 (8.1)	464 (6.2)
Number of Unsolicited Adverse Events	278	501	779
Infections and infestations	4 (0.1)	5 (0.1)	9 (0.1)
COVID-19	0	1 (<0.1)	1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)	1 (<0.1)
Conjunctivitis	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)
Cellulitis	1 (<0.1)	0	1 (<0.1)
Oral herpes	1 (<0.1)	0	1 (<0.1)
Rhinitis	1 (<0.1)	0	1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	5 (0.1)	11 (0.3)	16 (0.2)
Lymphadenopathy	4 (0.1)	11 (0.3)	15 (0.2)
Lymph node pain	1 (<0.1)	0	1 (<0.1)
Immune system disorders	0	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	0	5 (0.1)	5 (<0.1)
Depressed mood	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Insomnia	0	1 (<0.1)	1 (<0.1)
Nightmare	0	1 (<0.1)	1 (<0.1)
Sleep disorder	0	1 (<0.1)	1 (<0.1)
Suicidal ideation	0	1 (<0.1)	1 (<0.1)
Nervous system disorders	38 (1.0)	63 (1.7)	101 (1.3)
Headache	28 (0.7)	48 (1.3)	76 (1.0)
Dizziness	4 (0.1)	9 (0.2)	13 (0.2)
Hypoaesthesia	0	2 (<0.1)	2 (<0.1)
Balance disorder	0	1 (<0.1)	1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	1 (<0.1)
Dysgeusia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Essential tremor	0	1 (<0.1)	1 (<0.1)
Hyperaesthesia	0	1 (<0.1)	1 (<0.1)
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Sinus headache	0	1 (<0.1)	1 (<0.1)
Dysaesthesia	1 (<0.1)	0	1 (<0.1)
Migraine	1 (<0.1)	0	1 (<0.1)
Taste disorder	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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	0	2 (<0.1)	2 (<0.1)
Eye irritation	0	1 (<0.1)	1 (<0.1)
Visual impairment	0	1 (<0.1)	1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tinnitus	0	2 (<0.1)	2 (<0.1)
Vertigo positional	0	1 (<0.1)	1 (<0.1)
Vertigo	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	3 (<0.1)	1 (<0.1)	4 (<0.1)
Sinus tachycardia	0	1 (<0.1)	1 (<0.1)
Atrial fibrillation	1 (<0.1)	0	1 (<0.1)
Bradycardia	1 (<0.1)	0	1 (<0.1)
Palpitations	1 (<0.1)	0	1 (<0.1)
Vascular disorders	8 (0.2)	9 (0.2)	17 (0.2)
Hypertension	7 (0.2)	5 (0.1)	12 (0.2)
Flushing	0	2 (<0.1)	2 (<0.1)
Hot flush	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory, thoracic and mediastinal disorders	12 (0.3)	7 (0.2)	19 (0.3)
Oropharyngeal pain	4 (0.1)	4 (0.1)	8 (0.1)
Rhinorrhoea	6 (0.2)	3 (<0.1)	9 (0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Nasal congestion	4 (0.1)	2 (<0.1)	6 (<0.1)
Cough	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dyspnoea	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dysphonia	1 (<0.1)	0	1 (<0.1)
Productive cough	1 (<0.1)	0	1 (<0.1)
Tachypnoea	1 (<0.1)	0	1 (<0.1)
Throat irritation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	23 (0.6)	21 (0.6)	44 (0.6)
Diarrhoea	12 (0.3)	9 (0.2)	21 (0.3)
Nausea	8 (0.2)	7 (0.2)	15 (0.2)
Abdominal pain	0	2 (<0.1)	2 (<0.1)
Vomiting	0	2 (<0.1)	2 (<0.1)
Abdominal pain upper	0	1 (<0.1)	1 (<0.1)
Dyspepsia	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)	1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Gingival pain	1 (<0.1)	0	1 (<0.1)
Paraesthesia oral	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Salivary hypersecretion	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	8 (0.2)	26 (0.7)	34 (0.5)
Urticaria	1 (<0.1)	6 (0.2)	7 (<0.1)
Erythema	0	4 (0.1)	4 (<0.1)
Hyperhidrosis	0	3 (<0.1)	3 (<0.1)
Pruritus	3 (<0.1)	3 (<0.1)	6 (<0.1)
Rash	0	3 (<0.1)	3 (<0.1)
Rash macular	0	2 (<0.1)	2 (<0.1)
Rash pruritic	0	2 (<0.1)	2 (<0.1)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Night sweats	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rash maculo-papular	0	1 (<0.1)	1 (<0.1)
Dermatitis contact	1 (<0.1)	0	1 (<0.1)
Ecchymosis	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	41 (1.1)	62 (1.6)	103 (1.4)
Myalgia	20 (0.5)	34 (0.9)	54 (0.7)
Arthralgia	20 (0.5)	27 (0.7)	47 (0.6)
Pain in extremity	5 (0.1)	4 (0.1)	9 (0.1)
Back pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Muscle spasms	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Muscular weakness	0	2 (<0.1)	2 (<0.1)
Arthritis	0	1 (<0.1)	1 (<0.1)
Flank pain	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)
Neck pain	0	1 (<0.1)	1 (<0.1)
Osteoarthritis	0	1 (<0.1)	1 (<0.1)
Musculoskeletal pain	1 (<0.1)	0	1 (<0.1)
Musculoskeletal stiffness	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)	1 (<0.1)
Erectile dysfunction	0	1 (<0.1)	1 (<0.1)
General disorders and administration site conditions	73 (1.9)	170 (4.5)	243 (3.2)
Fatigue	34 (0.9)	65 (1.7)	99 (1.3)
Injection site erythema	8 (0.2)	36 (1.0)	44 (0.6)
Injection site pain	9 (0.2)	25 (0.7)	34 (0.5)
Injection site pruritus	2 (<0.1)	18 (0.5)	20 (0.3)
Injection site swelling	6 (0.2)	15 (0.4)	21 (0.3)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Pyrexia	3 (<0.1)	11 (0.3)	14 (0.2)
Chills	6 (0.2)	9 (0.2)	15 (0.2)
Injection site rash	0	8 (0.2)	8 (0.1)
Injection site macule	0	7 (0.2)	7 (<0.1)
Pain	2 (<0.1)	6 (0.2)	8 (0.1)
Injection site induration	3 (<0.1)	5 (0.1)	8 (0.1)
Injection site urticaria	0	4 (0.1)	4 (<0.1)
Axillary pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site warmth	0	2 (<0.1)	2 (<0.1)
Chest pain	0	1 (<0.1)	1 (<0.1)
Feeling hot	0	1 (<0.1)	1 (<0.1)
Injection site bruising	4 (0.1)	1 (<0.1)	5 (<0.1)
Injection site discolouration	0	1 (<0.1)	1 (<0.1)
Injection site haemorrhage	0	1 (<0.1)	1 (<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 lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site reaction	0	1 (<0.1)	1 (<0.1)
Oedema peripheral	0	1 (<0.1)	1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
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.)			
Vaccination site pain	0	1 (<0.1)	1 (<0.1)
Asthenia	1 (<0.1)	0	1 (<0.1)
Injection site haematoma	1 (<0.1)	0	1 (<0.1)
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Injection site paraesthesia	1 (<0.1)	0	1 (<0.1)
Malaise	2 (<0.1)	0	2 (<0.1)
Peripheral swelling	1 (<0.1)	0	1 (<0.1)
Investigations	2 (<0.1)	5 (0.1)	7 (<0.1)
Blood pressure increased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)	1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)	1 (<0.1)
Heart rate increased	0	1 (<0.1)	1 (<0.1)
Blood glucose increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tooth fracture	0	1 (<0.1)	1 (<0.1)
Fall	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011102.sas 01DEC2020 04:43

Table 14.3.1.13.3
Subject Incidence of Serious 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	153 (1.0)	147 (1.0)	300 (1.0)
Number of Unsolicited Adverse Events	211	207	418
Infections and infestations	35 (0.2)	20 (0.1)	55 (0.2)
Pneumonia	7 (<0.1)	5 (<0.1)	12 (<0.1)
Appendicitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Bronchitis	0	1 (<0.1)	1 (<0.1)
COVID-19	15 (<0.1)	1 (<0.1)	16 (<0.1)
Cellulitis	0	1 (<0.1)	1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)	1 (<0.1)
Gastroenteritis	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)
Postoperative abscess	0	1 (<0.1)	1 (<0.1)
Postoperative wound infection	0	1 (<0.1)	1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Salpingitis	0	1 (<0.1)	1 (<0.1)
Sepsis	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)
Viral pharyngitis	0	1 (<0.1)	1 (<0.1)
Wound infection	0	1 (<0.1)	1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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.)			
Clostridium difficile colitis	1 (<0.1)	0	1 (<0.1)
Diverticulitis	2 (<0.1)	0	2 (<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	4 (<0.1)	0	4 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (<0.1)	15 (<0.1)	25 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)	6 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Chronic lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Colorectal cancer	0	1 (<0.1)	1 (<0.1)
Gastric 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)
Meningioma	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)
Renal cancer	0	1 (<0.1)	1 (<0.1)
Renal cell carcinoma	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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 stage I	1 (<0.1)	0	1 (<0.1)
Colon cancer stage III	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	2 (<0.1)	0	2 (<0.1)
Leiomyosarcoma metastatic	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)
Blood and lymphatic system disorders	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Anaemia	2 (<0.1)	0	2 (<0.1)
Endocrine disorders	0	1 (<0.1)	1 (<0.1)
Thyroid disorder	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	7 (<0.1)	4 (<0.1)	11 (<0.1)
Dehydration	3 (<0.1)	3 (<0.1)	6 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)	1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyponatraemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gout	1 (<0.1)	0	1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Metabolic acidosis	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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	9 (<0.1)	4 (<0.1)	13 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Alcohol withdrawal syndrome	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)
Schizoaffective disorder	0	1 (<0.1)	1 (<0.1)
Anxiety	1 (<0.1)	0	1 (<0.1)
Anxiety disorder	1 (<0.1)	0	1 (<0.1)
Confusional state	2 (<0.1)	0	2 (<0.1)
Depression	3 (<0.1)	0	3 (<0.1)
Major depression	2 (<0.1)	0	2 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	10 (<0.1)	16 (0.1)	26 (<0.1)
Cerebrovascular accident	1 (<0.1)	3 (<0.1)	4 (<0.1)
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Seizure	0	2 (<0.1)	2 (<0.1)
Syncope	4 (<0.1)	2 (<0.1)	6 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	1 (<0.1)
Dizziness	0	1 (<0.1)	1 (<0.1)
Facial paralysis	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)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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.)			
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)
Multiple sclerosis	1 (<0.1)	0	1 (<0.1)
Paraesthesia	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Eye disorders	1 (<0.1)	0	1 (<0.1)
Retinal detachment	1 (<0.1)	0	1 (<0.1)
Retinal tear	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	24 (0.2)	22 (0.1)	46 (0.2)
Atrial fibrillation	5 (<0.1)	5 (<0.1)	10 (<0.1)
Myocardial infarction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Cardiac failure congestive	3 (<0.1)	3 (<0.1)	6 (<0.1)
Acute coronary syndrome	0	2 (<0.1)	2 (<0.1)
Acute myocardial infarction	4 (<0.1)	2 (<0.1)	6 (<0.1)
Coronary artery disease	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bradycardia	1 (<0.1)	1 (<0.1)	2 (<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)
Coronary artery thrombosis	0	1 (<0.1)	1 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)	3 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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.)			
Atrial flutter	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	1 (<0.1)	0	1 (<0.1)
Tachycardia	1 (<0.1)	0	1 (<0.1)
Vascular disorders	10 (<0.1)	8 (<0.1)	18 (<0.1)
Deep vein thrombosis	0	2 (<0.1)	2 (<0.1)
Hypertension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arteriosclerosis	0	1 (<0.1)	1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)	1 (<0.1)
Haematoma	0	1 (<0.1)	1 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypotension	1 (<0.1)	1 (<0.1)	2 (<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)
Peripheral artery aneurysm	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	19 (0.1)	13 (<0.1)	32 (0.1)
Pulmonary embolism	5 (<0.1)	4 (<0.1)	9 (<0.1)
Dyspnoea	0	3 (<0.1)	3 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Respiratory failure	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 14.3.1.13.3
Subject Incidence of Serious 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)
Cough	0	1 (<0.1)	1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Asthma	1 (<0.1)	0	1 (<0.1)
Chronic obstructive pulmonary disease	4 (<0.1)	0	4 (<0.1)
Hypoxia	1 (<0.1)	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Organising pneumonia	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)
Pneumothorax	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	10 (<0.1)	23 (0.2)	33 (0.1)
Abdominal pain upper	0	3 (<0.1)	3 (<0.1)
Nausea	1 (<0.1)	3 (<0.1)	4 (<0.1)
Colitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Diarrhoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hiatus hernia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Constipation	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)
Gastrointestinal haemorrhage	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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.)			
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)
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	5 (<0.1)	5 (<0.1)
Cholecystitis	0	3 (<0.1)	3 (<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)	1 (<0.1)	3 (<0.1)
Rash	0	1 (<0.1)	1 (<0.1)
Rash vesicular	0	1 (<0.1)	1 (<0.1)
Angioedema	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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 bullous	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	9 (<0.1)	12 (<0.1)	21 (<0.1)
Arthritis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Back pain	0	1 (<0.1)	1 (<0.1)
Flank pain	0	1 (<0.1)	1 (<0.1)
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	0	1 (<0.1)	1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neck pain	0	1 (<0.1)	1 (<0.1)
Osteoarthritis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0	1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	4 (<0.1)	4 (<0.1)	8 (<0.1)
Nephrolithiasis	0	3 (<0.1)	3 (<0.1)
Acute kidney injury	3 (<0.1)	1 (<0.1)	4 (<0.1)
Chronic kidney disease	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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)	0	1 (<0.1)
Abortion spontaneous	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	0	4 (<0.1)	4 (<0.1)
Benign prostatic hyperplasia	0	2 (<0.1)	2 (<0.1)
Ovarian cyst	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
General disorders and administration site conditions	6 (<0.1)	7 (<0.1)	13 (<0.1)
Chest pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)
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)
Systemic inflammatory response syndrome	1 (<0.1)	0	1 (<0.1)
Investigations	0	1 (<0.1)	1 (<0.1)
Transaminases increased	0	1 (<0.1)	1 (<0.1)
Injury, poisoning and procedural complications	20 (0.1)	16 (0.1)	36 (0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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.)			
Fall	3 (<0.1)	2 (<0.1)	5 (<0.1)
Road traffic accident	1 (<0.1)	2 (<0.1)	3 (<0.1)
Subdural haematoma	0	2 (<0.1)	2 (<0.1)
Animal bite	0	1 (<0.1)	1 (<0.1)
Back injury	0	1 (<0.1)	1 (<0.1)
Concussion	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)
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Head injury	0	1 (<0.1)	1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Humerus fracture	0	1 (<0.1)	1 (<0.1)
Incision site pain	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Skin laceration	1 (<0.1)	1 (<0.1)	2 (<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	3 (<0.1)	0	3 (<0.1)
Cartilage injury	1 (<0.1)	0	1 (<0.1)
Foot fracture	1 (<0.1)	0	1 (<0.1)
Gun shot wound	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.13.3
Subject Incidence of Serious 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.)			
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)
Thoracic vertebral fracture	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	4 (<0.1)	3 (<0.1)	7 (<0.1)
Ankle arthroplasty	0	1 (<0.1)	1 (<0.1)
Knee 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)
Jaw operation	1 (<0.1)	0	1 (<0.1)
Spinal fusion surgery	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)

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 14.3.1.14.1
Subject 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	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4 (<0.1)	6 (<0.1)	10 (<0.1)
Number of Unsolicited Adverse Events	8	8	16
Nervous system disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Paraesthesia	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dyspnoea	0	1 (<0.1)	1 (<0.1)
Pulmonary embolism	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)	1 (<0.1)
Nausea	0	1 (<0.1)	1 (<0.1)
Vomiting	0	1 (<0.1)	1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	3 (<0.1)	4 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oedema peripheral	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.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011401.sas 01DEC2020 04:44

Table 14.3.1.14.1
Subject 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	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
General disorders and administration site conditions (Cont.)			
Feeling hot	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0	2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	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 14.3.1.14.3
Subject Incidence of Serious Treatment-Related 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	5 (<0.1)	7 (<0.1)	12 (<0.1)
Number of Unsolicited Adverse Events	14	9	23
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)	1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	1 (<0.1)	0	1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Paraesthesia	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	1 (<0.1)	0	1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0	1 (<0.1)
Atrial fibrillation	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dyspnoea	0	1 (<0.1)	1 (<0.1)
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Pulmonary embolism	1 (<0.1)	0	1 (<0.1)
Respiratory failure	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011403.sas 01DEC2020 04:44

Table 14.3.1.14.3
Subject Incidence of Serious Treatment-Related 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	0	1 (<0.1)	1 (<0.1)
Nausea	0	1 (<0.1)	1 (<0.1)
Vomiting	0	1 (<0.1)	1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	1 (<0.1)	0	1 (<0.1)
Acute kidney injury	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	3 (<0.1)	4 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oedema peripheral	0	1 (<0.1)	1 (<0.1)
Feeling hot	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0	2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	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 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
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	93 (0.6)	59 (0.4)	152 (0.5)
Number of Unsolicited Adverse Events	108	66	174
Infections and infestations	52 (0.3)	20 (0.1)	72 (0.2)
COVID-19	45 (0.3)	13 (<0.1)	58 (0.2)
Asymptomatic COVID-19	0	2 (<0.1)	2 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Herpes simplex	0	1 (<0.1)	1 (<0.1)
Herpes zoster	0	1 (<0.1)	1 (<0.1)
Pneumonia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Viral infection	0	1 (<0.1)	1 (<0.1)
Diverticulitis	1 (<0.1)	0	1 (<0.1)
Osteomyelitis	1 (<0.1)	0	1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0	1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0	1 (<0.1)
Urinary tract infection	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)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gastric cancer	0	1 (<0.1)	1 (<0.1)
Lung cancer metastatic	0	1 (<0.1)	1 (<0.1)
Colon cancer stage III	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 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
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.)			
Prostate 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)
Metabolism and nutrition disorders	1 (<0.1)	0	1 (<0.1)
Dehydration	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	2 (<0.1)	0	2 (<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)
Nervous system disorders	5 (<0.1)	5 (<0.1)	10 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	1 (<0.1)
Headache	2 (<0.1)	1 (<0.1)	3 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)	1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)	1 (<0.1)
Seizure	0	1 (<0.1)	1 (<0.1)
Ageusia	1 (<0.1)	0	1 (<0.1)
Ischaemic stroke	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 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
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	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Eye disorders	2 (<0.1)	0	2 (<0.1)
Eye swelling	1 (<0.1)	0	1 (<0.1)
Retinal detachment	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0	1 (<0.1)
Vertigo	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	5 (<0.1)	3 (<0.1)	8 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)	2 (<0.1)
Coronary artery disease	0	1 (<0.1)	1 (<0.1)
Myocardial infarction	0	1 (<0.1)	1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0	1 (<0.1)
Arrhythmia	1 (<0.1)	0	1 (<0.1)
Atrial fibrillation	1 (<0.1)	0	1 (<0.1)
Palpitations	1 (<0.1)	0	1 (<0.1)
Vascular disorders	4 (<0.1)	2 (<0.1)	6 (<0.1)
Hypertension	3 (<0.1)	1 (<0.1)	4 (<0.1)
Orthostatic hypotension	0	1 (<0.1)	1 (<0.1)
Deep vein thrombosis	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 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
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	7 (<0.1)	3 (<0.1)	10 (<0.1)
Cough	0	1 (<0.1)	1 (<0.1)
Dyspnoea	0	1 (<0.1)	1 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Acute respiratory failure	1 (<0.1)	0	1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0	1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0	1 (<0.1)
Pleurisy	1 (<0.1)	0	1 (<0.1)
Pulmonary embolism	1 (<0.1)	0	1 (<0.1)
Throat tightness	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	1 (<0.1)	3 (<0.1)	4 (<0.1)
Abdominal pain upper	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Retching	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	4 (<0.1)	8 (<0.1)	12 (<0.1)
Urticaria	2 (<0.1)	4 (<0.1)	6 (<0.1)
Psoriasis	0	1 (<0.1)	1 (<0.1)
Rash	0	1 (<0.1)	1 (<0.1)
Rash macular	0	1 (<0.1)	1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Angioedema	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 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
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	3 (<0.1)	3 (<0.1)	6 (<0.1)
Arthralgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arthritis	0	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Synovitis	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	0	1 (<0.1)	1 (<0.1)
Morning sickness	0	1 (<0.1)	1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)	1 (<0.1)
Breast mass	0	1 (<0.1)	1 (<0.1)
General disorders and administration site conditions	5 (<0.1)	5 (<0.1)	10 (<0.1)
Injection site erythema	0	3 (<0.1)	3 (<0.1)
Fatigue	2 (<0.1)	1 (<0.1)	3 (<0.1)
Induration	0	1 (<0.1)	1 (<0.1)
Injection site swelling	0	1 (<0.1)	1 (<0.1)
Pain	0	1 (<0.1)	1 (<0.1)
Chest pain	1 (<0.1)	0	1 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Non-cardiac chest pain	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 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15166) n (%)	mRNA-1273 (N=15185) n (%)	Total (N=30351) n (%)
Investigations	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)	1 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	0	1 (<0.1)
Blood pressure increased	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	3 (<0.1)	4 (<0.1)	7 (<0.1)
Head injury	0	1 (<0.1)	1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Road traffic accident	0	1 (<0.1)	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Product issues	0	1 (<0.1)	1 (<0.1)
Device dislocation	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.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011501.sas 01DEC2020 04:44

Table 14.3.1.17.1
Subject Incidence of Unsolicited 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	202 (1.3)	234 (1.5)	436 (1.4)
Number of Unsolicited Adverse Events	242	291	533
Infections and infestations	25 (0.2)	16 (0.1)	41 (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	3 (<0.1)	1 (<0.1)	4 (<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	1 (<0.1)	1 (<0.1)	2 (<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	3 (<0.1)	1 (<0.1)	4 (<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)

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\t1403011701.sas 01DEC2020 04:44

Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
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)
Upper respiratory tract infection	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)	10 (<0.1)	17 (<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)
Malignant melanoma in situ	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)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
Blood and lymphatic system disorders	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anaemia	0	1 (<0.1)	1 (<0.1)
Lymphadenopathy	1 (<0.1)	1 (<0.1)	2 (<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)
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	7 (<0.1)	3 (<0.1)	10 (<0.1)
Depression	2 (<0.1)	1 (<0.1)	3 (<0.1)
Insomnia	1 (<0.1)	1 (<0.1)	2 (<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)
Major depression	1 (<0.1)	0	1 (<0.1)
Psychotic disorder	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
Nervous system disorders	21 (0.1)	30 (0.2)	51 (0.2)
Headache	12 (<0.1)	20 (0.1)	32 (0.1)
Syncope	1 (<0.1)	4 (<0.1)	5 (<0.1)
Cerebrovascular accident	0	1 (<0.1)	1 (<0.1)
Dizziness	2 (<0.1)	1 (<0.1)	3 (<0.1)
Migraine	2 (<0.1)	1 (<0.1)	3 (<0.1)
Movement disorder	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)
Subarachnoid haemorrhage	0	1 (<0.1)	1 (<0.1)
Aphasia	1 (<0.1)	0	1 (<0.1)
Presyncope	2 (<0.1)	0	2 (<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	3 (<0.1)	1 (<0.1)	4 (<0.1)
Vertigo	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cardiac disorders	13 (<0.1)	13 (<0.1)	26 (<0.1)
Atrial fibrillation	3 (<0.1)	4 (<0.1)	7 (<0.1)
Bradycardia	5 (<0.1)	4 (<0.1)	9 (<0.1)
Coronary artery disease	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
Cardiac disorders (Cont.)			
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)
Tachycardia	2 (<0.1)	0	2 (<0.1)
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	43 (0.3)	30 (0.2)	73 (0.2)
Hypertension	32 (0.2)	23 (0.2)	55 (0.2)
Systolic hypertension	4 (<0.1)	4 (<0.1)	8 (<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)
Accelerated hypertension	1 (<0.1)	0	1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0	1 (<0.1)
Hypertensive emergency	1 (<0.1)	0	1 (<0.1)
Hypotension	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	11 (<0.1)	11 (<0.1)	22 (<0.1)
Cough	2 (<0.1)	2 (<0.1)	4 (<0.1)
Dyspnoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rhinorrhoea	0	2 (<0.1)	2 (<0.1)
Asthma	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Nasal congestion	0	1 (<0.1)	1 (<0.1)
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)
Oropharyngeal pain	3 (<0.1)	1 (<0.1)	4 (<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)
Emphysema	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	14 (<0.1)	17 (0.1)	31 (0.1)
Nausea	1 (<0.1)	4 (<0.1)	5 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Diarrhoea	1 (<0.1)	3 (<0.1)	4 (<0.1)
Abdominal pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abdominal pain upper	2 (<0.1)	1 (<0.1)	3 (<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)

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MedDRA version 23.0.
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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (Cont.)			
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)
Skin and subcutaneous tissue disorders	2 (<0.1)	5 (<0.1)	7 (<0.1)
Rash	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dermatitis	0	1 (<0.1)	1 (<0.1)
Erythema	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	24 (0.2)	23 (0.2)	47 (0.2)
Myalgia	2 (<0.1)	10 (<0.1)	12 (<0.1)
Arthralgia	2 (<0.1)	8 (<0.1)	10 (<0.1)
Muscle spasms	0	2 (<0.1)	2 (<0.1)
Neck pain	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Spinal stenosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Back pain	7 (<0.1)	1 (<0.1)	8 (<0.1)
Pain in extremity	0	1 (<0.1)	1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)	1 (<0.1)
Tendonitis	2 (<0.1)	1 (<0.1)	3 (<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)
Foot deformity	1 (<0.1)	0	1 (<0.1)
Joint swelling	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)
Acute kidney injury	1 (<0.1)	0	1 (<0.1)
Renal colic	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	1 (<0.1)	3 (<0.1)	4 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)	1 (<0.1)
Breast mass	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
Reproductive system and breast disorders (Cont.)			
Uterine haemorrhage	0	1 (<0.1)	1 (<0.1)
Dysmenorrhoea	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	13 (<0.1)	49 (0.3)	62 (0.2)
Fatigue	6 (<0.1)	12 (<0.1)	18 (<0.1)
Injection site erythema	0	11 (<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)
Injection site pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Chills	0	2 (<0.1)	2 (<0.1)
Injection site lymphadenopathy	0	2 (<0.1)	2 (<0.1)
Pain	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pyrexia	0	2 (<0.1)	2 (<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)
Hernia	0	1 (<0.1)	1 (<0.1)
Injection site hypoaesthesia	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)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oedema peripheral	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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.)			
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)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Investigations	13 (<0.1)	23 (0.2)	36 (0.1)
Blood pressure increased	6 (<0.1)	11 (<0.1)	17 (<0.1)
Blood pressure systolic increased	7 (<0.1)	7 (<0.1)	14 (<0.1)
Blood pressure diastolic increased	0	3 (<0.1)	3 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)	2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Injury, poisoning and procedural complications	16 (0.1)	19 (0.1)	35 (0.1)
Foot fracture	0	3 (<0.1)	3 (<0.1)
Skin laceration	0	3 (<0.1)	3 (<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)

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MedDRA version 23.0.
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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
Injury, poisoning and procedural complications (Cont.)			
Head injury	0	1 (<0.1)	1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)	3 (<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)
Road traffic accident	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stab wound	0	1 (<0.1)	1 (<0.1)
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Tendon injury	0	1 (<0.1)	1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<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)
Joint injury	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	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.17.1
Subject Incidence of Unsolicited 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 (%)
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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Percentages are based on the number of safety subjects.
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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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	1465 (9.7)	1372 (9.0)	2837 (9.3)
Number of Unsolicited Adverse Events	2157	2121	4278
Infections and infestations	525 (3.5)	413 (2.7)	938 (3.1)
Urinary tract infection	85 (0.6)	62 (0.4)	147 (0.5)
Sinusitis	26 (0.2)	40 (0.3)	66 (0.2)
Upper respiratory tract infection	41 (0.3)	29 (0.2)	70 (0.2)
COVID-19	105 (0.7)	19 (0.1)	124 (0.4)
Tooth abscess	18 (0.1)	16 (0.1)	34 (0.1)
Tooth infection	10 (<0.1)	16 (0.1)	26 (<0.1)
Herpes zoster	10 (<0.1)	15 (<0.1)	25 (<0.1)
Pharyngitis streptococcal	16 (0.1)	12 (<0.1)	28 (<0.1)
Viral infection	17 (0.1)	11 (<0.1)	28 (<0.1)
Ear infection	9 (<0.1)	10 (<0.1)	19 (<0.1)
Rhinovirus infection	9 (<0.1)	10 (<0.1)	19 (<0.1)
Cellulitis	8 (<0.1)	8 (<0.1)	16 (<0.1)
Pharyngitis	9 (<0.1)	8 (<0.1)	17 (<0.1)
Conjunctivitis	5 (<0.1)	7 (<0.1)	12 (<0.1)
Gastroenteritis	5 (<0.1)	7 (<0.1)	12 (<0.1)
Localised infection	7 (<0.1)	7 (<0.1)	14 (<0.1)
Pneumonia	8 (<0.1)	7 (<0.1)	15 (<0.1)
Otitis externa	8 (<0.1)	6 (<0.1)	14 (<0.1)
Paronychia	3 (<0.1)	6 (<0.1)	9 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Diverticulitis	7 (<0.1)	5 (<0.1)	12 (<0.1)
Enterovirus infection	1 (<0.1)	5 (<0.1)	6 (<0.1)
Gingivitis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Otitis media	5 (<0.1)	5 (<0.1)	10 (<0.1)
Acute sinusitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Bacterial vaginosis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Folliculitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hordeolum	4 (<0.1)	4 (<0.1)	8 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)	4 (<0.1)
Bronchitis	5 (<0.1)	3 (<0.1)	8 (<0.1)
Cystitis	4 (<0.1)	3 (<0.1)	7 (<0.1)
Fungal infection	3 (<0.1)	3 (<0.1)	6 (<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)
Skin infection	2 (<0.1)	3 (<0.1)	5 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Subcutaneous abscess	0	3 (<0.1)	3 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asymptomatic COVID-19	0	2 (<0.1)	2 (<0.1)
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Chronic sinusitis	0	2 (<0.1)	2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)	2 (<0.1)
Impetigo	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Kidney infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lyme disease	0	2 (<0.1)	2 (<0.1)
Onychomycosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oral herpes	1 (<0.1)	2 (<0.1)	3 (<0.1)
Otitis media acute	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 upper respiratory tract infection	6 (<0.1)	2 (<0.1)	8 (<0.1)
Vulvovaginal mycotic infection	9 (<0.1)	2 (<0.1)	11 (<0.1)
Abscess	0	1 (<0.1)	1 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)	2 (<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)
Clostridium difficile colitis	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)
Gonorrhoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Infected bite	0	1 (<0.1)	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
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)
Oral candidiasis	2 (<0.1)	1 (<0.1)	3 (<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)
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)
Respiratory tract infection	4 (<0.1)	1 (<0.1)	5 (<0.1)
Rhinitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Soft tissue 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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
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 pharyngitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Viral rhinitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	1 (<0.1)	1 (<0.1)	2 (<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)
Conjunctivitis bacterial	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Denture stomatitis	1 (<0.1)	0	1 (<0.1)
Epididymitis	1 (<0.1)	0	1 (<0.1)
Fungal skin infection	1 (<0.1)	0	1 (<0.1)
Gardnerella infection	1 (<0.1)	0	1 (<0.1)
Gastroenteritis viral	3 (<0.1)	0	3 (<0.1)
Genital herpes	1 (<0.1)	0	1 (<0.1)
Mastoiditis	1 (<0.1)	0	1 (<0.1)
Nasopharyngitis	4 (<0.1)	0	4 (<0.1)
Pelvic abscess	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Postoperative wound infection	1 (<0.1)	0	1 (<0.1)
Respiratory tract infection viral	6 (<0.1)	0	6 (<0.1)
Root canal infection	1 (<0.1)	0	1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0	1 (<0.1)
Skin bacterial infection	1 (<0.1)	0	1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Suspected COVID-19	4 (<0.1)	0	4 (<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)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	36 (0.2)	38 (0.3)	74 (0.2)
Basal cell carcinoma	13 (<0.1)	6 (<0.1)	19 (<0.1)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Squamous cell carcinoma	5 (<0.1)	3 (<0.1)	8 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Malignant melanoma	2 (<0.1)	2 (<0.1)	4 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)	5 (<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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
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)
Invasive lobular breast carcinoma	0	1 (<0.1)	1 (<0.1)
Lung cancer metastatic	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)
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)
Uterine leiomyoma	0	1 (<0.1)	1 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Breast cancer	1 (<0.1)	0	1 (<0.1)
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Chondromatosis	1 (<0.1)	0	1 (<0.1)
Haemangioma of liver	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Hepatic 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)
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	18 (0.1)	33 (0.2)	51 (0.2)
Lymphadenopathy	12 (<0.1)	21 (0.1)	33 (0.1)
Anaemia	1 (<0.1)	5 (<0.1)	6 (<0.1)
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lymphadenitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Immune system disorders	12 (<0.1)	6 (<0.1)	18 (<0.1)
Seasonal allergy	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hypersensitivity	2 (<0.1)	1 (<0.1)	3 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Allergy to plants	1 (<0.1)	0	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0	1 (<0.1)
Drug hypersensitivity	1 (<0.1)	0	1 (<0.1)
Food allergy	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (Cont.)			
Serum sickness	1 (<0.1)	0	1 (<0.1)
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	6 (<0.1)	4 (<0.1)	10 (<0.1)
Hypothyroidism	3 (<0.1)	3 (<0.1)	6 (<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)
Metabolism and nutrition disorders	52 (0.3)	46 (0.3)	98 (0.3)
Hyperlipidaemia	8 (<0.1)	11 (<0.1)	19 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	9 (<0.1)	10 (<0.1)
Vitamin D deficiency	3 (<0.1)	6 (<0.1)	9 (<0.1)
Dehydration	4 (<0.1)	3 (<0.1)	7 (<0.1)
Hypercholesterolaemia	11 (<0.1)	3 (<0.1)	14 (<0.1)
Decreased appetite	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hypertriglyceridaemia	0	2 (<0.1)	2 (<0.1)
Hyponatraemia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abnormal loss of weight	0	1 (<0.1)	1 (<0.1)
Diabetes mellitus	2 (<0.1)	1 (<0.1)	3 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Glucose tolerance impaired	4 (<0.1)	1 (<0.1)	5 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Metabolism and nutrition disorders (Cont.)			
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Gout	5 (<0.1)	1 (<0.1)	6 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Dyslipidaemia	3 (<0.1)	0	3 (<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)
Metabolic acidosis	1 (<0.1)	0	1 (<0.1)
Obesity	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	48 (0.3)	51 (0.3)	99 (0.3)
Depression	12 (<0.1)	22 (0.1)	34 (0.1)
Anxiety	18 (0.1)	20 (0.1)	38 (0.1)
Attention deficit hyperactivity disorder	4 (<0.1)	4 (<0.1)	8 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	0	1 (<0.1)	1 (<0.1)
Bipolar disorder	3 (<0.1)	1 (<0.1)	4 (<0.1)
Completed suicide	0	1 (<0.1)	1 (<0.1)
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Insomnia	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Psychiatric disorders (Cont.)			
Major depression	2 (<0.1)	1 (<0.1)	3 (<0.1)
Post-traumatic stress 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)
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 status changes	2 (<0.1)	0	2 (<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	121 (0.8)	127 (0.8)	248 (0.8)
Headache	62 (0.4)	64 (0.4)	126 (0.4)
Migraine	4 (<0.1)	6 (<0.1)	10 (<0.1)
Paraesthesia	7 (<0.1)	6 (<0.1)	13 (<0.1)
Sciatica	6 (<0.1)	6 (<0.1)	12 (<0.1)
Anosmia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Dizziness	10 (<0.1)	4 (<0.1)	14 (<0.1)
Syncope	8 (<0.1)	4 (<0.1)	12 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	3 (<0.1)	5 (<0.1)
Cerebrovascular accident	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Ageusia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cervical radiculopathy	0	2 (<0.1)	2 (<0.1)
Nerve compression	0	2 (<0.1)	2 (<0.1)
Presyncope	5 (<0.1)	2 (<0.1)	7 (<0.1)
Seizure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Transient ischaemic attack	0	2 (<0.1)	2 (<0.1)
Amnesia	0	1 (<0.1)	1 (<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)
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Facial paralysis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperaesthesia	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hyposmia	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 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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
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)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Dementia	1 (<0.1)	0	1 (<0.1)
Head discomfort	1 (<0.1)	0	1 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Lumbar radiculopathy	1 (<0.1)	0	1 (<0.1)
Neuralgia	2 (<0.1)	0	2 (<0.1)
Restless legs syndrome	1 (<0.1)	0	1 (<0.1)
Speech disorder	1 (<0.1)	0	1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Tension headache	1 (<0.1)	0	1 (<0.1)
Eye disorders	24 (0.2)	16 (0.1)	40 (0.1)
Retinal detachment	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cataract	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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Eye disorders (Cont.)			
Eye discharge	0	1 (<0.1)	1 (<0.1)
Eye disorder	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)
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Scleritis	0	1 (<0.1)	1 (<0.1)
Vision blurred	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)
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Blepharitis	2 (<0.1)	0	2 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Conjunctivitis allergic	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)
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)

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MedDRA version 23.0.
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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Eye disorders (Cont.)			
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)
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	28 (0.2)	18 (0.1)	46 (0.2)
Vertigo positional	1 (<0.1)	5 (<0.1)	6 (<0.1)
Ear pain	5 (<0.1)	4 (<0.1)	9 (<0.1)
Vertigo	2 (<0.1)	4 (<0.1)	6 (<0.1)
Cerumen impaction	2 (<0.1)	1 (<0.1)	3 (<0.1)
Deafness neurosensory	0	1 (<0.1)	1 (<0.1)
Ear canal erythema	3 (<0.1)	1 (<0.1)	4 (<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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Ear and labyrinth disorders (Cont.)			
Tympanic membrane perforation	3 (<0.1)	0	3 (<0.1)
Cardiac disorders	29 (0.2)	33 (0.2)	62 (0.2)
Atrial fibrillation	7 (<0.1)	9 (<0.1)	16 (<0.1)
Cardiac failure congestive	3 (<0.1)	4 (<0.1)	7 (<0.1)
Palpitations	2 (<0.1)	4 (<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)
Tachycardia	4 (<0.1)	3 (<0.1)	7 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Angina pectoris	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus tachycardia	0	2 (<0.1)	2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)	2 (<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)
Arrhythmia	2 (<0.1)	0	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)
Pericarditis	1 (<0.1)	0	1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Cardiac disorders (Cont.)			
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Vascular disorders	73 (0.5)	73 (0.5)	146 (0.5)
Hypertension	56 (0.4)	61 (0.4)	117 (0.4)
Hypertensive urgency	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hot flush	1 (<0.1)	2 (<0.1)	3 (<0.1)
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Flushing	0	1 (<0.1)	1 (<0.1)
Haematoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypotension	0	1 (<0.1)	1 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)	1 (<0.1)
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)
Deep vein thrombosis	2 (<0.1)	0	2 (<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)
Varicose vein	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Respiratory, thoracic and mediastinal disorders	168 (1.1)	143 (0.9)	311 (1.0)
Cough	63 (0.4)	57 (0.4)	120 (0.4)
Nasal congestion	41 (0.3)	52 (0.3)	93 (0.3)
Rhinorrhoea	37 (0.2)	48 (0.3)	85 (0.3)
Oropharyngeal pain	48 (0.3)	36 (0.2)	84 (0.3)
Dyspnoea	20 (0.1)	19 (0.1)	39 (0.1)
Asthma	5 (<0.1)	5 (<0.1)	10 (<0.1)
Respiratory tract congestion	3 (<0.1)	5 (<0.1)	8 (<0.1)
Sinus congestion	6 (<0.1)	5 (<0.1)	11 (<0.1)
Upper-airway cough syndrome	2 (<0.1)	5 (<0.1)	7 (<0.1)
Chronic obstructive pulmonary disease	7 (<0.1)	4 (<0.1)	11 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)	6 (<0.1)
Respiratory failure	0	2 (<0.1)	2 (<0.1)
Rhinitis allergic	4 (<0.1)	2 (<0.1)	6 (<0.1)
Sneezing	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)
Atelectasis	0	1 (<0.1)	1 (<0.1)
Bronchiectasis	0	1 (<0.1)	1 (<0.1)
Dysphonia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dyspnoea exertional	0	1 (<0.1)	1 (<0.1)
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)	1 (<0.1)
Pharyngeal erythema	4 (<0.1)	1 (<0.1)	5 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pleuritic pain	4 (<0.1)	1 (<0.1)	5 (<0.1)
Productive cough	0	1 (<0.1)	1 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sinus pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tonsillolith	2 (<0.1)	1 (<0.1)	3 (<0.1)
Acute respiratory failure	1 (<0.1)	0	1 (<0.1)
Dry throat	1 (<0.1)	0	1 (<0.1)
Emphysema	1 (<0.1)	0	1 (<0.1)
Epistaxis	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)
Paranasal sinus hypersecretion	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)
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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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	134 (0.9)	139 (0.9)	273 (0.9)
Diarrhoea	29 (0.2)	33 (0.2)	62 (0.2)
Nausea	26 (0.2)	27 (0.2)	53 (0.2)
Gastrooesophageal reflux disease	5 (<0.1)	16 (0.1)	21 (<0.1)
Toothache	10 (<0.1)	13 (<0.1)	23 (<0.1)
Vomiting	8 (<0.1)	12 (<0.1)	20 (<0.1)
Dental caries	8 (<0.1)	8 (<0.1)	16 (<0.1)
Abdominal pain	7 (<0.1)	5 (<0.1)	12 (<0.1)
Abdominal pain upper	3 (<0.1)	5 (<0.1)	8 (<0.1)
Constipation	3 (<0.1)	5 (<0.1)	8 (<0.1)
Inguinal hernia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Colitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Haematochezia	0	3 (<0.1)	3 (<0.1)
Hiatus hernia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Food poisoning	4 (<0.1)	2 (<0.1)	6 (<0.1)
Gastric ulcer	1 (<0.1)	2 (<0.1)	3 (<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)
Abdominal pain lower	4 (<0.1)	1 (<0.1)	5 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)
Diverticulum	0	1 (<0.1)	1 (<0.1)
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (Cont.)			
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)
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)
Mouth ulceration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oesophageal ulcer	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	0	1 (<0.1)	1 (<0.1)
Periodontal disease	0	1 (<0.1)	1 (<0.1)
Proctalgia	0	1 (<0.1)	1 (<0.1)
Proctitis	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)	1 (<0.1)
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)
Stomatitis	0	1 (<0.1)	1 (<0.1)
Swollen tongue	0	1 (<0.1)	1 (<0.1)
Tooth impacted	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (Cont.)			
Volvulus	0	1 (<0.1)	1 (<0.1)
Aphthous ulcer	1 (<0.1)	0	1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Dyspepsia	2 (<0.1)	0	2 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Flatulence	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 haemorrhage	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)
Retching	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)
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)

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Subject Incidence of Unsolicited 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 (%)
Hepatobiliary disorders (Cont.)			
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	68 (0.4)	79 (0.5)	147 (0.5)
Rash	10 (<0.1)	10 (<0.1)	20 (<0.1)
Dermatitis contact	10 (<0.1)	9 (<0.1)	19 (<0.1)
Pruritus	4 (<0.1)	6 (<0.1)	10 (<0.1)
Urticaria	3 (<0.1)	6 (<0.1)	9 (<0.1)
Acne	4 (<0.1)	5 (<0.1)	9 (<0.1)
Dermatitis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Actinic keratosis	0	4 (<0.1)	4 (<0.1)
Erythema	3 (<0.1)	4 (<0.1)	7 (<0.1)
Rash maculo-papular	0	3 (<0.1)	3 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)	5 (<0.1)
Skin lesion	3 (<0.1)	3 (<0.1)	6 (<0.1)
Dermatitis atopic	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Pityriasis rosea	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)
Dermal cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dermatitis allergic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eczema	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (Cont.)			
Hand dermatitis	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	1 (<0.1)	1 (<0.1)
Hyperhidrosis	2 (<0.1)	1 (<0.1)	3 (<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	0	1 (<0.1)	1 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash vesicular	0	1 (<0.1)	1 (<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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (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	163 (1.1)	180 (1.2)	343 (1.1)
Arthralgia	32 (0.2)	29 (0.2)	61 (0.2)
Myalgia	23 (0.2)	23 (0.2)	46 (0.2)
Back pain	31 (0.2)	18 (0.1)	49 (0.2)
Neck pain	6 (<0.1)	15 (<0.1)	21 (<0.1)
Muscle spasms	6 (<0.1)	12 (<0.1)	18 (<0.1)
Pain in extremity	17 (0.1)	11 (<0.1)	28 (<0.1)
Musculoskeletal pain	5 (<0.1)	10 (<0.1)	15 (<0.1)
Tendonitis	7 (<0.1)	8 (<0.1)	15 (<0.1)
Arthritis	1 (<0.1)	6 (<0.1)	7 (<0.1)
Musculoskeletal chest pain	5 (<0.1)	6 (<0.1)	11 (<0.1)
Osteoarthritis	10 (<0.1)	6 (<0.1)	16 (<0.1)
Bursitis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	4 (<0.1)	5 (<0.1)
Rotator cuff syndrome	4 (<0.1)	4 (<0.1)	8 (<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)
Spinal stenosis	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Trigger finger	0	3 (<0.1)	3 (<0.1)
Exostosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscular weakness	0	2 (<0.1)	2 (<0.1)
Neck mass	0	2 (<0.1)	2 (<0.1)
Osteopenia	0	2 (<0.1)	2 (<0.1)
Osteoporosis	0	2 (<0.1)	2 (<0.1)
Spinal osteoarthritis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bone pain	0	1 (<0.1)	1 (<0.1)
Fibromyalgia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Flank pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Floating patella	0	1 (<0.1)	1 (<0.1)
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Groin pain	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint range of motion decreased	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 twitching	0	1 (<0.1)	1 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
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)
Tendon disorder	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Undifferentiated connective tissue disease	0	1 (<0.1)	1 (<0.1)
Axillary mass	2 (<0.1)	0	2 (<0.1)
Bone lesion	1 (<0.1)	0	1 (<0.1)
Cervical spinal stenosis	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)
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	33 (0.2)	24 (0.2)	57 (0.2)
Nephrolithiasis	18 (0.1)	9 (<0.1)	27 (<0.1)
Dysuria	2 (<0.1)	2 (<0.1)	4 (<0.1)
Urinary hesitation	0	2 (<0.1)	2 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic kidney disease	0	1 (<0.1)	1 (<0.1)
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
Haematuria	4 (<0.1)	1 (<0.1)	5 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
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)
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	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)
Reproductive system and breast disorders	23 (0.2)	30 (0.2)	53 (0.2)
Pelvic pain	0	3 (<0.1)	3 (<0.1)
Benign prostatic hyperplasia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Dysmenorrhoea	0	2 (<0.1)	2 (<0.1)
Prostatitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Uterine haemorrhage	0	2 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Adnexal torsion	0	1 (<0.1)	1 (<0.1)
Balanoposthitis	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
Reproductive system and breast disorders (Cont.)			
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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)	2 (<0.1)
Erectile dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Menopausal symptoms	0	1 (<0.1)	1 (<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)
Ovarian cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Uterine polyp	0	1 (<0.1)	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Amenorrhoea	1 (<0.1)	0	1 (<0.1)
Bartholin's cyst	1 (<0.1)	0	1 (<0.1)
Cystocele	1 (<0.1)	0	1 (<0.1)
Endometriosis	1 (<0.1)	0	1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)
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)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
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	110 (0.7)	115 (0.8)	225 (0.7)
Fatigue	50 (0.3)	42 (0.3)	92 (0.3)
Pain	14 (<0.1)	18 (0.1)	32 (0.1)
Chills	13 (<0.1)	12 (<0.1)	25 (<0.1)
Pyrexia	10 (<0.1)	11 (<0.1)	21 (<0.1)
Injection site erythema	1 (<0.1)	9 (<0.1)	10 (<0.1)
Injection site pain	3 (<0.1)	8 (<0.1)	11 (<0.1)
Injection site induration	0	6 (<0.1)	6 (<0.1)
Chest discomfort	7 (<0.1)	5 (<0.1)	12 (<0.1)
Chest pain	3 (<0.1)	5 (<0.1)	8 (<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)
Oedema peripheral	3 (<0.1)	2 (<0.1)	5 (<0.1)
Adverse drug reaction	0	1 (<0.1)	1 (<0.1)
Axillary pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Crying	0	1 (<0.1)	1 (<0.1)
Cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Feeling hot	1 (<0.1)	1 (<0.1)	2 (<0.1)
Granuloma	0	1 (<0.1)	1 (<0.1)
Hernia	0	1 (<0.1)	1 (<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	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mass	0	1 (<0.1)	1 (<0.1)
Nodule	0	1 (<0.1)	1 (<0.1)
Peripheral swelling	4 (<0.1)	1 (<0.1)	5 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Asthenia	2 (<0.1)	0	2 (<0.1)
Facial pain	1 (<0.1)	0	1 (<0.1)
Gait disturbance	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)

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Subject Incidence of Unsolicited 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.)			
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Precancerous condition	2 (<0.1)	0	2 (<0.1)
Investigations	23 (0.2)	24 (0.2)	47 (0.2)
Hepatic enzyme increased	0	3 (<0.1)	3 (<0.1)
Transaminases increased	0	3 (<0.1)	3 (<0.1)
Blood pressure increased	3 (<0.1)	2 (<0.1)	5 (<0.1)
Blood pressure systolic increased	1 (<0.1)	2 (<0.1)	3 (<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 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	0	1 (<0.1)	1 (<0.1)
Blood triglycerides increased	0	1 (<0.1)	1 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)	2 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Glycosylated haemoglobin increased	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)
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited 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 (%)
Investigations (Cont.)			
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Alanine aminotransferase increased	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)
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)
Injury, poisoning and procedural complications	170 (1.1)	164 (1.1)	334 (1.1)
Skin laceration	25 (0.2)	19 (0.1)	44 (0.1)
Ligament sprain	7 (<0.1)	17 (0.1)	24 (<0.1)
Muscle strain	11 (<0.1)	13 (<0.1)	24 (<0.1)
Foot fracture	8 (<0.1)	10 (<0.1)	18 (<0.1)
Limb injury	6 (<0.1)	10 (<0.1)	16 (<0.1)
Procedural pain	11 (<0.1)	8 (<0.1)	19 (<0.1)
Arthropod bite	7 (<0.1)	7 (<0.1)	14 (<0.1)
Fall	6 (<0.1)	7 (<0.1)	13 (<0.1)
Tooth fracture	9 (<0.1)	7 (<0.1)	16 (<0.1)

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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Concussion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Hand fracture	1 (<0.1)	4 (<0.1)	5 (<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)
Animal bite	6 (<0.1)	3 (<0.1)	9 (<0.1)
Arthropod sting	3 (<0.1)	3 (<0.1)	6 (<0.1)
Contusion	9 (<0.1)	3 (<0.1)	12 (<0.1)
Bone contusion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Epicondylitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Facial bones fracture	0	2 (<0.1)	2 (<0.1)
Head injury	1 (<0.1)	2 (<0.1)	3 (<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)
Post-traumatic pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Road traffic accident	4 (<0.1)	2 (<0.1)	6 (<0.1)
Tendon rupture	2 (<0.1)	2 (<0.1)	4 (<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)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Ankle fracture	4 (<0.1)	1 (<0.1)	5 (<0.1)
Back injury	2 (<0.1)	1 (<0.1)	3 (<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)
Clavicle fracture	0	1 (<0.1)	1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Craniocerebral 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)
Hip fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injury	0	1 (<0.1)	1 (<0.1)
Joint dislocation	0	1 (<0.1)	1 (<0.1)
Joint injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Nasal injury	0	1 (<0.1)	1 (<0.1)
Overdose	0	1 (<0.1)	1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)	1 (<0.1)
Post procedural haemorrhage	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 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Post procedural swelling	0	1 (<0.1)	1 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Scar	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)
Tendon injury	0	1 (<0.1)	1 (<0.1)
Thermal burn	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	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)
Exposure to SARS-CoV-2	1 (<0.1)	0	1 (<0.1)
Eye injury	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)
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)
Post procedural haematoma	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)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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.)			
Scratch	1 (<0.1)	0	1 (<0.1)
Skin abrasion	5 (<0.1)	0	5 (<0.1)
Superficial injury of eye	1 (<0.1)	0	1 (<0.1)
Tibia fracture	1 (<0.1)	0	1 (<0.1)
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Wound	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	11 (<0.1)	10 (<0.1)	21 (<0.1)
Endodontic procedure	2 (<0.1)	2 (<0.1)	4 (<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	0	1 (<0.1)	1 (<0.1)
Skin neoplasm excision	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)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.19.1
Subject Incidence of Unsolicited 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 (%)
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.
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