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I. Summary of Clinical Data

Table 1: All Clinical Trials

Study Number	Type of Study (Efficacy, Safety, Nonclinical)	Population (N)	Study Design and Type of Control	Test Product(s); Dosing Regimens	Study Status
mRNA-1273-P301	Efficacy, safety	30420 randomized	A Phase 3, randomized, stratified, observer-blind, placebo-controlled study	mRNA-1273; 100 µg	Ongoing, vaccine efficacy demonstrated at the primary analysis (at least 151 cases)
mRNA-1273-P201	Safety, immunogenicity	600 randomized	A Phase 2a, randomized, observer-blind, placebo-controlled, dose-confirmation study	mRNA-1273; 50, 100 µg	Ongoing, Day 57 primary analysis completed

II. Human Clinical Efficacy

1. Study Disposition

Table 2: Subject Disposition - mRNA-1273-P301 (Source: Table 14.1.1.1.1.1, Table 14.1.2.1, Table 14.1.1.1.3.2, Table 14.1.6.2.1, Table 14.1.6.4)

	Vaccine Group (N = 15210) n (%)	Placebo Group (N = 15210) n (%)	Total (N= 30420) n (%)
Enrolled	15210	15210	30420
Randomized¹	15210	15210	30420
Exposed	15185	15166	30351 (99.8)
Safety Set²	15185	15166	30351
Completed at least 1 month follow up after dose 1 ³	14095 (92.8)	14095 (92.9)	28190 (92.9)
Completed at least 2 months follow up after dose 1 ³	13498 (88.9)	13454 (88.7)	26952 (88.8)
Completed at least 1 month follow up after dose 2 ³	13386 (88.2)	13297 (87.7)	26683 (87.9)
Completed at least 2 months follow up after dose 2 ³	8163 (53.8)	8111 (53.5)	16274 (53.6)
Full Analysis Set¹	15181 (99.8)	15170 (99.7)	330351 (99.8)

	Vaccine Group (N = 15210) n (%)	Placebo Group (N = 15210) n (%)	Total (N= 30420) n (%)
Per Protocol Set¹	14134 (92.9)	14073 (92.5)	28207 (92.7)
Completed at least 7 weeks follow up ⁴	13217 (93.5)	13173 (93.6)	26390 (93.6)
Completed at least 8 weeks follow up ⁴	12930 (91.5)	12862 (91.4)	25792 (91.4)
Completed at least 2 months follow up ⁴	12702 (89.9)	12605 (89.6)	25307 (89.7)
Completed at least 4 weeks follow up after dose 2 ⁴	12881 (91.1)	12786 (90.9)	25667 (91.0)
Completed at least 8 weeks follow up after dose 2 ⁴	9102 (64.4)	8987 (63.9)	18089 (64.1)
Completed at least 2 months follow up after dose 2 ⁴	7903 (55.9)	7849 (55.8)	15752 (55.8)
Randomized Set			
Completed 1 dose	15181 (99.8)	15170 (99.7)	30351 (99.8)
Completed 2 doses	14711 (96.7)	14617 (96.1)	29328 (96.4)
Discontinued from Study	159 (1.0)	206 (1.4)	365 (1.2)
Reason for Discontinuation			
Adverse Event	4 (<0.1)	1 (<0.1)	5 (<0.1)
Serious Adverse Event	9 (<0.1)	15 (<0.1)	24 (<0.1)
Death	4 (<0.1)	6 (<0.1)	10 (<0.1)
Withdrawal by Subject	85 (0.6)	146 (1.0)	231 (0.8)
Lost to Follow-up	33 (0.2)	35 (0.2)	68 (0.2)
Protocol Deviation	1 (<0.1)	0	1 (<0.1)
Physician Decision	15 (<0.1)	3 (<0.1)	18 (<0.1)
Other	14 (<0.1)	13 (<0.1)	27 (<0.1)
Per-Protocol Set¹	14134 (92.9)	14073 (92.5)	28207 (92.7)
Completed 1 dose⁴	14134 (100)	14073 (100)	28207 (100)
Completed 2 doses⁴	14104 (99.8)	14025 (99.7)	28129 (99.7)
Discontinued from Study⁴	36 (0.3)	51 (0.4)	87 (0.3)
Reason for Discontinuation⁴			
Adverse Event	0	0	0
Serious Adverse Event	0	0	0
Death	1 (<0.1)	3 (<0.1)	4 (<0.1)
Withdrawal by Subject	25 (0.2)	35 (0.2)	60 (0.2)
Lost to Follow-up	5 (<0.1)	10 (<0.1)	15 (<0.1)
Protocol Deviation	0	0	0
Physician Decision	3 (<0.1)	1 (<0.1)	4 (<0.1)
Other	2 (<0.1)	2 (<0.1)	4 (<0.1)

¹ Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.

² Numbers are based on actual treatment group and percentages are based on the number of safety subjects.

³ Percentage based on number of subjects in the Safety Set.

⁴ Percentage based on number of subjects in the Per-Protocol Set.

2. Subject Demographics and Other Baseline Characteristics

Table 3: Demographic Characteristics – Full Analysis Set (Source: Table 14.1.3.1.2)

	Vaccine Group (N=15181) n (%)	Placebo Group (N= 15170) n (%)	Total (N=30351) n (%)
Sex			
Female	7258 (47.8)	7108 (46.9)	14366 (47.3)
Male	7923 (52.2)	8062 (53.1)	15985 (52.7)
Age (years)			
Mean (SD)	51.4 (15.50)	51.3 (15.60)	51.4 (15.55)
Median	53.0	52.0	52.0
Min, max	18, 95	18, 95	18, 95
Age – Subgroups (years)			
≥ 18 to < 65	11413 (75.2)	11418 (75.3)	22831 (75.2)
65 and older	3768 (24.8)	3752 (24.7)	7520 (24.8)
Race			
American Indian or Alaska Native	112 (0.7)	121 (0.8)	233 (0.8)
Asian	651 (4.3)	731 (4.8)	1382 (4.6)
Black or African American	1563 (10.3)	1527 (10.1)	3090 (10.2)
Native Hawaiian or other Pacific islander	35 (0.2)	32 (0.2)	67 (0.2)
White	12029 (79.2)	11995 (79.1)	24024 (79.2)
Other	321 (2.1)	316 (2.1)	637 (2.1)
Multiracial	315 (2.1)	321 (2.1)	636 (2.1)
Ethnicity			
Hispanic or Latino	3121 (20.6)	3114 (20.5)	6235 (20.5)
Not Hispanic or Latino	11918 (78.5)	11917 (78.6)	23835 (78.5)
Race and Ethnicity			
Non-Hispanic White	9529 (62.8)	9461 (62.4)	18990 (62.6)
Communities of color	5626 (37.1)	5683 (37.5)	11309 (37.3)
Occupational Risk*	12429 (81.9)	12505 (82.4)	24934 (82.2)
Healthcare worker	3790 (25.0)	3831 (25.3)	7621 (25.1)
High Risk Condition**			
One high risk condition present	3399 (22.4)	3418 (22.5)	6817 (22.5)
No high risk condition	11782 (77.6)	11752 (77.5)	23534 (77.5)
Age and Health Risk for Severe COVID-19***			
≥ 18 to < 65 years and not at risk	8888 (58.5)	8886 (58.6)	17774 (58.6)
≥ 18 to <65 years and at risk	2530 (16.7)	2535 (16.7)	5065 (16.7)
≥ 65 years	3763 (24.8)	3749 (24.7)	7512 (24.8)

*Occupational risk includes: Healthcare Workers, Emergency Response, Retail/Restaurant Operations, Manufacturing and Production Operations, Warehouse Shipping and Fulfillment centers, Transportation and Delivery Services, Border Protection and Military Personnel, and Personal care and in-home services, Hospitality and Tourism Workers, Pastoral, Social or Public Health Workers, Educators and Students.

**High risk is defined as patients who meet at least one of the following criteria (protocol-defined):

- Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Severe obesity (body mass index ≥ 40 kg/m²)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human immunodeficiency virus (HIV) infection

***Age and health risk for severe COVID-19 is used as stratification factor for randomization.

Table 4: Demographic Characteristics (All Randomized) – Per-Protocol Set (Source: Table 14.1.3.4.2)

	Vaccine Group (N=14134) n (%)	Placebo Group (N= 14073) n (%)	Total (N=28207) n (%)
Sex			
Female	6768 (47.9)	6611 (47.0)	13379 (47.4)
Male	7366 (52.1)	7462 (53.0)	14828 (52.6)
Age (years)			
Mean (SD)	51.6 (15.44)	51.6 (15.54)	51.6 (15.49)
Median	53.0	52.0	53.0
Min, max	18, 95	18, 95	18, 95
Age – Subgroups (years)			
18 to <65	10551 (74.6)	10521 (74.8)	21072 (74.7)
65 and older	3583 (25.4)	3552 (25.2)	7135 (25.3)
Race			
American Indian or Alaska Native	108 (0.8)	111 (0.8)	219 (0.8)
Asian	620 (4.4)	689 (4.9)	1309 (4.6)
Black or African American	1385 (9.8)	1349 (9.6)	2734 (9.7)
Native Hawaiian or Other Pacific Islander	35 (0.2)	31 (0.2)	66 (0.2)
White	11253 (79.6)	11174 (79.4)	22427 (79.5)
Other	299 (2.1)	295 (2.1)	594 (2.1)
Ethnicity			
Hispanic or Latino	2789 (19.7)	2780 (19.8)	5569 (19.7)
Not Hispanic or Latino	11212 (79.3)	11165 (79.3)	22377 (79.3)
Race and Ethnicity			
Non-Hispanic White	9023 (63.8)	8916 (63.4)	17939 (63.6)
Communities of color	5088 (36.0)	5132 (36.5)	10220 (36.2)
Occupational Risk*	11586 (82.0)	11590 (82.4)	23176 (82.2)
Healthcare worker	3593 (25.4)	3581 (25.4)	7174 (25.4)
High Risk Condition**			
One high risk condition present	2616 (18.5)	2591 (18.4)	5207 (18.5)
Two or more high risk conditions present	590 (4.2)	576 (4.1)	1166 (4.1)
No high risk condition	10928 (77.3)	10906 (77.5)	21834 (77.4)
Age and Health Risk for Severe COVID-19***			
18 to <65 years and not at risk	8189 (57.9)	8200 (58.3)	16389 (58.1)
18 to <65 years and at risk	2367 (16.7)	2324 (16.5)	4691 (16.6)
≥ 65 years	3578 (25.3)	3549 (25.2)	7127 (25.3)

* Occupational risk includes: Healthcare Workers; Emergency Response; Retail/Restaurant Operations; Manufacturing and Production; Operations, Warehouse Shipping and Fulfillment centers, Transportation and Delivery Services, Border Protection and Military Personnel Personal care and in-home services; Hospitality and Tourism Workers, Pastoral; Social or Public Health Workers; and Educators and Students.

** High risk for severe COVID-19 is defined as patients who meet at least one of the following criteria (protocol-defined):

- Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Severe obesity (body mass index ≥ 40 kg/m²)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human immunodeficiency virus (HIV) infection

*** Age and health risk for severe COVID-19 is used as stratification factor for randomization.

3. Efficacy Results

Primary Endpoint (primary efficacy analysis set)

Table 5: Primary Efficacy Analysis : COVID-19 Starting 14 Says After the Second Dose –Per-Protocol Set (Source: Table 14.2.2.1.1.1.1, Table 14.2.2.1.1.6.1.1)

	Vaccine Group N= 13934 Cases n (%) (Incidence Rate per 1,000 Person- Years)*	Placebo Group N= 13883 Cases n (%) (Incidence Rate per 1,000 Person- Years)*	Vaccine Efficacy (VE) % (95% Confidence Interval)**	Met Predefined Success Criterion***
Primary endpoint: COVID-19 (per adjudication committee assessment)				
All subjects	11 (<0.1); 3.328	185 (1.3); 56.510	94.1% (89.3%, 96.8%)	p-value < 0.0001**
18 to <65 years ¹	7 / 10551 (<0.1); 2.875	156 / 10521 (1.5); 64.625	95.6%; (90.6%, 97.9%)	
65 years and older ²	4 / 3583 (0.1); 4.595	29 / 3552 (0.8); 33.728	86.4%; (61.4%, 95.5%)	

COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least 2 systemic symptoms or 1 respiratory symptom. Cases starting 14 days after the second dose. All potential COVID-19 cases starting 14 days after the second dose in the clinical database as of 21-Nov-2020 have been sent to adjudication committee, and have been adjudicated for this analysis (21-Nov-2020 is the data cutoff date for efficacy).

* Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

**VE and 95% CI from the stratified Cox proportional hazard model

***The one-sided p-value is <0.0001 from the stratified Cox proportional hazard model to test the null hypothesis of VE ≤ 30%, achieving the pre-specified efficacy boundary.

¹ Percentage based on number of subjects in the 18 to <65 years of age group.

² Percentage based on number of subjects in the ≥65 years of age group.

Figure 1: Cumulative Incidence Curve of COVID-19 Cases Over Time (Vaccine vs Placebo) Starting 14 Days After the Second Dose Based on Adjudication Committee Assessments – Per-Protocol Set (Source: Figure 14.2.2.1.1.1)

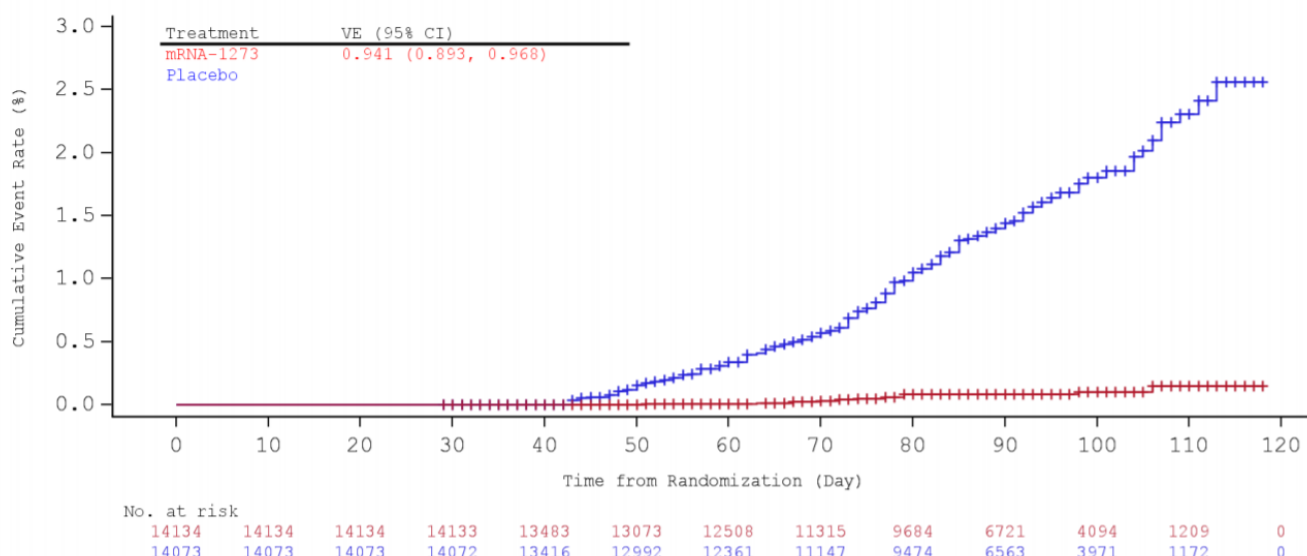


Table 6: Secondary Efficacy Analysis -Per-protocol Set (Source: Table 14.2.2.2.1.1.1, Table 14.2.2.1.2.3.1, Table 14.2.2.1.2.5.1, Table 14.2.2.2.2.5.1, Table 14.2.2.4.1.1, Table 14.2.2.7.1.1, Table 14.2.2.1.6.1)

	Vaccine Group N= 13934 Cases n (%) (incidence rate per 1,000 person-years)	Placebo Group N= 13883 Cases n (%) (incidence rate per 1,000 person-years)	Vaccine Efficacy (VE) % (95% confidence interval)*
Severe cases 14 days after dose 2 based on Adjudication Committee Assessments			
All subjects	0	30 (0.2); 9.138	100%
18 to <65 years	0	20 (0.2); 8.259	100%
65 years and older	0	10 (0.3); 11.613	100%
Symptomatic COVID-19 14 days after dose 1	11 (<0.1); 3.329	225 (1.6); 68.785	95.2% (91.2%, 97.4%)
Symptomatic COVID-19 after randomization	12 (<0.1); 3.631	225 (1.6); 68.785	94.8% (90.6%%, 97.1%)
Severe cases after randomization	0	39 (0.3); 11.881	100%
Asymptomatic SARS-CoV-2 infection	Not available		

	Vaccine Group N= 13934 Cases n (%) (incidence rate per 1,000 person-years)	Placebo Group N= 13883 Cases n (%) (incidence rate per 1,000 person-years)	Vaccine Efficacy (VE) % (95% confidence interval)*
Symptomatic COVID-19 14 days after dose 2 regardless of prior SARS-CoV-2 infection based on Adjudication Committee Assessments*	12 / 15181 (<0.1); 3.404	187 / 15170 (1.2); 53.309	93.6% (88.6%, 96.5%)
Secondary definition of symptomatic COVID-19 14 days after dose 2	11 (<0.1); 3.329	221 (1.6); 67.589	95.1% (91.1%, 97.3%)

Secondary efficacy endpoints to be tested at one-sided alpha=0.025, i.e. to compare the lower bound of the two-sided 95% CI with threshold such as 0%.

* Percentage based on number of subjects in Full Analysis Set.

Additional Analyses Conducted on the Individual Trial

Table 7: Subgroup Analyses of Vaccine Efficacy - COVID-19 14 Days After Dose 2 per Adjudication Committee Assessments (Primary Efficacy Analysis Set) – Per-Protocol Set (Source: Table 14.2.2.1.1.6.1.1, Table 14.2.2.1.1.6.3.1, Table 4.2.2.1.1.6.7.1, Table 14.2.2.1.1.6.10.1, Table 14.2.2.1.1.6.4.1, Table 14.2.2.1.1.6.2.1, Table 14.2.2.1.1.6.5.1, Table 14.2.2.1.1.6.6.1, Table 14.2.2.7.1.6.10)

Subgroup	Vaccine Group Cases N (%) Incidence Rate in 1,000 Person-Years	Placebo Group Cases N (%) Incidence Rate in 1,000 Person-Years	VE % (95% Confidence Interval)
Age (years)¹			
18 to <65	7 / 10551 (<0.1); 2.875	156 / 10521 (1.5); 64.625	95.6% (90.6%, 97.9%)
65 and older	4 / 3583 (0.1); 4.595	29 / 3552 (0.8); 33.728	86.4% (61.4%, 95.2%)
75 and older	0 / 630	7 / 688 (1.0); 41.968	100%
At risk for severe COVID-19 due to comorbidity, regardless of age^{1*}			
Yes	4 / 3206 (0.1); 5.227	43 / 3167 (1.4); 57.202	90.9% (74.7%, 96.7%)
No	7 / 10928 (<0.1); 2.756	142 / 10906 (1.3); 56.304	95.1% (89.6%, 98.1%)
Age and risk for severe COVID-19^{1**}			
18 and <65 and not at risk	5 / 8396 (<0.1) 2.594	121 / 8403 (1.4) 63.054	95.9% (90.0%, 98.3%)
18 and <65 and at risk	2 / 2155 (<0.1) 3.947	35 / 2118 (1.7) 70.716	94.4% (76.9%, 98.7%)
≥65	4 / 3583 (0.1); 4.595	29 / 3552 (0.8); 33.728	86.4% (61.4%, 95.2%)

Subgroup	Vaccine Group Cases N (%) Incidence Rate in 1,000 Person-Years	Placebo Group Cases N (%) Incidence Rate in 1,000 Person-Years	VE % (95% Confidence Interval)
Baseline SARS-CoV-2 ¹			
Positive	0 / 343	1 / 336 (0.3); 13.915	100%
Negative	12 / 14550 (<0.1); 3.540	185 / 14598 (1.3); 54.688	93.6% (88.5%, 96.4%)
Sex ¹			
Female	7 / 6768 (0.1); 4.364	98 / 6611 (1.5); 62.870	93.1% (85.2%, 96.8%)
Male	4 / 7366 (<0.1); 2.3.52	87 / 7462 (1.2); 50.730	95.4% (87.4%, 98.3%)
Race and Ethnicity ¹			
Non-Hispanic White	10 / 9023 (0.1); 4.413	144 / 8916 (1.6); 64.608	93.2% (87.1%, 96.4%)
Communities of color	1 / 5088 (<0.1); 0.967	41 / 5132 (0.8); 39.443	97.5% (82.2%, 99.7%)
Ethnicity ¹			
Hispanic or Latino	1 / 2789 (<0.1); 1.758	28 / 2780 (1.0); 49.662	96.5% (74.4%, 99.5%)
Not Hispanic or Latino	10 / 11212 (<0.1); 3.699	156 / 11165 (1.4); 58.211	93.7% (88.1%, 96.7%)
Race ¹			
American Indian or Alaska Native	0 / 108	1 / 111 (0.9); 44.788	100%
Asian	0 / 620	5 / 689 (0.7); 35.599	100%
Black or African American	0 / 1385	6 / 1349 (0.4); 22.283	100%
Native Hawaiian or Other Pacific Islander	0 / 35	0 / 31	
White	11 / 11253 (<0.1); 4.032	166 / 11174 (1.5); 61.606	93.5% (88.0%, 96.5%)
Multiple	0 / 295	3 / 307 (1.0); 48.476	100%
Other	0 / 299	2 / 295 (0.7); 36.221	100%

¹ Percentage based on number of subjects in each subgroup

* At risk for severe COVID-19 due to comorbidity, regardless of age. High risk is defined as patients who meet at least one of the following criteria (protocol-defined):

- Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Severe obesity (body mass index ≥ 40 kg/m²)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human immunodeficiency virus (HIV) infection

** Age and health risk for severe COVID-19 is used as stratification factor for randomization

***Endpoint based on the FAS Set.

III. Human Clinical Safety

4. Overall Exposure

mRNA-1273 was given as a 2-dose vaccination regimen with each dose administered approximately one month apart. As of 25 Nov 2020, the median follow-up time in the study was 92 days after randomization (dose 1) or 63 days after dose 2.

Table 8: Summary of Vaccine Exposure (Safety Set) (Source: Table 14.1.6.2.1)

Total number of doses	Vaccine Group N= 15185 n (%)	Placebo Group N = 15166 n (%)
Received dose 1	15185 (100)	15166 (100)
Received dose 2	14715 (96.9)	14613 (96.4)

N = number of subjects in each group or in total included in the considered cohort.

n/% = number/percentage of subjects receiving the specified total number of doses.

Table 9: Safety Population, Size and Denominators (Safety Set)

Safety Database for the Study Vaccine ¹ N=15385		
Clinical Trial Groups ²	Vaccine Group	Control Group
Study mRNA-1273-P301	15185	15166
Study mRNA-1273-P201	200 ³	200

¹ Study vaccine means the vaccine being considered for approval.

² Controlled trials conducted for this indication. Subjects in Phase 1 Study 20-0003 are not included in this table. A total of 120 subjects received mRNA-1273 in Study, and 35 of them received mRNA-1273 100µg.

³ In Study mRNA-1273-P201, 200 subjects on mRNA-1273 100 µg, 200 subjects on mRNA-1273 50 µg.

5. Safety Results

Table 10: Safety Overview (Safety Set) (Source: Table 14.3.1.1.3, Table 14.3.1.7.1, Table 14.3.1.7.3, Table 14.3.1.7.7, Table 14.3.1.7.10)

Subjects reporting at least one	Vaccine Group n / N (%)	Placebo Group n / N (%)
Solicited adverse reactions after any injection	14400 / 15179 (94.9)	9108 / 15163 (60.1)
Solicited local adverse reaction	14027 / 15179 (92.4)	4450 / 15162 (29.3)
Grade 3 solicited injection site reaction	1418 / 15179 (9.3)	145 / 15162 (1.0)
Solicited systemic adverse reaction	12770 / 15179 (84.1)	8112 / 15163 (53.5)
Grade 3 or 4 solicited systemic adverse reaction	2629 / 15179 (17.3)	565 / 15163 (3.7)

Subjects reporting at least one	Vaccine Group n / N (%)	Placebo Group n / N (%)
Unsolicited adverse event up to 28 days after any injection	3632 / 15185 (23.9)	3277 / 15166 (21.6)
Baseline SARS-CoV-2 negative	3520 / 14554 (24.2)	3179 / 14594 (21.8)
Baseline SARS-CoV-2 positive	58 / 343 (16.9)	63 / 337 (18.7)
Unsolicited non-serious adverse event	3589 / 15185 (23.6)	3234 / 15166 (21.3)
Grade 3 non-serious unsolicited adverse event	198 / 15185 (1.3)	160 / 15166 (1.1)
Related unsolicited adverse events	1242 / 15185 (8.2)	686 / 15166 (4.5)
Baseline SARS-CoV-2 negative	1216 / 14554 (8.4)	664 / 14594 (4.5)
Baseline SARS-CoV-2 positive	16 / 343 (4.7)	14 / 337 (4.2)
Related Grade 3 non-serious unsolicited adverse event	70 / 15185 (0.5)	27 / 15166 (0.2)
Medically attended adverse events up to 28 days after any injection	1372 / 15185 (9.0)	1465 / 15166 (9.7)
Baseline SARS-CoV-2 negative	1331 / 14554 (9.1)	1430 / 14594 (9.8)
Baseline SARS-CoV-2 positive	22 / 343 (6.4)	23 / 337 (6.8)
Related medically attended adverse events	140 / 15185 (0.9)	83 / 15166 (0.5)
Baseline SARS-CoV-2 negative	140 / 14554 (1.0)	78 / 14594 (0.5)
Baseline SARS-CoV-2 positive	0 / 343	5 / 337 (1.5)
Serious adverse event up to 28 days after any injection	93 / 15185 (0.6)	89 / 15166 (0.6)
Baseline SARS-CoV-2 negative	91 / 14554 (0.6)	86 / 14594 (0.6)
Baseline SARS-CoV-2 positive	0 / 343	3 / 337 (0.9)
Related serious adverse event	6 / 15185 (<0.1)	4 / 15166 (<0.1)
Baseline SARS-CoV-2 negative	6 / 14554 (<0.1)	4 / 14594 (<0.1)
Baseline SARS-CoV-2 positive	0 / 343	0 / 337
Death*	4 / 15185 (<0.1)	6 / 15166 (<0.1)
Related deaths*	0 / 15185	0 / 15166
AE leading to discontinuation of the vaccine up to 28 days after any injection	50 / 15185 (0.3)	80 / 15166 (0.5)
Baseline SARS-CoV-2 negative	41 / 14554 (0.3)	75 / 14594 (0.5)
Baseline SARS-CoV-2 positive	6 / 343 (1.7)	5 / 337 (1.5)

n= # of participants with specified reaction.

N= number of exposed subjects who submitted any data for the event, percentages are based on n/N.

*Deaths reported for entire study period (overall stage) as of 25 Nov 2020.

6. Solicited Adverse Events

Table 11: Solicited Local Reactions (Safety Set*) (Source: Table 14.3.1.1.1, Table 14.3.1.1.2, Table 14.3.1.1.3)

	Vaccine Group Dose 1 n (%)	Placebo Group Dose 1 n (%)	Vaccine Group Dose 2 n (%)	Placebo Group Dose 2 n (%)	Vaccine Group Any Dose n (%)	Placebo Group Any Dose n (%)
Local injection site reaction	N=15164	N=15151	N=14673	N=14562	N=15179	N=15162
Any	12765 (84.2)	2997 (19.8)	13006 (88.6)	2735 (18.8)	14027 (92.4)	4450 (29.3)
Grade 3 or 4	529 (3.5)	78 (0.5)	1020 (7.0)	72 (0.5)	1418 (9.3)	145 (1.0)
Pain	N=15164	N=15151	N=14673	N=14562	N=15179	N=15162
Any	12690 (83.7)	2658 (17.5)	12943 (88.2)	2477 (17.0)	13965 (92.0)	4037 (26.6)
Grade 3 or 4 ^a	416 (2.7)	55 (0.4)	604 (4.1)	40 (0.3)	922 (6.1)	92 (0.6)

	Vaccine Group Dose 1 n (%)	Placebo Group Dose 1 n (%)	Vaccine Group Dose 2 n (%)	Placebo Group Dose 2 n (%)	Vaccine Group Any Dose n (%)	Placebo Group Any Dose n (%)
Erythema	N=15163	N=15151	N=14673	N=14562	N=15179	N=15162
Any	430 (2.8)	67 (0.4)	1257 (8.6)	56 (0.4)	1522 (10.0)	117 (0.8)
Grade 3 or 4 ^b	42 (0.3)	13 (<0.1)	287 (2.0)	15 (0.1)	324 (2.1)	27 (0.2)
Swelling / induration	N=15163	N=15151	N=14673	N=14562	N=15179	N=15162
Any	932 (6.1)	52 (0.3)	1789 (12.2)	49 (0.3)	2232 (14.7)	95 (0.6)
Grade 3 or 4 ^b	82 (0.5)	6 (<0.1)	254 (1.7)	11 (<0.1)	326 (2.1)	16 (0.1)
Axillary swelling/Tenderness ^c	N=15163	N=15151	N=14673	N=14562	N=15179	N=15162
Any	1553 (10.2)	722 (4.8)	2090 (14.2)	567 (3.9)	3011 (19.8)	1098 (7.2)
Grade 3 or 4	49 (0.3)	27 (0.2)	67 (0.5)	19 (0.1)	110 (0.7)	45 (0.3)

*Safety Set: all randomized participants who received ≥1 vaccine or control dose.

Note: Adverse reaction data were collected on the electronic diary (e-Diary) by participants and those collected on the eCRF indicated as solicited adverse reactions.

n= # of participants with specified reaction.

N= number of exposed subjects who submitted any data for the event, percentages are based on n/N.

^a Pain- Grade 3: any use of Rx pain reliever/prevents daily activity; Grade 4: requires E.R. visit or hospitalization.

^b Erythema and Swelling/Induration- Grade 3: >100mm/>10cm; Grade 4: necrosis/exfoliative dermatitis.

^c Axillary Swelling/Tenderness collected as solicited local adverse reaction (i.e. lymphadenopathy: localized axillary swelling or tenderness ipsilateral to the vaccination group) - Grade 3: any use of Rx pain reliever/prevents daily activity; Grade 4: requires E.R. visit or hospitalization.

Table 12: Solicited Systemic Adverse Events (Safety Set*) (Source: Table 14.3.1.1.1, Table 14.3.1.1.2, Table 14.3.1.1.3)

	Vaccine Group Dose 1 n (%)	Placebo Group Dose 1 n (%)	Vaccine Group Dose 2 n (%)	Placebo Group Dose 2 n (%)	Vaccine Group Any Dose n (%)	Placebo Group Any Dose n (%)
Systemic adverse reaction	N=15167	N=15155	N=14677	N=14565	N=15179	N=15163
Any	8320 (54.9)	6399 (42.2)	11652 (79.4)	5323 (36.5)	12770 (84.1)	8112 (53.5)
Grade 3 or 4	452 (3.0)	314 (2.1)	2339 (15.9)	285 (2.0)	2629 (17.3)	565 (3.7)
Fever	N=15164	N=15153	N=14669	N=14559	N=15178	N=15162
Any	115 (0.8)	44 (0.3)	2278 (15.5)	43 (0.3)	2353 (15.5)	86 (0.6)
Grade 3 or 4 ^a	15 (<0.1)	8 (<0.1)	215 (1.5)	5 (<0.1)	229 (1.5)	13 (<0.1)
Headache	N=15163	N=15150	N=14673	N=14562	N=15179	N=15162
Any	4951 (32.7)	4027 (26.6)	8602 (58.6)	3410 (23.4)	9825 (64.7)	5603 (37.0)
Grade 3 or 4 ^b	271 (1.8)	196 (1.3)	659 (4.5)	162 (1.1)	869 (5.7)	341 (2.2)
Fatigue	N=15163	N=15150	N=14673	N=14560	N=15179	N=15162
Any	5635 (37.2)	4133 (27.3)	9582 (65.3)	3403 (23.4)	10627 (70.0)	5544 (36.6)
Grade 3 or 4 ^c	151 (1.0)	105 (0.7)	1428 (9.7)	106 (0.7)	1529 (10.1)	200 (1.3)
Myalgia	N=15163	N=15150	N=14673	N=14560	N=15179	N=15162
Any	3441 (22.7)	2071 (13.7)	8508 (58.0)	1809 (12.4)	9334 (61.5)	3113 (20.5)
Grade 3 or 4 ^c	90 (0.6)	47 (0.3)	1318 (9.0)	52 (0.4)	1382 (9.1)	98 (0.6)

	Vaccine Group Dose 1 n (%)	Placebo Group Dose 1 n (%)	Vaccine Group Dose 2 n (%)	Placebo Group Dose 2 n (%)	Vaccine Group Any Dose n (%)	Placebo Group Any Dose n (%)
Arthralgia	N=15163	N=15150	N=14673	N=14560	N=15179	N=15162
Any	2511 (16.6)	1783 (11.8)	6284 (42.8)	1569 (10.8)	7044 (46.4)	2666 (17.6)
Grade 3 or 4 ^c	61 (0.4)	37 (0.2)	770 (5.2)	44 (0.3)	813 (5.4)	80 (0.5)
Nausea / vomiting	N=15163	N=15150	N=14673	N=14560	N=15179	N=15162
Any	1262 (8.3)	1074 (7.1)	2785 (19.0)	934 (6.4)	3484 (23.0)	1716 (11.3)
Grade 3 or 4 ^d	10 (<0.1)	12 (<0.1)	21 (0.1)	11 (<0.1)	30 (0.2)	23 (0.2)
Chills	N=15163	N=15150	N=14673	N=14560	N=15179	N=15162
Any	1253 (8.3)	878 (5.8)	6482 (44.2)	809 (5.6)	6891 (45.4)	1470 (9.7)
Grade 3 or 4 ^e	24 (0.2)	14 (<0.1)	191 (1.3)	17 (0.1)	211 (1.4)	31 (0.2)

*Safety Set: all randomized participants who received ≥1 vaccine or control dose.

Note: Adverse reaction data were collected on the electronic diary (e-Diary) by participants and those collected on the eCRF indicated as solicited adverse reactions.

n = # of participants with specified reaction

N = number of exposed subjects who submitted any data for the event, percentages are based on n/N

^a Fever - Grade 3: ≥39.0 – ≤ 40.0°C or ≥102.1 – ≤104.0°F; Grade 4: > 40.0°C > 104.0°F

^b Headache – Grade 3: Significant; any use of Rx pain reliever or prevents daily activity; Grade 4: Requires E.R. visit or hospitalization

^c Fatigue, Myalgia, Arthralgia – Grade 3: Significant; prevents daily activity; Grade 4: Requires E.R. visit or hospitalization

^d Nausea/Vomiting – Grade 3: Prevents daily activity, requires outpatient intravenous hydration; Grade 4: Requires E.R. visit or hospitalization for hypotensive shock

^e Chills – Grade 3: Prevents daily activity and requires medical intervention; Grade 4: Requires E.R. visit or hospitalization

Table 13: Percentage of Subjects Reporting the Occurrence of More Than 1% Unsolicited AEs Classified by MedDRA Primary System Organ Class and Preferred Term (Safety Set*) (Source: Table 14.3.1.8.1, Table 14.3.1.17.1)

Primary System Organ Class (CODE) Preferred Term (CODE)	Vaccine Group (N=15185)		Placebo Group (N=15166)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Infections and infestations Adverse events in any PT	611 (4.0)	16 (0.1)	734 (4.8)	25 (0.2)
Nervous system disorders Adverse events in any PT	684 (4.5)	30 (0.2)	622 (4.1)	21 (0.1)
Headache	466 (3.1)	20 (0.1)	458 (3.0)	12 (<0.1)
Vascular disorders Adverse events in any PT	163 (1.1)	30 (0.2)	152 (1.0)	43 (0.3)
Respiratory, thoracic and mediastinal disorders Adverse events in any PT	536 (3.5)	11 (<0.1)	583 (3.8)	11 (<0.1)
Cough	164 (1.1)	2 (<0.1)	156 (1.0)	2 (<0.1)
Oropharyngeal pain	147 (1.0)	1 (<0.1)	203 (1.3)	3 (<0.1)
Gastrointestinal disorders Adverse events in any PT	478 (3.1)	17 (0.1)	440 (2.9)	14 (<0.1)
Diarrhoea	189 (1.2)	3 (<0.1)	162 (1.1)	1 (<0.1)
Skin and subcutaneous tissue disorders Adverse events in any PT	264 (1.7)	5 (<0.1)	193 (1.3)	2 (<0.1)
Musculoskeletal and connective tissue disorders Adverse events in any PT	671 (4.4)	23 (0.2)	617 (4.1)	24 (0.2)
Myalgia	207 (1.4)	10 (<0.1)	167 (1.1)	2 (<0.1)
Arthralgia	200 (1.3)	8 (<0.1)	181 (1.2)	2 (<0.1)
General disorders and administration site Adverse events in any PT	1006 (6.6)	49 (0.3)	622 (4.1)	13 (<0.1)

Primary System Organ Class (CODE) Preferred Term (CODE)	Vaccine Group (N=15185)		Placebo Group (N=15166)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Fatigue	372 (2.4)	12 (<0.1)	336 (2.2)	6 (<0.1)
Injury, poisoning and procedural complications Adverse events in any PT	280 (1.8)	19 (0.1)	318 (2.1)	16 (0.1)

*Safety Set: all randomized participants who received ≥ 1 vaccine or control dose.
 n/% = number (percentage) of subjects reporting the adverse event at least once
 Percentages are based on the number of safety subjects.

Table 14: Percentage of Subjects Reporting the Occurrence of More Than 1% Unsolicited MAAE up to 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term (Safety Set*) (Source: Table 14.3.1.19.1, Table 14.3.1.19.10)

Primary System Organ Class (CODE) Preferred Term (CODE)	Vaccine Group (N=15185)		Placebo Group (N=15166)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Infections and infestations Adverse events in any PT	413 (2.7)	16 (0.1)	525 (3.5)	22 (0.1)
Respiratory, thoracic and mediastinal disorders Adverse events in any PT	143 (0.9)	8 (<0.1)	168 (1.1)	9 (<0.1)
Musculoskeletal and connective tissue disorders Adverse events in any PT	180 (1.2)	11 (<0.1)	163 (1.1)	15 (<0.1)
Injury, poisoning and procedural complications Adverse events in any PT	164 (1.1)	15 (<0.1)	170 (1.1)	13 (<0.1)

*Safety Set: all randomized participants who received ≥ 1 vaccine or control dose.
 At least one adverse event = at least one adverse event experienced (regardless of the MedDRA Preferred Term)
 N = number of treated subjects included in each treatment group
 n/% = number/percentage of subjects reporting the adverse event at least once
 There was no preferred term reported in $\geq 1\%$ of subjects in either of the treatment group.

Table 15: Percentage of Subjects Reporting the Occurrence SAEs (at Least 3 Subjects in Either Group) Classified by MedDRA Primary System Organ Class and Preferred Term (Safety Set*) (Source: Table 14.3.1.13.10, Table 14.3.1.13.3)

Primary System Organ Class (CODE) Preferred Term (CODE)	Vaccine Group (N=15185) n (%) [n]	Placebo Group (N=15166) n (%) [n]
Infections and infestations Adverse events in any PT Pneumonia Appendicitis COVID-19 Urinary tract infection	20 (0.1) [23] 5 (<0.1) [5] 2 (<0.1) [2] 1 (<0.1) [1] 0	35 (0.2) [39] 7 (<0.1) [7] 3 (<0.1) [3] 15 (<0.1) [15] 4 (<0.1) [4]
Neoplasms benign, malignant and unspecified (including cysts and polyps) Adverse events in any PT Prostate cancer	15 (<0.1) [16] 3 (<0.1) [3]	10 (<0.1) [10] 3 (<0.1) [3]
Metabolism and nutrition disorders Adverse events in any PT Dehydration	4 (<0.1) [6] 3 (<0.1) [3]	7 (<0.1) [9] 3 (<0.1) [4]

Primary System Organ Class (CODE) Preferred Term (CODE)	Vaccine Group (N=15185) n (%) [n]	Placebo Group (N=15166) n (%) [n]
Psychiatric disorders Adverse events in any PT Depression	4 (<0.1) [6] 0	9 (<0.1) [13] 3 (<0.1) [3]
Nervous system disorders Adverse events in any PT Cerebrovascular accident Syncope	16 (<0.1) [16] 3 (<0.1) [3] 2 (<0.1) [2]	10 (<0.1) [12] 1 (<0.1) [1] 4 (<0.1) [4]
Cardiac disorders Adverse events in any PT Myocardial infarction Atrial fibrillation Cardiac failure congestive Acute myocardial infarction	22 (0.1) [25] 5 (<0.1) [5] 5 (<0.1) [5] 3 (<0.1) [3] 2 (<0.1) [2]	24 (0.2) [28] 3 (<0.1) [3] 5 (<0.1) [5] 3 (<0.1) [3] 4 (<0.1) [4]
Vascular disorders* Adverse events in any PT	8 (<0.1) [10]	10 (<0.1) [11]
Respiratory, thoracic and mediastinal disorders Adverse events in any PT Pulmonary embolism Dyspnoea Chronic obstructive pulmonary disease	13 (<0.1) [14] 4 (<0.1) [4] 3 (<0.1) [3] 0	19 (0.1) [21] 5 (<0.1) [5] 0 4 (<0.1) [4]
Gastrointestinal disorders Adverse events in any PT Abdominal pain upper Nausea	23 (0.2) [26] 3 (<0.1) [3] 3 (<0.1) [3]	10 (<0.1) [12] 0 1 (<0.1) [1]
Hepatobiliary disorders Adverse events in any PT Cholecystitis	5 (<0.1) [5] 3 (<0.1) [3]	0 0
Musculoskeletal and connective tissue disorders* Adverse events in any PT	12 (<0.1) [12]	9 (<0.1) [9]
Renal and urinary disorders Adverse events in any PT Nephrolithiasis Acute kidney injury	4 (<0.1) [4] 3 (<0.1) [3] 1 (<0.1) [1]	4 (<0.1) [4] 0 [0] 3 (<0.1) [3]
Reproductive system and breast disorders* Adverse events in any PT	4 (<0.1) [5]	0
General disorders and administration site conditions* Adverse events in any PT	7 (<0.1) [7]	6 (<0.1) [7]
Injury, poisoning and procedural complications Adverse events in any PT Fall Ankle fracture	16 (0.1) [24] 2 (<0.1) [2] 0	20 (0.1) [23] 3 (<0.1) [3] 3 (<0.1) [3]
Surgical and medical procedures* Adverse events in any PT	3 (<0.1) [3]	4 (<0.1) [4]

*Safety Set: all randomized participants who received ≥1 vaccine or control dose.

At least one adverse event = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

N = number of treated subjects included in each treatment group

n (%) = number (percentage) of subjects reporting the adverse event at least once

[n] = number of events reported

Percentages are based on the number of safety subjects.

*There was no preferred term reported in ≥ 3 subjects in either of the treatment group.

7. SMQ analyses

Table 16: Summary of Vasculitis (Safety Set) (Source: Table 14.3.1.22.1)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Subjects with any TEAE within SMQ	0	1 (<0.1)
Polymyalgia rheumatica	0	1 (<0.1)

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Vasculitis is identified through selected SMQ.

Table 17: Summary of Hypersensitivity (Safety Set) (Source: Table 14.3.1.22.2)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Subjects with any TEAE within SMQ	233 (1.5)	166 (1.1)
Allergic sinusitis	2 (<0.1)	1 (<0.1)
Anaphylactic reaction	1 (<0.1)	1 (<0.1)
Angioedema	1 (<0.1)	3 (<0.1)
Bronchospasm	1 (<0.1)	0
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)
Dermatitis	8 (<0.1)	8 (<0.1)
Dermatitis allergic	2 (<0.1)	3 (<0.1)
Dermatitis atopic	4 (<0.1)	7 (<0.1)
Dermatitis bullous	0	2 (<0.1)
Dermatitis contact	21 (0.1)	29 (0.2)
Drug hypersensitivity	4 (<0.1)	4 (<0.1)
Eczema	3 (<0.1)	4 (<0.1)
Exfoliative rash	1 (<0.1)	0
Eye swelling	2 (<0.1)	2 (<0.1)
Gingival swelling	0	1 (<0.1)
Hand dermatitis	2 (<0.1)	0
Hypersensitivity	5 (<0.1)	4 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)
Injection site rash	37 (0.2)	1 (<0.1)
Injection site urticaria	15 (<0.1)	0
Laryngeal oedema	0	1 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)
Palatal oedema	0	1 (<0.1)
Periorbital oedema	0	1 (<0.1)
Periorbital swelling	0	2 (<0.1)
Rash	45 (0.3)	34 (0.2)
Rash erythematous	6 (<0.1)	2 (<0.1)
Rash follicular	0	1 (<0.1)
Rash macular	6 (<0.1)	4 (<0.1)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Rash maculo-papular	11 (<0.1)	2 (<0.1)
Rash pruritic	6 (<0.1)	4 (<0.1)
Rash pustular	1 (<0.1)	0
Rash vesicular	3 (<0.1)	0
Rhinitis allergic	10 (<0.1)	13 (<0.1)
Serum sickness	0	1 (<0.1)
Swelling face	4 (<0.1)	2 (<0.1)
Swelling of eyelid	2 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	0
Type IV hypersensitivity reaction	1 (<0.1)	0
Urticaria	27 (0.2)	23 (0.2)
Urticaria papular	3 (<0.1)	5 (<0.1)
Vaccination site rash	1 (<0.1)	0

Percentages are based on the number of safety subjects.
 MedDRA version 23.0.
 Hypersensitivity is identified through selected SMQ.

Table 18: Summary of Arthritis (Safety Set) (Source: Table 14.3.1.22.3)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Subjects with any TEAE within SMQ	36 (0.2)	39 (0.3)
Arthritis	11 (<0.1)	3 (<0.1)
Chondrocalcinosis pyrophosphate	1 (<0.1)	0
Gout	5 (<0.1)	9 (<0.1)
Osteoarthritis	11 (<0.1)	21 (0.1)
Periarthritis	1 (<0.1)	1 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0
Spinal osteoarthritis	3 (<0.1)	3 (<0.1)
Spondylitis	1 (<0.1)	0
Synovitis	0	1 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	1 (<0.1)

Percentages are based on the number of safety subjects.
 MedDRA version 23.0.
 Arthritis is identified through selected SMQ.

Table 19: Summary of Angioedema (Safety Set) (Source: Table 14.3.1.22.4)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Subjects with any TEAE within SMQ	41 (0.3)	43 (0.3)
Angioedema	1 (<0.1)	3 (<0.1)
Eye swelling	2 (<0.1)	2 (<0.1)
Gingival swelling	0	1 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Laryngeal oedema	0	1 (<0.1)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Lip swelling	2 (<0.1)	2 (<0.1)
Palatal oedema	0	1 (<0.1)
Periorbital oedema	0	1 (<0.1)
Periorbital swelling	0	2 (<0.1)
Swelling face	4 (<0.1)	2 (<0.1)
Swelling of eyelid	2 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	0
Urticaria	27 (0.2)	23 (0.2)
Urticaria papular	3 (<0.1)	5 (<0.1)

Percentages are based on the number of safety subjects.
 MedDRA version 23.0.
 Angioedema is identified through selected SMQ.

Table 20: Summary of Peripheral Neuropathy (Safety Set) (Source: Table 14.3.1.22.5)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Subjects with any TEAE within SMQ	6 (<0.1)	5 (<0.1)
Neuralgia	1 (<0.1)	3 (<0.1)
Neuropathy peripheral	2 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	2 (<0.1)	0
Small fibre neuropathy	1 (<0.1)	0

Percentages are based on the number of safety subjects.
 MedDRA version 23.0.
 Peripheral Neuropathy is identified through selected SMQ.

Table 21: Summary of Demyelinating Disease of Central Nervous System (Safety Set) (Source: Table 14.3.1.22.6)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Subjects with any TEAE within SMQ	0	1 (<0.1)
Multiple sclerosis	0	1 (<0.1)

Percentages are based on the number of safety subjects.
 MedDRA version 23.0.
 Demyelinating Disease of Central Nervous System is identified through selected SMQ.

Table 22: Summary of Convulsions (Safety Set) (Source: Table 14.3.1.22.7)

Dictionary Derived Term Number of Subjects (%)	Vaccine Group (N=15185)	Placebo Group (N=15166)
Subjects with any TEAE within SMQ	3 (<0.1)	1 (<0.1)
Seizure	3 (<0.1)	1 (<0.1)

Percentages are based on the number of safety subjects.
 MedDRA version 23.0.
 [1] Convulsions is identified through selected SMQ.