Table 17: Summary of Unsolicited TEAEs up to 28 Days After Any Injection in Study mRNA-1273-P301 (Safety Set)

	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Unsolicited TEAEs regardless of relationship to study vaccination			
All	2949 (19.4)	3325 (21.9)	6274 (20.7)
Serious	86 (0.6)	82 (0.5)	168 (0.6)
Fatal	3 (<0.1)	2 (<0.1)	5 (<0.1)
Medically attended	1276 (8.4)	1215 (8.0)	2491 (8.2)
Leading to discontinuation from study vaccine	71 (0.5)	41 (0.3)	112 (0.4)
Leading to discontinuation from participation in the study	0	0	0
Severe	190 (1.3)	216 (1.4)	406 (1.3)
Unsolicited TEAEs related to study vaccination			
All	609 (4.0)	1127 (7.4)	1736 (5.7)
Serious	4 (<0.1)	5 (<0.1)	9 (<0.1)
Fatal	0	0	0
Medically attended	73 (0.5)	122 (0.8)	195 (0.6)
Leading to discontinuation from study vaccine	13 (<0.1)	15 (<0.1)	28 (<0.1)
Leading to discontinuation from participation in the study	0	0	0
Severe	29 (0.2)	70 (0.5)	99 (0.3)

Note: A 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 were based on the number of safety participants.

Source: mRNA-1273-P301 Table 14.3.1.7.1.

The numbers and titles of the mRNA-1273-P301 table referenced in this section are as follows:

Table Number	Title
14.3.1.7.1	Summary of Unsolicited TEAE up to 28 Days After Any Injection - Safety Set
14.3.1.7.3	Summary of Unsolicited TEAE in Overall Stage - Safety Set

2.5.5.1.2.2 Most Common Unsolicited Adverse Events

The incidence of unsolicited TEAEs in the 28 days after injection was generally similar between participants who received mRNA-1273 (3325 [21.9%] participants) and those who received placebo (2949 [19.4%] participants; Table 18). Overall, the most commonly reported unsolicited TEAE in all participants in the 28 days after injection by PT was headache (844 [2.8%] participants). In the mRNA-1273 group, unsolicited TEAEs reported in ≥ 2% of participants in the 28 days after injection by PT included headache and fatigue.

Similar results were noted during the overall study period as of 11 Nov 2020 (data snapshot date) (mRNA-1273-P301 Table 14.3.1.8.3).

Table 18: Summary of Most Common Unsolicited TEAE Reported by at Least 1% of Participants in Any Treatment Group up to 28 Days After Any Injection in Study mRNA-1273-P301 (Safety Set)

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Number of participants reporting unsolicited AEs	2949 (19.4)	3325 (21.9)	6274 (20.7)
Number of unsolicited AEs	5348	6157	11505
Nervous system disorders	552 (3.6)	624 (4.1)	1176 (3.9)
Headache	409 (2.7)	435 (2.9)	844 (2.8)
Respiratory, thoracic and mediastinal disorders	522 (3.4)	480 (3.2)	1002 (3.3)
Cough	143 (0.9)	148 (1.0)	291 (1.0)
Oropharyngeal pain	184 (1.2)	137 (0.9)	321 (1.1)
Gastrointestinal disorders	387 (2.6)	426 (2.8)	813 (2.7)
Diarrhoea	147 (1.0)	178 (1.2)	325 (1.1)
Musculoskeletal and connective tissue disorders	521 (3.4)	586 (3.9)	1107 (3.6)
Arthralgia	152 (1.0)	174 (1.1)	326 (1.1)
Myalgia	138 (0.9)	172 (1.1)	310 (1.0)
General disorders and administration site conditions	560 (3.7)	894 (5.9)	1454 (4.8)
Fatigue	307 (2.0)	344 (2.3)	651 (2.1)
Injection site pain	49 (0.3)	147 (1.0)	196 (0.6)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities.

Notes: A 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 were based on the number of safety participants. All AEs were coded using MedDRA Version 23.0.

Uncoded AEs (from 397 participants) are reported at this interim database lock; however, all AEs will be coded by the time of final database lock and clinical study report submission.

Source: mRNA-1273-P301 Table 14.3.1.8.1.

The numbers and titles of the mRNA-1273-P301 tables referenced in this section are as follows:

Table Number	Title
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
14.3.1.8.3	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set

2.5.5.1.2.3 Treatment-Related Unsolicited Adverse Events

Treatment-related TEAEs were reported by 1127 (7.4%) participants who received mRNA-1273 and 609 (4.0%) participants who received placebo (mRNA-1273-P301 Table 14.3.1.11.1). In the

Table 19: Summary of Unsolicited Severe TEAEs Reported by at Least 5 Participants in Any Treatment Group up to 28 Days After Any Injection in Study mRNA-1273-P301 (Safety Set)

System Organ Class Preferred Term	Placebo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Number of participants reporting unsolicited severe AEs	190 (1.3)	216 (1.4)	406 (1.3)
Number of unsolicited severe AEs	225	275	500
Nervous system disorders	21 (0.1)	27 (0.2)	48 (0.2)
Headache	13 (<0.1)	19 (0.1)	32 (0.1)
Cardiac disorders	13 (<0.1)	11 (<0.1)	24 (<0.1)
Bradycardia	5 (<0.1)	3 (<0.1)	8 (<0.1)
Vascular disorders	39 (0.3)	28 (0.2)	67 (0.2)
Hypertension	29 (0.2)	22 (0.1)	51 (0.2)
Musculoskeletal and connective tissue disorders	18 (0.1)	24 (0.2)	42 (0.1)
Myalgia	0	11 (<0.1)	11 (<0.1)
Arthralgia	2 (<0.1)	10 (<0.1)	12 (<0.1)
Back pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
General disorders and administration site conditions	13 (<0.1)	43 (0.3)	56 (0.2)
Fatigue	7 (<0.1)	12 (<0.1)	19 (<0.1)
Injection site erythema	0	11 (<0.1)	11 (<0.1)
Injection site pain	1 (<0.1)	6 (<0.1)	7 (<0.1)
Investigations	13 (<0.1)	22 (0.1)	35 (0.1)
Blood pressure increased	7 (<0.1)	10 (<0.1)	17 (<0.1)
Blood pressure systolic increased	6 (<0.1)	8 (<0.1)	14 (<0.1)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities.

Notes: A 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 were based on the number of safety participants. All AEs were coded using MedDRA Version 23.0.

Uncoded AEs (from 16 participants) are reported at this interim database lock; however, all AEs will be coded by the time of final database lock and clinical study report submission.

Source: mRNA-1273-P301 Table 14.3.1.17.1.

The numbers and titles of the mRNA-1273-P301 tables referenced in this section are as follows:

Table Number	Title
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
14.3.1.18.1	Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set

2.5.5.1.2.5 Unsolicited Medically Attended Adverse Events

An MAAE was an AE that led to an unscheduled visit (including a telemedicine visit) to a healthcare practitioner (including unscheduled visits to the study site).

The incidence of MAAEs within 28 days of injection was generally similar between participants who received mRNA-1273 (1215 [8.0%] participants) and those who received placebo (1276 [8.4%] participants; mRNA-1273-P301 Table 14.3.1.19.1).

The incidence of MAAEs was similar in the mRNA-1273 and placebo groups (9.3% and 10.1%, respectively) during the overall study period as of 11 Nov 2020 (data snapshot date) (mRNA-1273-P301 Table 14.3.1.19.3).

The numbers and titles of the mRNA-1273-P301 tables referenced in this section are as follows:

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

2.5.5.1.2.6 Deaths, Other Serious Adverse Events, and Other Significant Unsolicited Adverse Events

2.5.5.1.2.6.1 Deaths

A total of 8 deaths were reported in Study mRNA-1273-P301 through 11 Nov 2020 (data snapshot date), with 4 occurring in the mRNA-1273 group and 4 occurring in the placebo group (mRNA-1273-P301 Table 14.3.1.7.3). A summary of participants with SAEs resulting in death is presented in Table 20. None were considered related to IP or were due to COVID-19.

Table 20: Participants with SAEs Resulting in Death in Study mRNA-1273-P301

Treatment Assignment	Preferred Term(s)
mRNA-1273	Cardio-respiratory arrest
mRNA-1273	PPD
mRNA-1273	Head injury
mRNA-1273	Myocardial infarction
Placebo	Systemic inflammatory response syndrome; Dermatitis bullous
Placebo	Myocardial infarction
Placebo	Abdominal injury (intra-abdominal perforation)
Placebo	Cardio-respiratory arrest

Source: mRNA-1273-P301 Listing 16.2.7.9.

The number and title of the mRNA-1273-P301 table referenced in this section are as follows:

Table Number	Title
14.3.1.7.3	Summary of Unsolicited TEAE in Overall Stage - Safety Set

2.5.5.1.2.6.2 Other Serious Adverse Events

The incidence of other SAEs in the 28 days after IP injection was similar between treatment groups (Table 21).

The incidence of treatment-related SAEs in the 28 days after IP injection was similar between treatment groups (mRNA-1273-P301 Table 14.3.1.14.1).

The incidence of SAEs was similar in the mRNA-1273 and placebo groups during the overall study period as of 11 Nov 2020 (data snapshot date) (mRNA-1273-P301 Table 14.3.1.13.3 and Table 14.3.1.14.3).