

Ad-hoc Table IR13.1.1
Summary of Unsolicited AE Occurring within 30 Minutes of 1st Vaccination
Safety Set (Dose 1)

	Placbo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination	0	0	0
All	62 (0.4)	60 (0.4)	122 (0.4)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	9 (<0.1)	9 (<0.1)	18 (<0.1)
Leading to Discontinuation from Study Vaccine	1 (<0.1)	0	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	9 (<0.1)	4 (<0.1)	13 (<0.1)
	0	0	0
Unsolicited TEAEs Related to Study Vaccination	0	0	0
All	17 (0.1)	15 (<0.1)	32 (0.1)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (<0.1)	3 (<0.1)	8 (<0.1)
Leading to Discontinuation from Study Vaccine	1 (<0.1)	0	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

N: Number of participants in Safety Set who received 1st injection

n: Number of participants who reported AEs in specified category

Source code: adhoc-t-ir13-1-1.sas

adhoc-t-ir13-1-1.rtf

Date/Time Generated: 12/10/2020 9:35

Ad-hoc Table IR13.1.2
Summary of Unsolicited AE Occurring within 30 Minutes of 2nd Vaccination
Safety Set (Dose 2)

	Placbo (N=13913) n (%)	mRNA-1273 (N=13985) n (%)	Total (N=27898) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination	0	0	0
All	27 (0.2)	33 (0.2)	60 (0.2)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	3 (<0.1)	0	3 (<0.1)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	3 (<0.1)	3 (<0.1)
Unsolicited TEAEs Related to Study Vaccination	0	0	0
All	8 (<0.1)	12 (<0.1)	20 (<0.1)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	1 (<0.1)	0	1 (<0.1)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

N: Number of participants in Safety Set who received 2nd injection

n: Number of participants who reported AEs in specified category

Source code: adhoc-t-ir13-1-2.sas

adhoc-t-ir13-1-2.rtf

Date/Time Generated: 12/10/2020 9:35

Ad-hoc Table IR13.1.3
Summary of Unsolicited AE Occurring within 30 Minutes of Any Vaccination
Safety Set

	Placbo (N=15165) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30350) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination	0	0	0
All	85 (0.6)	88 (0.6)	173 (0.6)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	12 (<0.1)	9 (<0.1)	21 (<0.1)
Leading to Discontinuation from Study Vaccine	1 (<0.1)	0	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	9 (<0.1)	7 (<0.1)	16 (<0.1)
	0	0	0
Unsolicited TEAEs Related to Study Vaccination	0	0	0
All	25 (0.2)	26 (0.2)	51 (0.2)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	6 (<0.1)	3 (<0.1)	9 (<0.1)
Leading to Discontinuation from Study Vaccine	1 (<0.1)	0	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)

Ad-hoc Table IR13.2.1

Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of First Vaccination by Preferred Term
Safety Set (Dose 1)

Preferred Term	Placebo (N=15165)		mRNA-1273 (N=15184)		Total (N=30350)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Number of Subjects with Immediate Unsolicited Adverse Events	62 (0.4)	9 (<0.1)	60 (0.4)	4 (<0.1)	122 (0.4)	13 (<0.1)
Number of Immediate Unsolicited Adverse Events	67	9	69	4	136	13
Tachypnoea	16 (0.1)	0	13 (<0.1)	0	29 (<0.1)	0
Hypertension	14 (<0.1)	4 (<0.1)	12 (<0.1)	2 (<0.1)	26 (<0.1)	6 (<0.1)
Bradycardia	5 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	9 (<0.1)	3 (<0.1)
Arthralgia	0	0	3 (<0.1)	0	3 (<0.1)	0
Blood pressure increased	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	6 (<0.1)	2 (<0.1)
Dizziness	5 (<0.1)	0	3 (<0.1)	0	8 (<0.1)	0
Fatigue	0	0	3 (<0.1)	0	3 (<0.1)	0
Haematoma	0	0	2 (<0.1)	0	2 (<0.1)	0
Hypoaesthesia	0	0	2 (<0.1)	0	2 (<0.1)	0
Injection site pain	4 (<0.1)	0	2 (<0.1)	0	6 (<0.1)	0
Presyncope	3 (<0.1)	0	2 (<0.1)	0	5 (<0.1)	0
Tachycardia	2 (<0.1)	0	2 (<0.1)	0	4 (<0.1)	0
Feeling hot	0	0	1 (<0.1)	0	1 (<0.1)	0
Flushing	0	0	1 (<0.1)	0	1 (<0.1)	0
Headache	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Hyperhidrosis	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Hypersensitivity	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site bruising	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site haematoma	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site pruritus	0	0	1 (<0.1)	0	1 (<0.1)	0
Limb discomfort	0	0	1 (<0.1)	0	1 (<0.1)	0
Musculoskeletal chest pain	0	0	1 (<0.1)	0	1 (<0.1)	0

N: Number of participants in Safety Set who received 1st injection; n: Number of participants who reported AEs in specified category; %=n/N*100.

MedDRA version 23.0

Preferred term is sorted by descending frequency in mRNA-1273 Any column.

Program: adhoc-t-ir13-2-1.sas

Run date: 10DEC2020 15:01

Ad-hoc Table IR13.2.1

Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of First Vaccination by Preferred Term
Safety Set (Dose 1)

Preferred Term	Placebo (N=15165)		mRNA-1273 (N=15184)		Total (N=30350)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Myalgia	0	0	1 (<0.1)	0	1 (<0.1)	0
Non-cardiac chest pain	0	0	1 (<0.1)	0	1 (<0.1)	0
Paraesthesia	0	0	1 (<0.1)	0	1 (<0.1)	0
Pruritus	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Salivary hypersecretion	0	0	1 (<0.1)	0	1 (<0.1)	0
Syncope	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Uncoded: JOINT PAIN, RIGHT SHOULDER	0	0	1 (<0.1)	0	1 (<0.1)	0
Vessel puncture site haemorrhage	0	0	1 (<0.1)	0	1 (<0.1)	0
Blood pressure systolic increased	1 (<0.1)	0	0	0	1 (<0.1)	0
Dysgeusia	2 (<0.1)	0	0	0	2 (<0.1)	0
Hypotension	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Procedural nausea	1 (<0.1)	0	0	0	1 (<0.1)	0
Systolic hypertension	2 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	1 (<0.1)
Uncoded: HEAT (L NECK)	1 (<0.1)	0	0	0	1 (<0.1)	0
Varicella zoster virus infection	1 (<0.1)	0	0	0	1 (<0.1)	0
Vessel puncture site bruise	1 (<0.1)	0	0	0	1 (<0.1)	0

N: Number of participants in Safety Set who received 1st injection; n: Number of participants who reported AEs in specified category; %=n/N*100.

MedDRA version 23.0

Preferred term is sorted by descending frequency in mRNA-1273 Any column.

Program: adhoc-t-ir13-2-1.sas

Run date: 10DEC2020 15:01

Ad-hoc Table IR13.2.2

Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Second Vaccination by Preferred Term
Safety Set (Dose 2)

Preferred Term	Placebo (N=13913)		mRNA-1273 (N=13985)		Total (N=27898)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Number of Subjects with Immediate Unsolicited Adverse Events	27 (0.2)	0	33 (0.2)	3 (<0.1)	60 (0.2)	3 (<0.1)
Number of Immediate Unsolicited Adverse Events	30	0	38	4	68	4
Dizziness	3 (<0.1)	0	5 (<0.1)	0	8 (<0.1)	0
Hypertension	6 (<0.1)	0	5 (<0.1)	1 (<0.1)	11 (<0.1)	1 (<0.1)
Blood pressure increased	0	0	4 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)
Bradycardia	4 (<0.1)	0	3 (<0.1)	0	7 (<0.1)	0
Dysgeusia	1 (<0.1)	0	2 (<0.1)	0	3 (<0.1)	0
Arthralgia	0	0	1 (<0.1)	0	1 (<0.1)	0
Blood pressure systolic increased	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Chills	0	0	1 (<0.1)	0	1 (<0.1)	0
Ecchymosis	0	0	1 (<0.1)	0	1 (<0.1)	0
Headache	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site bruising	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site erythema	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site haematoma	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site induration	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Injection site pain	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site swelling	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Limb discomfort	0	0	1 (<0.1)	0	1 (<0.1)	0
Malaise	0	0	1 (<0.1)	0	1 (<0.1)	0
Myalgia	0	0	1 (<0.1)	0	1 (<0.1)	0
Pain in extremity	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Paraesthesia	0	0	1 (<0.1)	0	1 (<0.1)	0
Tachycardia	0	0	1 (<0.1)	0	1 (<0.1)	0

N: Number of participants in Safety Set who received 2nd injection; n: Number of participants who reported AEs in specified category; %=n/N*100.

MedDRA version 23.0

Preferred term is sorted by descending frequency in mRNA-1273 Any column.

Program: adhoc-t-ir13-2-2.sas

Run date: 10DEC2020 14:59

Ad-hoc Table IR13.2.2

Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Second Vaccination by Preferred Term
Safety Set (Dose 2)

Preferred Term	Placebo (N=13913)		mRNA-1273 (N=13985)		Total (N=27898)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Anxiety	1 (<0.1)	0	0	0	1 (<0.1)	0
Disturbance in attention	1 (<0.1)	0	0	0	1 (<0.1)	0
Fatigue	1 (<0.1)	0	0	0	1 (<0.1)	0
Feeling abnormal	1 (<0.1)	0	0	0	1 (<0.1)	0
Hypotension	1 (<0.1)	0	0	0	1 (<0.1)	0
Injection site haemorrhage	1 (<0.1)	0	0	0	1 (<0.1)	0
Injection site pruritus	1 (<0.1)	0	0	0	1 (<0.1)	0
Musculoskeletal chest pain	1 (<0.1)	0	0	0	1 (<0.1)	0
Nausea	2 (<0.1)	0	0	0	2 (<0.1)	0

N: Number of participants in Safety Set who received 2nd injection; n: Number of participants who reported AEs in specified category; %=n/N*100.

MedDRA version 23.0

Preferred term is sorted by descending frequency in mRNA-1273 Any column.

Program: adhoc-t-ir13-2-2.sas

Run date: 10DEC2020 14:59

Ad-hoc Table IR13.2.3

Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term Safety Set

Preferred Term	Placebo (N=15165)		mRNA-1273 (N=15184)		Total (N=30350)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Number of Subjects with Immediate Unsolicited Adverse Events	85 (0.6)	9 (<0.1)	88 (0.6)	7 (<0.1)	173 (0.6)	16 (<0.1)
Number of Immediate Unsolicited Adverse Events	97	9	107	8	204	17
Hypertension	19 (0.1)	4 (<0.1)	15 (<0.1)	3 (<0.1)	34 (0.1)	7 (<0.1)
Tachypnoea	16 (0.1)	0	13 (<0.1)	0	29 (<0.1)	0
Blood pressure increased	3 (<0.1)	1 (<0.1)	7 (<0.1)	2 (<0.1)	10 (<0.1)	3 (<0.1)
Dizziness	8 (<0.1)	0	7 (<0.1)	0	15 (<0.1)	0
Bradycardia	8 (<0.1)	2 (<0.1)	6 (<0.1)	1 (<0.1)	14 (<0.1)	3 (<0.1)
Arthralgia	0	0	4 (<0.1)	0	4 (<0.1)	0
Fatigue	1 (<0.1)	0	3 (<0.1)	0	4 (<0.1)	0
Injection site pain	5 (<0.1)	0	3 (<0.1)	0	8 (<0.1)	0
Tachycardia	2 (<0.1)	0	3 (<0.1)	0	5 (<0.1)	0
Dysgeusia	3 (<0.1)	0	2 (<0.1)	0	5 (<0.1)	0
Haematoma	0	0	2 (<0.1)	0	2 (<0.1)	0
Headache	2 (<0.1)	0	2 (<0.1)	0	4 (<0.1)	0
Hypoaesthesia	0	0	2 (<0.1)	0	2 (<0.1)	0
Injection site bruising	2 (<0.1)	0	2 (<0.1)	0	4 (<0.1)	0
Injection site haematoma	0	0	2 (<0.1)	0	2 (<0.1)	0
Limb discomfort	0	0	2 (<0.1)	0	2 (<0.1)	0
Myalgia	0	0	2 (<0.1)	0	2 (<0.1)	0
Paraesthesia	0	0	2 (<0.1)	0	2 (<0.1)	0
Presyncope	3 (<0.1)	0	2 (<0.1)	0	5 (<0.1)	0
Blood pressure systolic increased	2 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	0
Chills	0	0	1 (<0.1)	0	1 (<0.1)	0
Ecchymosis	0	0	1 (<0.1)	0	1 (<0.1)	0

N: Number of participants in Safety Set who received any injection; n: Number of participants who reported AEs in specified category; %=n/N*100.

MedDRA version 23.0

Preferred term is sorted by descending frequency in mRNA-1273 Any column.

Program: adhoc-t-ir13-2-3.sas

Run date: 10DEC2020 15:06

Ad-hoc Table IR13.2.3

Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term
Safety Set

Preferred Term	Placebo (N=15165)		mRNA-1273 (N=15184)		Total (N=30350)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Feeling hot	0	0	1 (<0.1)	0	1 (<0.1)	0
Flushing	0	0	1 (<0.1)	0	1 (<0.1)	0
Hyperhidrosis	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Hypersensitivity	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site erythema	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site induration	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Injection site pruritus	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site swelling	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Malaise	0	0	1 (<0.1)	0	1 (<0.1)	0
Musculoskeletal chest pain	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Non-cardiac chest pain	0	0	1 (<0.1)	0	1 (<0.1)	0
Pain in extremity	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Pruritus	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Salivary hypersecretion	0	0	1 (<0.1)	0	1 (<0.1)	0
Syncope	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Uncoded: JOINT PAIN, RIGHT SHOULDER	0	0	1 (<0.1)	0	1 (<0.1)	0
Vessel puncture site haemorrhage	0	0	1 (<0.1)	0	1 (<0.1)	0
Anxiety	1 (<0.1)	0	0	0	1 (<0.1)	0
Disturbance in attention	1 (<0.1)	0	0	0	1 (<0.1)	0
Feeling abnormal	1 (<0.1)	0	0	0	1 (<0.1)	0
Hypotension	2 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	1 (<0.1)
Injection site haemorrhage	1 (<0.1)	0	0	0	1 (<0.1)	0
Nausea	2 (<0.1)	0	0	0	2 (<0.1)	0
Procedural nausea	1 (<0.1)	0	0	0	1 (<0.1)	0
Systolic hypertension	2 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	1 (<0.1)
Uncoded: HEAT (L NECK)	1 (<0.1)	0	0	0	1 (<0.1)	0
Varicella zoster virus infection	1 (<0.1)	0	0	0	1 (<0.1)	0
Vessel puncture site bruise	1 (<0.1)	0	0	0	1 (<0.1)	0

N: Number of participants in Safety Set who received any injection; n: Number of participants who reported AEs in specified category; %=n/N*100.

MedDRA version 23.0

Preferred term is sorted by descending frequency in mRNA-1273 Any column.

Program: adhoc-t-ir13-2-3.sas

Run date: 10DEC2020 15:06