

16.2.7 Adverse Event Listings (Each Participant)

[Listing 16.2.7.9.3](#) [Serious Adverse Events in Open-Label Phase Safety Set](#)

[Listing 16.2.7.10.3](#) [Serious Treatment-Related Adverse Events in Open-Label Phase Safety Set](#)

[Listing 16.2.12.3](#) [Death Listing in Open-Label Phase Safety Set](#)

Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3042309; Age (years): 39; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 190.5; Weight (kg): 139.4; BMI (kg/m ²): 38.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 22AUG2020:14:17:00; Follow-up Days after 1st Dose: 217; Dose 2 Date/Time: 24SEP2020:09:14:00; Follow-up Days after 2nd Dose: 184					
Injury, poisoning and procedural complications/ Stab wound/ ABDOMINAL STAB WOUND	2021-02-13 (143)/ 2021-03-04 (162)	Yes/ Yes/ No	4 2021-02-16)	Yes/3 (2021-02-13/ NR	NR/ NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
					RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3112221; Age (years): 48; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 179.1; Weight (kg): 93.2; BMI (kg/m²): 29.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:17:05:00; Follow-up Days after 1st Dose: 182; Dose 2 Date/Time: 08SEP2020:17:12:00; Follow-up Days after 2nd Dose: 155					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Colorectal cancer metastatic/ METASTATIC STAGE 4 COLORECTAL CARCINOMA	2021-01-19 (134)/ Ongoing	Yes/ Yes/ No	4	Yes/2/6	NR/ NR NOT RECOVERED/ APPLICABLE/ NOT RESOLVED NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [2]	Action Taken Other Action Taken	Outcome
Subject ID: US3132046; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 157.5; Weight (kg): 48.6; BMI (kg/m²): 19.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14SEP2020:12:05:00; Follow-up Days after 1st Dose: 137; Dose 2 Date/Time: 12OCT2020:11:09:00; Follow-up Days after 2nd Dose: 109						
Psychiatric disorders/ Agitation/ ACUTE AGITATION	2021-01-20 (101) / 2021-01-22 (103)	Yes/ Yes/ No	2	Yes/3 (2021-01-20 / 2021-01-21)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Psychiatric disorders/ Delirium/ DELIRIUM	2021-01-20 (101) / 2021-01-22 (103)	Yes/ Yes/ No	3	Yes/3 (2021-01-20 / 2021-01-21)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3402204; Age (years): 63; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 181.5; Weight (kg): 101.5; BMI (kg/m ²): 30.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03AUG2020:11:29:00; Follow-up Days after 1st Dose: 236; Dose 2 Date/Time: 31AUG2020:10:24:00; Follow-up Days after 2nd Dose: 208					
Infections and infestations/ Pericarditis infective/ ACUTE INFECTIVE PERICARDITIS	2021-01-30 (153)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-01-30/ 2021-01-31)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3432617; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D; Height (cm): 185.0; Weight (kg): 101.8; BMI (kg/m ²): 29.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20OCT2020:08:58:00; Follow-up Days after 1st Dose: 158; Dose 2 Date/Time: 02DEC2020:13:45:00; Follow-up Days after 2nd Dose: 115					
Psychiatric disorders/ Drug dependence/ OPIOID DETOX FOR DRUG ADDICTION	2021-01-10 (40)/ 2021-02-03 (64)	Yes/ Yes/ No	3 Yes/3 (2021-01-10/ 2021-02-03)	NR/ NR	NOT APPLICABLE/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3772007; Age (years): 33; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 156.0; Weight (kg): 42.3; BMI (kg/m ²): 17.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:09:22:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 08SEP2020:16:54:00; Follow-up Days after 2nd Dose: 200					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Invasive ductal breast carcinoma/ LEFT BREAST DUCTAL CELL CARCINOMA	2021-02-05 (151)/ Ongoing	Yes/ Yes/ No	4	Yes/2	NR/ NR NOT RECOVERED/ APPLICABLE/ NOT RESOLVED NONE
Subject ID: US3932147; Age (years): 84; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 151.0; Weight (kg): 79.8; BMI (kg/m ²): 35.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 16SEP2020:14:33:00; Follow-up Days after 1st Dose: 128; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Cardiac disorders/ Ventricular arrhythmia/ ARRHYTHMIA (VENTRICULAR)	2021-01-21 (128)/ 2021-01-21 (128)	Yes/ Yes/ No	5	Yes/1	NR/ NR NOT APPLICABLE/ NONE FATAL

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3012073; Age (years): 70; Sex: M; Race: OTHER: EURO AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 64.2; BMI (kg/m ²): 22.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:19:37:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: 03SEP2020:16:29:00; Follow-up Days after 2nd Dose: 184					
Nervous system disorders/ Amyotrophic lateral sclerosis/ WORSENING OF AMYOTROPHIC LATERAL SCLEROSIS	2021-02-26 (19)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-02-26/ 2021-03-02)/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3032108; Age (years): 29; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 157.4; Weight (kg): 48.5; BMI (kg/m ²): 19.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:19:12:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 09SEP2020:16:38:00; Follow-up Days after 2nd Dose: 199					
Gastrointestinal disorders/ Dental caries/ TOOTH DECAY ON RIGHT SIDE OF THE MOUTH.	2021-04-12 (42)/ 2021-04-25 (55)	Yes/ Yes/ No	3 Yes/3 (2021-04-22/ 2021-04-25)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3]	Action Taken Taken	Outcome
Subject ID: US3032249; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 160.0; Weight (kg): 96.6; BMI (kg/m²): 37.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:18:35:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 21SEP2020:11:35:00; Follow-up Days after 2nd Dose: 187						
Infections and infestations/ COVID-19/ COVID-19	2021-02-02 (6) / 2021-03-01 (33)	Yes/ Yes/ No	3	Yes/3 (2021-02-09/ 2021-02-12)	NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: DEVELOPED BILATERAL PNEUMONIA AND RE-HOSPITALIZE D
Infections and infestations/ Pneumonia/ BILATERAL PNEUMONIA	2021-03-01 (33) / 2021-03-05 (37)	Yes/ Yes/ No	3	Yes/3 (2021-03-01/ 2021-03-05)	NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3052312; Age (years): 51; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Risk Factors for Severe COVID-19[4]:; Height (cm): ; Weight (kg): ; BMI (kg/m ²): ; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28AUG2020:11:36:00; Follow-up Days after 1st Dose: 211; Dose 2 Date/Time: 25SEP2020:10:47:00; Follow-up Days after 2nd Dose: 183					
Infections and infestations/ Arthritis bacterial/ SEPTIC RIGHT KNEE	2021-01-27 (12)/ 2021-01-31 (16)	Yes/ Yes/ No	3 2021-01-29)	Yes/3 (2021-01-27/ NR 2021-01-29)	DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED
Subject ID: US3062102; Age (years): 20; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SO; Height (cm): 180.0; Weight (kg): 131.0; BMI (kg/m ²): 40.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:16:25:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 02SEP2020:17:15:00; Follow-up Days after 2nd Dose: 206					
Psychiatric disorders/ Suicidal ideation/ SUICIDAL IDEATION	2021-01-26 (13)/ 2021-02-03 (21)	Yes/ Yes/ No	4 2021-02-03)	Yes/3 (2021-01-27/ NR 2021-02-03)	DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3062118; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 167.0; Weight (kg): 74.0; BMI (kg/m ²): 26.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:12:39:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:12:26:00; Follow-up Days after 2nd Dose: 205					
Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING ARTHRITIS RIGHT KNEE	2021-04-20 (49) / 2021-04-20 (49)	Yes/ Yes/ No	4 Yes/3 (2021-04-20/ 2021-04-21)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED
Subject ID: US3062157; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 164.0; Weight (kg): 100.2; BMI (kg/m ²): 37.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:16:26:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 04SEP2020:15:55:00; Follow-up Days after 2nd Dose: 204					
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OSTEOARTHRTIS BILATERAL KNEES	2021-01-27 (9) / 2021-03-27 (68)	Yes/ Yes/ No	4 Yes/3 (2021-02-11/ 2021-03-27)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3082122; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 161.3; Weight (kg): 53.4; BMI (kg/m ²): 20.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 27AUG2020:10:09:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: 29SEP2020:09:19:00; Follow-up Days after 2nd Dose: 179					
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2021-02-17 (27) / 2021-02-26 (36)	Yes/ Yes/ No	2 	Yes/3 (2021-02-26/ 2021-02-27)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Subject ID: US3092176; Age (years): 47; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 190.5; Weight (kg): 117.3; BMI (kg/m ²): 32.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:15:34:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 18SEP2020:11:05:00; Follow-up Days after 2nd Dose: 190					
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2021-03-30 (33) / 2021-04-10 (44)	Yes/ Yes/ No	2 	Yes/3 (2021-03-30/ 2021-04-10)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3092238; Age (years): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 164.0; Weight (kg): 157.2; BMI (kg/m ²): 58.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 27AUG2020:10:28:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: 01OCT2020:10:28:00; Follow-up Days after 2nd Dose: 177					
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2021-04-17 (23) / 2021-04-21 (27)	Yes/ Yes/ No	2 2021-04-21)	Yes/3 (2021-04-18/ 2021-04-21)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Subject ID: US3092259; Age (years): 58; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 184.0; Weight (kg): 103.7; BMI (kg/m ²): 30.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28AUG2020:12:09:00; Follow-up Days after 1st Dose: 211; Dose 2 Date/Time: 01OCT2020:10:02:00; Follow-up Days after 2nd Dose: 177					
Infections and infestations/ Sepsis/ SEPSIS	2021-01-25 (21) / 2021-02-02 (29)	Yes/ Yes/ No	3 2021-02-03)	Yes/3 (2021-01-25/ 2021-02-03)	NR/ NR DOSE NOT CHANGED/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3112119; Age (years): 49; Sex: M; Race: ASIAN; Risk Factors for Severe COVID-19[4]: D; Height (cm): 160.0; Weight (kg): 83.7; BMI (kg/m ²): 32.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:16:38:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 03SEP2020:17:09:00; Follow-up Days after 2nd Dose: 205					
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS SECONDARY TO CHOLELITHIASIS	2021-04-01 (57) / 2021-04-01 (57)	Yes/ Yes/ No	3 2021-04-01/ 2021-04-02)	NR/ NR NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE
Subject ID: US3112173; Age (years): 77; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 162.6; Weight (kg): 71.4; BMI (kg/m ²): 27.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10AUG2020:14:01:00; Follow-up Days after 1st Dose: 229; Dose 2 Date/Time: 10SEP2020:12:01:00; Follow-up Days after 2nd Dose: 198					
Surgical and medical procedures/ Hip arthroplasty/ REVISION OF LEFT HIP REPLACEMENT	2021-04-19 (77) / 2021-04-19 (77)	Yes/ Yes/ No	1 2021-04-20)	NR/ NR NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3112262; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 170.0; Weight (kg): 104.5; BMI (kg/m ²): 36.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:12:40:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:13:22:00; Follow-up Days after 2nd Dose: 197					
Infections and infestations/ Sepsis/ SEPTICEMIA	2021-03-26 (52) / 2021-04-04 (61)	Yes/ Yes/ No	3 Yes/3 (2021-03-28/ 2021-03-31)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3122083; Age (years): 57; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 157.5; Weight (kg): 87.8; BMI (kg/m ²): 35.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28JUL2020:15:51:00; Follow-up Days after 1st Dose: 242; Dose 2 Date/Time: 26AUG2020:14:43:00; Follow-up Days after 2nd Dose: 213					
Immune system disorders/ Anaphylactic reaction/ ANAPHYLACTIC REACTION TO STEROID SHOT	2021-04-22 (72) / 2021-04-22 (72)	Yes/ Yes/ No	3 Yes/2/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3122090; Age (years): 62; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.6; Weight (kg): 94.1; BMI (kg/m ²): 35.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29JUL2020:10:35:00; Follow-up Days after 1st Dose: 241; Dose 2 Date/Time: 26AUG2020:13:31:00; Follow-up Days after 2nd Dose: 213					
Musculoskeletal and connective tissue disorders/ Bursitis/ SUBACROMIAL BURSITIS	2021-02-10 17:00 (1)/ 2021-04-20 00:00 (69)	Yes/ Yes/ No	3 Yes/4	NR/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED
Subject ID: US3132138; Age (years): 85; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 185.4; Weight (kg): 99.1; BMI (kg/m ²): 28.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19OCT2020:14:43:00; Follow-up Days after 1st Dose: 159; Dose 2 Date/Time: 16NOV2020:13:01:00; Follow-up Days after 2nd Dose: 131					
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2021-02-26 (8)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-02-26/ 2021-03-07)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome	
Subject ID: US3132138; Age (years): 85; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 185.4; Weight (kg): 99.1; BMI (kg/m²): 28.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19OCT2020:14:43:00; Follow-up Days after 1st Dose: 159; Dose 2 Date/Time: 16NOV2020:13:01:00; Follow-up Days after 2nd Dose: 131							
Injury, poisoning and procedural complications/ Femur fracture/ BROKEN LEFT FEMUR	2021-02-26 (8) / 2021-03-04 (14)	Yes/ Yes/ No	3	Yes/3 (2021-02-26/ 2021-03-07)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: RESIDUAL PAIN
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ ACUTE GASTROINTESTINAL BLEED	2021-03-15 (25) / 2021-03-28 (38)	Yes/ Yes/ No	3	Yes/3 (2021-03-15/ 2021-03-19) /6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3]	Action Taken Taken	Outcome
Subject ID: US3142137; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): ; Weight (kg): ; BMI (kg/m ²): ; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:14:24:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 04SEP2020:15:03:00; Follow-up Days after 2nd Dose: 204						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Renal cancer/ LEFT KIDNEY CARCINOMA	2021-02-09 (23)/ 2021-03-04 (46)	Yes/ Yes/ No	3 Yes/3 (2021-03-04/ 2021-03-07)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3142139; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 160.0; Weight (kg): 70.5; BMI (kg/m ²): 27.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:15:42:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:15:09:00; Follow-up Days after 2nd Dose: 205						
Renal and urinary disorders/ Nephrolithiasis/ HOSPITALIZATION DUE TO A KIDNEY STONE	2021-04-02 (30)/ 2021-04-04 (32)	Yes/ Yes/ No	3 Yes/3 (2021-04-02/ 2021-04-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3142236; Age (years): 41; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.5; Weight (kg): 116.7; BMI (kg/m ²): 39.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:12:50:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 16SEP2020:15:31:00; Follow-up Days after 2nd Dose: 192					
Nervous system disorders/ Paraesthesia/ LEFT ARM PARESTHESIA	2021-01-20 (9)/ 2021-01-22 (11)	Yes/ Yes/ No	3 2021-01-21/ 2021-01-21)	R/ R	DOSE DELAYED/ NONE
Subject ID: US3152037; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 175.0; Weight (kg): 105.7; BMI (kg/m ²): 34.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29JUL2020:17:57:00; Follow-up Days after 1st Dose: 241; Dose 2 Date/Time: 26AUG2020:15:51:00; Follow-up Days after 2nd Dose: 213					
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2021-01-14 (7)/ 2021-01-17 (10)	Yes/ Yes/ No	3 2021-01-14/ 2021-01-19)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3152037; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 175.0; Weight (kg): 105.7; BMI (kg/m ²): 34.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29JUL2020:17:57:00; Follow-up Days after 1st Dose: 241; Dose 2 Date/Time: 26AUG2020:15:51:00; Follow-up Days after 2nd Dose: 213					
Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY INSUFFICIENCY WITH HYPOXIA	2021-01-14 (7) / 2021-01-17 (10)	Yes/ Yes/ No	4 	Yes/3 (2021-01-14/ 2021-01-19)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Blood and lymphatic system disorders/ Leukocytosis/ LEUCOCYTOSIS	2021-01-15 (8) / 2021-01-17 (10)	Yes/ Yes/ No	3 	Yes/3 (2021-01-14/ 2021-01-19)	NR/ NR DOSE NOT CHANGED/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3152118; Age (years): 24; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 166.0; Weight (kg): 115.7; BMI (kg/m²): 42.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:14:38:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 09SEP2020:14:55:00; Follow-up Days after 2nd Dose: 199						
Respiratory, thoracic and mediastinal disorders/ Atelectasis/ ATELECTASIS	2021-03-24 (42)/ Ongoing	Yes/ No/ No	3 Yes/3 (2021-03-23/ 2021-03-26)	NR/ NR	NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3152175; Age (years): 53; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 151.5; Weight (kg): 60.4; BMI (kg/m²): 26.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:18:00:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 11SEP2020:15:53:00; Follow-up Days after 2nd Dose: 197						
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2021-03-02 (36)/ 2021-03-03 (37)	Yes/ Yes/ No	4 Yes/3 (2021-03-03/ 2021-03-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3162068; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 177.8; Weight (kg): 84.1; BMI (kg/m ²): 26.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:12:43:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 04SEP2020:14:30:00; Follow-up Days after 2nd Dose: 204					
Infections and infestations/ Osteomyelitis/ OSTEOMYELITIS RIGHT GREAT TOE	2021-03-29 (40) / 2021-04-07 (49)	Yes/ Yes/ No	4 	Yes/3 (2021-04-07/ 2021-04-10)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3162072; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 81.8; BMI (kg/m ²): 25.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:15:47:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:14:46:00; Follow-up Days after 2nd Dose: 205					
Cardiac disorders/ Angina unstable/ CRESCENDO ANGINA	2021-02-15 (14) / 2021-03-12 (39)	Yes/ Yes/ No	4 	Yes/3 (2021-03-11/ 2021-03-23)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3162072; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 81.8; BMI (kg/m ²): 25.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:15:47:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:14:46:00; Follow-up Days after 2nd Dose: 205					
Respiratory, thoracic and mediastinal disorders/ Pneumothorax/ BILATERAL PNEUMOTHORAX	2021-03-16 (15)/ 2021-03-23 (22)	Yes/ Yes/ No	4 Yes/3 (2021-03-11/ 2021-03-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE
Subject ID: US3162090; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 188.0; Weight (kg): 81.8; BMI (kg/m ²): 23.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10AUG2020:14:40:00; Follow-up Days after 1st Dose: 229; Dose 2 Date/Time: 08SEP2020:16:23:00; Follow-up Days after 2nd Dose: 200					
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARCTION	2021-04-27 (72)/ 2021-04-27 (72)	Yes/ Yes/ No	4 Yes/3 (2021-04-27/ 2021-04-29)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3162139; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.6; Weight (kg): 70.9; BMI (kg/m ²): 26.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 18AUG2020:14:31:00; Follow-up Days after 1st Dose: 221; Dose 2 Date/Time: 15SEP2020:13:57:00; Follow-up Days after 2nd Dose: 193						
General disorders and administration site conditions/ Chest pain/ WORSENING OF ATYPICAL CHEST PAIN	2021-02-01 (8) / 2021-02-17 (24)	Yes/ Yes/ No	4	Yes/3 (2021-02-16/ 2021-02-17) /6	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Vascular disorders/ Hypertension/ WORSENING OF HYPERTENSION	2021-02-16 (23) / 2021-02-17 (24)	Yes/ Yes/ No	4	Yes/3 (2021-02-16/ 2021-02-17)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3162238; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D; Height (cm): 170.2; Weight (kg): 90.3; BMI (kg/m ²): 31.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15SEP2020:16:58:00; Follow-up Days after 1st Dose: 193; Dose 2 Date/Time: 13OCT2020:15:08:00; Follow-up Days after 2nd Dose: 165					
Respiratory, thoracic and mediastinal disorders/ Hypoxia/ POST-OPERATIVE HYPOXIA	2021-02-25 (15)/ 2021-02-26 (16)	Yes/ Yes/ No	4 Yes/3 (2021-02-25/ 2021-02-26)	NR/ NR NONE	NOT APPLICABLE/ RESOLVED
Subject ID: US3172028; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 178.0; Weight (kg): 94.3; BMI (kg/m ²): 29.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:10:50:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:10:49:00; Follow-up Days after 2nd Dose: 200					
Cardiac disorders/ Arrhythmia/ CARDIAC ARRHYTHMIA	2021-04-05 (25)/ 2021-04-06 (26)	Yes/ Yes/ No	3 Yes/3 (2021-04-05/ 2021-04-06)	NR/ NR CONCOMITANT MEDICATION	DOSE NOT CHANGED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3172119; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 155.4; Weight (kg): 53.0; BMI (kg/m ²): 21.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:15:17:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:13:02:00; Follow-up Days after 2nd Dose: 197					
Injury, poisoning and procedural complications/ Rib fracture/ LEFT SIDE RIB CAGE MULTIPLE FRACTURE	2021-02-09 (19)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2021-02-09/ 2021-02-12)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ LEFT PLEURAL EFFUSION SECONDARY TO LEFT RIB FRACTURE	2021-02-19 (29)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2021-02-19/ 2021-02-21)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3172211; Age (years): 53; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 164.0; Weight (kg): 92.1; BMI (kg/m ²): 34.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:13:42:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 16SEP2020:11:31:00; Follow-up Days after 2nd Dose: 192					
Gastrointestinal disorders/ Abdominal pain/ ACUTE EXACERBATION OF ABDOMINAL PAIN	2021-04-08 (18)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2021-04-10/ 2021-04-11)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Musculoskeletal and connective tissue disorders/ Muscle spasms/ WORSENING BACK MUSCLE SPASM	2021-04-10 (20)/ Ongoing	Yes/ Yes/ No	2	Yes/3 (2021-04-10/ 2021-04-11)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3172250; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 163.0; Weight (kg): 117.0; BMI (kg/m ²): 44.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:15:34:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 18SEP2020:12:13:00; Follow-up Days after 2nd Dose: 190						
Nervous system disorders/ Sciatica/ LEFT SCIATIC EXACERBATION	2021-02-26 (3) / Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-02-26/ 2021-03-03)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2021-02-26 (3) / 2021-02-27 (4)	Yes/ Yes/ No	3	Yes/3 (2021-02-26/ 2021-03-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3172250; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 163.0; Weight (kg): 117.0; BMI (kg/m ²): 44.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:15:34:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 18SEP2020:12:13:00; Follow-up Days after 2nd Dose: 190					
Cardiac disorders/ Acute myocardial infarction/ NON ST MYOCARDIAL INFARCTION (NSTMI)	2021-02-26 (3) / 2021-03-01 (6)	Yes/ Yes/ No	3 Yes/3 (2021-02-26/ 2021-03-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED
Subject ID: US3172374; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 171.6; Weight (kg): 71.0; BMI (kg/m ²): 24.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 16OCT2020:11:18:00; Follow-up Days after 1st Dose: 162; Dose 2 Date/Time: 13NOV2020:12:13:00; Follow-up Days after 2nd Dose: 134					
Skin and subcutaneous tissue disorders/ Decubitus ulcer/ LEFT FEET SECOND TOE PRESSURE ULCER STAGE III	2021-04-19 (53) / Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-04-19/ 2021-04-22)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3182065; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 166.0; Weight (kg): 66.2; BMI (kg/m ²): 24.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29JUL2020:16:27:00; Follow-up Days after 1st Dose: 241; Dose 2 Date/Time: 28AUG2020:11:59:00; Follow-up Days after 2nd Dose: 211					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Pancreatic carcinoma stage IV/ STAGE 4 PANCREATIC CANCER.	2021-02-11 (29)/ Ongoing	Yes/ Yes/ No	3 Yes/6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED
Subject ID: US3182114; Age (years): 53; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 176.0; Weight (kg): 105.4; BMI (kg/m ²): 34.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31JUL2020:15:31:00; Follow-up Days after 1st Dose: 239; Dose 2 Date/Time: 31AUG2020:14:15:00; Follow-up Days after 2nd Dose: 208					
Gastrointestinal disorders/ Abdominal pain/ ABDOMINAL PAIN	2021-04-05 (42)/ Ongoing	Yes/ Yes/ No	4 Yes/3 (2021-04-06/)	NR/ NR	NOT APPLICABLE/ NONE UNKNOWN

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3202070; Age (years): 48; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 153.0; Weight (kg): 78.5; BMI (kg/m ²): 33.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08AUG2020:11:03:00; Follow-up Days after 1st Dose: 231; Dose 2 Date/Time: 14SEP2020:17:22:00; Follow-up Days after 2nd Dose: 194					
Reproductive system and breast disorders/ Cervical dysplasia/ RECURRENT CERVICAL DYSPLASIA (WITH HIGH RISK HPV)	2021-02-19 (9)/ 2021-02-20 (10)	Yes/ Yes/ No	2 Yes/3 (2021-02-19/ 2021-02-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3202179; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 178.0; Weight (kg): 101.0; BMI (kg/m ²): 31.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:10:28:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 24SEP2020:09:38:00; Follow-up Days after 2nd Dose: 184					
Cardiac disorders/ Acute coronary syndrome/ ACUTE CORONARY SYNDROME >24 HRS DURATION	2021-03-19 (19)/ 2021-03-22 (22)	Yes/ Yes/ No	2 Yes/3 (2021-03-19/ 2021-03-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3202179; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 178.0; Weight (kg): 101.0; BMI (kg/m ²): 31.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:10:28:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 24SEP2020:09:38:00; Follow-up Days after 2nd Dose: 184					
Cardiac disorders/ Coronary artery disease/ WORSENING OF CORONARY ARTERY DISEASE	2021-03-19 (19) / 2021-03-22 (22)	Yes/ Yes/ No	2	Yes/3 (2021-03-19/ 2021-03-24)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Cardiac disorders/ Ventricular tachycardia/ WIDE COMPLEX VENTRICULAR TACHYCARDIA	2021-03-20 (20) / 2021-03-21 (21)	Yes/ Yes/ No	2	Yes/3 (2021-03-19/ 2021-03-24)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Other Action Taken	Outcome
Subject ID: US3202183; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 158.0; Weight (kg): 102.0; BMI (kg/m ²): 40.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:11:17:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 22SEP2020:11:35:00; Follow-up Days after 2nd Dose: 186						
Musculoskeletal and connective tissue disorders/ Intervertebral disc degeneration/ WORSENING OF CERVICAL DEGENERATIVE DISC DISEASE	2021-03-01 (6) / 2021-03-01 (6)	Yes/ Yes/ No	2	Yes/3 (2021-03-01/ 2021-03-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3202185; Age (years): 56; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 178.5; Weight (kg): 85.6; BMI (kg/m ²): 26.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:12:00:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 14SEP2020:11:17:00; Follow-up Days after 2nd Dose: 194					
General disorders and administration site conditions/ Asthenia/ WEAKNESS	2021-04-06 (37)/ 2021-04-13 (44)	Yes/ Yes/ No	2 Yes/3 (2021-04-06/ 2021-04-13)	NR/ NR	NOT APPLICABLE/ NONE RECOVERED/ RESOLVED
Subject ID: US3202217; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 168.4; Weight (kg): 89.6; BMI (kg/m ²): 31.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17AUG2020:10:11:00; Follow-up Days after 1st Dose: 222; Dose 2 Date/Time: 14SEP2020:11:57:00; Follow-up Days after 2nd Dose: 194					
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING RIGHT KNEE OSTEOARTHRITIS	2021-02-11 (18)/ 2021-02-12 (19)	Yes/ Yes/ No	2 Yes/3 (2021-02-11/ 2021-02-12)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3202395; Age (years): 76; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 159.0; Weight (kg): 57.7; BMI (kg/m ²): 22.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:13:22:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 07OCT2020:11:42:00; Follow-up Days after 2nd Dose: 171					
Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ DYSPNEA ON EXERTION	2021-04-06 (37)/ Ongoing	Yes/ Yes/ No	2 	Yes/3 (2021-04-08/ 2021-04-09)	NR/ NR NOT APPLICABLE/ NONE
Subject ID: US3212121; Age (years): 53; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 182.9; Weight (kg): 109.0; BMI (kg/m ²): 32.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:13:10:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:16:10:00; Follow-up Days after 2nd Dose: 200					
Gastrointestinal disorders/ Oesophageal rupture/ ESOPHAGEAL TEAR	2021-04-23 (63)/ Ongoing	Yes/ Yes/ No	3 	Yes/3 (2021-04-23/)	NR/ NR DOSE NOT CHANGED/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3212121; Age (years): 53; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 182.9; Weight (kg): 109.0; BMI (kg/m ²): 32.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:13:10:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:16:10:00; Follow-up Days after 2nd Dose: 200					
Infections and infestations/ Oesophageal candidiasis/ ESOPHAGEAL CANDIDIASIS	2021-04-23 (63)/ Ongoing	Yes/ Yes/ No	3)	Yes/2/3 (2021-04-23/ NR	NR/ DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Subject ID: US3212166; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.6; Weight (kg): 57.3; BMI (kg/m ²): 21.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:14:04:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 09SEP2020:13:38:00; Follow-up Days after 2nd Dose: 199					
Nervous system disorders/ Ischaemic cerebral infarction/ ISCHEMIC CEREBROVASCULAR ACCIDENT	2021-04-18 (60)/ Ongoing	Yes/ Yes/ No	3)	Yes/2/3 (2021-04-18/ 2021-04-23) NR	NR/ DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3212181; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 188.0; Weight (kg): 79.9; BMI (kg/m ²): 22.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:14:56:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 02OCT2020:13:36:00; Follow-up Days after 2nd Dose: 176					
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2021-03-05 (11) / Ongoing	Yes/ Yes/ No	3 2021-04-08)	Yes/3 (2021-03-24/ 2021-04-08)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3222524; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/SO; Height (cm): 155.2; Weight (kg): 105.2; BMI (kg/m ²): 43.7; Baseline SARS-CoV-2 Status: ; Baseline RT-PCR: ; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: ; Dose 1 Date/Time: 05SEP2020:12:27:00; Follow-up Days after 1st Dose: 189; Dose 2 Date/Time: 09OCT2020:12:45:00; Follow-up Days after 2nd Dose: 155					
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2021-03-01 (16) / 2021-03-03 (18)	Yes/ Yes/ No	2 2021-03-03)	Yes/3 (2021-03-01/ 2021-03-03)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3222524; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/SO; Height (cm): 155.2; Weight (kg): 105.2; BMI (kg/m ²): 43.7; Baseline SARS-CoV-2 Status: ; Baseline RT-PCR: ; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: ; Dose 1 Date/Time: 05SEP2020:12:27:00; Follow-up Days after 1st Dose: 189; Dose 2 Date/Time: 09OCT2020:12:45:00; Follow-up Days after 2nd Dose: 155					
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2021-03-12 (27) / 2021-03-12 (27)	Yes/ Yes/ No	5	Yes/1/3 (2021-03-12/ 2021-03-12)	NR/ NR NOT APPLICABLE/ NONE
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL BLEED	2021-03-12 (27) / 2021-03-12 (27)	Yes/ Yes/ No	5	Yes/1/3 (2021-03-12/ 2021-03-12)	NR/ NR NOT APPLICABLE/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3222524; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/SO; Height (cm): 155.2; Weight (kg): 105.2; BMI (kg/m²): 43.7; Baseline SARS-CoV-2 Status: ; Baseline RT-PCR: ; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: ; Dose 1 Date/Time: 05SEP2020:12:27:00; Follow-up Days after 1st Dose: 189; Dose 2 Date/Time: 09OCT2020:12:45:00; Follow-up Days after 2nd Dose: 155						
Investigations/ Anticoagulation drug level above therapeutic/ SUPRA THERAPEUTIC INR	2021-03-12 (27) / 2021-03-12 (27)	Yes/ Yes/ No	5 2021-03-12)	Yes/1/3 (2021-03-12/ 2021-03-12)	NR/ NR NONE	FATAL
Subject ID: US3232063; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.0; Weight (kg): 65.8; BMI (kg/m²): 22.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 18AUG2020:11:20:00; Follow-up Days after 1st Dose: 221; Dose 2 Date/Time: 25SEP2020:09:58:00; Follow-up Days after 2nd Dose: 183						
Infections and infestations/ Meningitis/ ACUTE MENINGITIS	2021-04-13 (47) / Ongoing	Yes/ Yes/ No	2 2021-04-16)	Yes/3 (2021-04-13/ 2021-04-16)	NR/ NR CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3232157; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 179.0; Weight (kg): 80.7; BMI (kg/m ²): 25.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:14:20:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:13:03:00; Follow-up Days after 2nd Dose: 171					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Pancreatic carcinoma metastatic/ METASTATIC PANCREATIC CANCER	2021-03-22 (40)/ Ongoing	Yes/ Yes/ No	3 Yes/6	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERING/ RESOLVING
Subject ID: US3242013; Age (years): 33; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 156.2; Weight (kg): 68.8; BMI (kg/m ²): 28.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:17:22:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:16:37:00; Follow-up Days after 2nd Dose: 205					
Pregnancy, puerperium and perinatal conditions/ Abortion spontaneous/ SPONTANEOUS ABORTION	2021-03-17 (51)/ 2021-03-17 (51)	Yes/ Yes/ No	4 Yes/2	NR/ NR	DRUG WITHDRAWN/ NONE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3242089; Age (years): 30; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 177.8; Weight (kg): 117.7; BMI (kg/m ²): 37.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:13:19:00; Follow-up Days after 1st Dose: 203; Dose 2 Date/Time: 11SEP2020:14:34:00; Follow-up Days after 2nd Dose: 175					
Injury, poisoning and procedural complications/ Accidental overdose/ INADVERTENT DRUG OVERDOSE	2021-03-02 (8)/ 2021-03-04 (10)	Yes/ No/ No	5 	Yes/1 	NR/ NR NOT APPLICABLE/ NONE FATAL
Subject ID: US3252215; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/D; Height (cm): 165.1; Weight (kg): 77.5; BMI (kg/m ²): 28.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17AUG2020:15:11:00; Follow-up Days after 1st Dose: 222; Dose 2 Date/Time: 14SEP2020:08:47:00; Follow-up Days after 2nd Dose: 194					
Vascular disorders/ Peripheral arterial occlusive disease/ WORSENING PERIPHERAL ARTERY DISEASE	2021-03-01 (26)/ 2021-03-23 (48)	Yes/ Yes/ No	2 	Yes/3 (2021-03-23/ 2021-03-24)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3252382; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.6; Weight (kg): 87.4; BMI (kg/m ²): 33.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29AUG2020:11:39:00; Follow-up Days after 1st Dose: 210; Dose 2 Date/Time: 26SEP2020:13:19:00; Follow-up Days after 2nd Dose: 182					
General disorders and administration site conditions/ Chest pain/ ATYPICAL CHEST PAIN	2021-04-13 (36)/ 2021-04-15 (38)	Yes/ Yes/ No	2 Yes/3 (2021-04-13/ 2021-04-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3252399; Age (years): 47; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 165.1; Weight (kg): 81.4; BMI (kg/m ²): 29.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:08:39:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 28SEP2020:08:26:00; Follow-up Days after 2nd Dose: 180					
Reproductive system and breast disorders/ Cervical dysplasia/ CERVICAL DYSPLASIA	2021-03-08 (11)/ 2021-03-09 (12)	Yes/ Yes/ No	4 Yes/3 (2021-03-08/ 2021-03-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3262259; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC; Height (cm): 179.0; Weight (kg): 118.0; BMI (kg/m ²): 36.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:08:49:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:10:43:00; Follow-up Days after 2nd Dose: 171					
Gastrointestinal disorders/ Diarrhoea/ DIARRHEA OF UNKNOWN ETIOLOGY	2021-05-01 (60)/ Ongoing	Yes/ Yes/ No	3)	Yes/3 (2021-05-01/ NR	NR/ DOSE NOT CHANGED/ NONE
Subject ID: US3272315; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 160.0; Weight (kg): 90.5; BMI (kg/m ²): 35.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 23AUG2020:12:12:00; Follow-up Days after 1st Dose: 216; Dose 2 Date/Time: 26SEP2020:12:04:00; Follow-up Days after 2nd Dose: 182					
Vascular disorders/ Aortic stenosis/ AORTIC STENOSIS	2021-02-01 (25)/ 2021-03-31 (83)	Yes/ Yes/ No	4)	Yes/2/3 (2021-03-29/ 2021-04-01)	NR/ DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3272315; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 160.0; Weight (kg): 90.5; BMI (kg/m ²): 35.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 23AUG2020:12:12:00; Follow-up Days after 1st Dose: 216; Dose 2 Date/Time: 26SEP2020:12:04:00; Follow-up Days after 2nd Dose: 182					
Cardiac disorders/ Cardiac failure/ REDUCED EJECTION FRACTION HEART FAILURE	2021-02-15 (12)/ 2021-03-03 (28)	Yes/ Yes/ No	4 Yes/2/3 (2021-03-29/ 2021-04-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3292128; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 172.0; Weight (kg): 104.7; BMI (kg/m ²): 35.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:14:22:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:12:14:00; Follow-up Days after 2nd Dose: 200					
Injury, poisoning and procedural complications/ Animal bite/ DOG BITE R ARM	2021-03-03 (6)/ 2021-04-01 (35)	Yes/ Yes/ No	2 Yes/3 (2021-03-04/ 2021-03-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3292149; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 179.6; Weight (kg): 39.7; BMI (kg/m ²): 12.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:12:12:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 12SEP2020:12:27:00; Follow-up Days after 2nd Dose: 196					
Cardiac disorders/ Sinus node dysfunction/ SICK SINUS SYNDROME	2021-02-01 (21)/ 2021-02-03 (23)	Yes/ Yes/ No	3 Yes/3 (2021-02-01/ 2021-02-03)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3292173; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 94.2; BMI (kg/m ²): 29.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:17:27:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 12SEP2020:11:36:00; Follow-up Days after 2nd Dose: 196					
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2021-04-28 (51)/ 2021-04-28 (51)	Yes/ Yes/ No	3 Yes/3 (2021-04-28/ 2021-04-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3292259; Age (years): 50; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 160.0; Weight (kg): 86.2; BMI (kg/m ²): 33.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:16:59:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 17SEP2020:11:37:00; Follow-up Days after 2nd Dose: 191					
Infections and infestations/ Post procedural infection/ ABDOMINAL HERNIA REPAIR INFECTION	2021-02-02 (6)/ 2021-02-18 (22)	Yes/ Yes/ No	4 Yes/3 (2021-02-13/ 2021-02-18)	NR/ NR	NOT RECOVERED/ APPLICABLE/ RESOLVED CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3302455; Age (years): 67; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D; Height (cm): 162.6; Weight (kg): 97.3; BMI (kg/m ²): 36.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21SEP2020:11:38:00; Follow-up Days after 1st Dose: 187; Dose 2 Date/Time: 19OCT2020:09:43:00; Follow-up Days after 2nd Dose: 159					
Nervous system disorders/ Cerebrovascular accident/ ACUTE CVA	2021-03-06 (24)/ 2021-03-10 (28)	Yes/ Yes/ No	4 Yes/2/3 (2021-03-06/ 2021-03-10)	NR/ NR	NOT RECOVERED/ APPLICABLE/ RESOLVED CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3312093; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 175.3; Weight (kg): 113.1; BMI (kg/m ²): 36.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:17:12:00; Follow-up Days after 1st Dose: 222; Dose 2 Date/Time: 11SEP2020:14:10:00; Follow-up Days after 2nd Dose: 194					
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLUS	2021-02-08 (18) / 2021-02-10 (20)	Yes/ Yes/ No	3 Yes/3 (2021-02-08/ 2021-02-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3312224; Age (years): 84; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 182.9; Weight (kg): 77.3; BMI (kg/m ²): 23.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24AUG2020:10:02:00; Follow-up Days after 1st Dose: 215; Dose 2 Date/Time: 21SEP2020:10:05:00; Follow-up Days after 2nd Dose: 187					
Neoplasms benign, malignant and unspecified (incl cysts and polyps) / Myelodysplastic syndrome/ MYELODYSPLASTIC SYNDROME	2021-02-19 01:00 (1) / Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-02-19/ 2021-02-24) /6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3312224; Age (years): 84; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 182.9; Weight (kg): 77.3; BMI (kg/m ²): 23.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24AUG2020:10:02:00; Follow-up Days after 1st Dose: 215; Dose 2 Date/Time: 21SEP2020:10:05:00; Follow-up Days after 2nd Dose: 187					
Nervous system disorders/ Haemorrhage intracranial/ INTRACRANIAL HEMMORRHAGE	2021-02-19 01:00 (1) / 2021-03-18 (29)	Yes/ Yes/ No	3 2021-02-25)	Yes/3 (2021-02-19/ 2021-02-25)	NR/ NR NONE
Subject ID: US3312434; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 58.6; BMI (kg/m ²): 20.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:13:24:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 29SEP2020:12:55:00; Follow-up Days after 2nd Dose: 179					
Injury, poisoning and procedural complications/ Anaemia postoperative/ POST OPERATIVE ANEMIA	2021-02-02 (23) / 2021-02-03 (24)	Yes/ Yes/ No	3 2021-02-03)	Yes/3 (2021-02-01/ 2021-02-03)	NR/ NR NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3342085; Age (years): 51; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 167.5; Weight (kg): 76.9; BMI (kg/m ²): 27.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17AUG2020:14:59:00; Follow-up Days after 1st Dose: 222; Dose 2 Date/Time: 16SEP2020:16:07:00; Follow-up Days after 2nd Dose: 192					
Infections and infestations/ Appendicitis/ APPENDICITIS	2021-02-02 (22)/ 2021-02-03 (23)	Yes/ Yes/ No	4 Yes/3 (2021-02-02/ 2021-02-03)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3342354; Age (years): 51; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D; Height (cm): 165.5; Weight (kg): 66.4; BMI (kg/m ²): 24.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13OCT2020:11:38:00; Follow-up Days after 1st Dose: 165; Dose 2 Date/Time: 12NOV2020:11:50:00; Follow-up Days after 2nd Dose: 135					
Infections and infestations/ Sepsis/ SEPTICEMIA	2021-04-18 (52)/ Ongoing	Yes/ Yes/ No	4 Yes/2/3 (2021-04-18/ 2021-04-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3352213; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 175.0; Weight (kg): 99.3; BMI (kg/m ²): 32.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 22AUG2020:15:19:00; Follow-up Days after 1st Dose: 217; Dose 2 Date/Time: 19SEP2020:12:42:00; Follow-up Days after 2nd Dose: 189					
Nervous system disorders/ Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT	2021-01-29 (14)/ 2021-02-03 (19)	Yes/ Yes/ No	4 Yes/3 (2021-01-29/ 2021-02-03)	NR/ NR NR	DOSE DELAYED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: DYSARTHRIA HEMIPATESIS
Subject ID: US3352297; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.0; Weight (kg): 79.9; BMI (kg/m ²): 27.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:11:19:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 29SEP2020:09:38:00; Follow-up Days after 2nd Dose: 179					
Injury, poisoning and procedural complications/ Limb injury/ LEFT HAND TRAUMA	2021-01-20 (5)/ 2021-02-18 (34)	Yes/ Yes/ No	4 Yes/3 (2021-01-20/ 2021-01-23)	NR/ NR NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3352304; Age (years): 33; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 160.2; Weight (kg): 77.9; BMI (kg/m ²): 30.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:13:55:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 29SEP2020:15:24:00; Follow-up Days after 2nd Dose: 179					
Pregnancy, puerperium and perinatal conditions/ Abortion spontaneous/ MISCARRIAGE	2021-04-09 (21) / 2021-04-09 (21)	Yes/ Yes/ No	4 	Yes/3 (2021-04-09 / 2021-04-09)	NR/ NR NONE RECOVERED/ RESOLVED
Subject ID: US3352349; Age (years): 51; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 168.0; Weight (kg): 89.8; BMI (kg/m ²): 31.8; Baseline SARS-CoV-2 Status: Positive; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Positive; Dose 1 Date/Time: 10SEP2020:15:16:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 08OCT2020:14:40:00; Follow-up Days after 2nd Dose: 170					
Infections and infestations/ Hepatic infection/ UNSPECIFIED LIVER INFECTION	2021-02-26 (24) / 2021-04-24 (81)	Yes/ Yes/ No	4 	Yes/3 (2021-02-26 / 2021-03-26)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3362029; Age (years): 52; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.0; Weight (kg): 96.3; BMI (kg/m ²): 29.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04AUG2020:10:17:00; Follow-up Days after 1st Dose: 235; Dose 2 Date/Time: 01SEP2020:10:50:00; Follow-up Days after 2nd Dose: 207					
Infections and infestations/ Pneumonia/ PNEUMONIA	2021-02-16 (14) / 2021-03-04 (30)	Yes/ Yes/ No	4	Yes/6 NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED
Subject ID: US3362125; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 183.0; Weight (kg): 96.9; BMI (kg/m ²): 28.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:11:35:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 15SEP2020:14:01:00; Follow-up Days after 2nd Dose: 193					
Cardiac disorders/ Atrioventricular block complete/ COMPLETE AV BLOCK	2021-03-17 (24) / 2021-03-19 (26)	Yes/ Yes/ No	4	Yes/3 (2021-03-17/ 2021-03-20) NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3372089; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.5; Weight (kg): 98.1; BMI (kg/m ²): 31.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:16:11:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 09SEP2020:15:19:00; Follow-up Days after 2nd Dose: 199					
Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS LOWER EXTREMITIES	2021-02-16 02:50 (1) / 2021-02-17 11:57 (3)	Yes/ Yes/ No	3 Yes/3 (2021-02-16/ 2021-02-17)	R/ R	NOT APPLICABLE/ NONE RECOVERED/ RESOLVED
Subject ID: US3372348; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 176.0; Weight (kg): 88.1; BMI (kg/m ²): 28.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15SEP2020:10:25:00; Follow-up Days after 1st Dose: 193; Dose 2 Date/Time: 13OCT2020:10:12:00; Follow-up Days after 2nd Dose: 165					
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2021-04-02 (39) / 2021-04-04 (41)	Yes/ Yes/ No	3 Yes/3 (2021-04-02/ 2021-04-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
Subject ID: US3392065; Age (years): 70; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 167.6; Weight (kg): 82.1; BMI (kg/m ²): 29.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21AUG2020:11:05:00; Follow-up Days after 1st Dose: 218; Dose 2 Date/Time: 16SEP2020:10:17:00; Follow-up Days after 2nd Dose: 192					
General disorders and administration site conditions/ Chest pain/ CHEST PAIN, UNSPECIFIED	2021-03-24 (48)/ 2021-03-25 (49)	Yes/ Yes/ No	2 	Yes/3 (2021-03-24/ 2021-03-25)	NR/ NR NONE RECOVERED/ RESOLVED
Subject ID: US3402225; Age (years): 48; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 160.0; Weight (kg): 80.4; BMI (kg/m ²): 31.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04AUG2020:14:52:00; Follow-up Days after 1st Dose: 235; Dose 2 Date/Time: 01SEP2020:12:44:00; Follow-up Days after 2nd Dose: 207					
Infections and infestations/ Appendicitis perforated/ RUPTURED APPENDIX	2021-01-25 (8)/ 2021-02-16 (30)	Yes/ Yes/ No	3 	Yes/3 (2021-02-08/ 2021-02-16)	NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3402288; Age (years): 42; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 166.0; Weight (kg): 161.0; BMI (kg/m²): 58.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08AUG2020:10:22:00; Follow-up Days after 1st Dose: 231; Dose 2 Date/Time: 08SEP2020:11:01:00; Follow-up Days after 2nd Dose: 200						
Gastrointestinal disorders/ Abdominal hernia/ ABDOMINAL HERNIA	2021-04-02 (57) / 2021-04-11 (66)	Yes/ Yes/ No	3 2021-04-11)	Yes/3 (2021-04-02/ NR 2021-04-11)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Subject ID: US3402420; Age (years): 55; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 176.0; Weight (kg): 95.2; BMI (kg/m²): 30.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 22AUG2020:09:23:00; Follow-up Days after 1st Dose: 217; Dose 2 Date/Time: 23SEP2020:08:10:00; Follow-up Days after 2nd Dose: 185						
Cardiac disorders/ Angina unstable/ UNSTABLE ANGINA	2021-03-19 (32) / 2021-03-24 (37)	Yes/ Yes/ No	2 2021-03-24)	Yes/3 (2021-03-23/ NR 2021-03-24)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3412022; Age (years): 50; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 185.7; Weight (kg): 169.4; BMI (kg/m ²): 49.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29JUL2020:15:30:00; Follow-up Days after 1st Dose: 241; Dose 2 Date/Time: 26AUG2020:18:10:00; Follow-up Days after 2nd Dose: 213					
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2021-01-28 (23) / 2021-02-02 (28)	Yes/ Yes/ No	4 Yes/3 (2021-01-28/ 2021-02-02) /6	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Subject ID: US3412030; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 195.5; Weight (kg): 98.3; BMI (kg/m ²): 25.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 30JUL2020:09:45:00; Follow-up Days after 1st Dose: 240; Dose 2 Date/Time: 27AUG2020:08:25:00; Follow-up Days after 2nd Dose: 212					
Reproductive system and breast disorders/ Benign prostatic hyperplasia/ WORSENING BPH/URINARY RETENTION	2021-04-18 (76) / 2021-04-22 (80)	Yes/ Yes/ No	4 Yes/3 (2021-04-18/ 2021-04-22)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3412296; Age (years): 52; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 158.2; Weight (kg): 65.1; BMI (kg/m ²): 26.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:15:10:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 24SEP2020:11:10:00; Follow-up Days after 2nd Dose: 184					
Infections and infestations/ Breast cellulitis/ CELLULITIS LEFT BREAST	2021-03-03 (21) / Ongoing	Yes/ Yes/ No	4	Yes/3 (2021-03-08/ 2021-03-10)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 171.1; Weight (kg): 77.0; BMI (kg/m ²): 26.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:13:54:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Respiratory, thoracic and mediastinal disorders/ Interstitial lung disease/ IDIOPATHIC INTERSTITIAL PNEUMONITIS	2021-01-28 (13) / Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-01-29/ 2021-02-16)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 171.1; Weight (kg): 77.0; BMI (kg/m ²): 26.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:13:54:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Eye disorders/ Diplopia/ DIPLOPIA	2021-03-31 (75)/ Ongoing	Yes/ Yes/ No	3 2021-04-07)	Yes/3 (2021-04-04/ NR	NR/ DOSE NOT CHANGED/ CONCOMITANT PROCEDURE
Subject ID: US3432120; Age (years): 46; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 158.0; Weight (kg): 55.2; BMI (kg/m ²): 22.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:18:19:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 08SEP2020:11:50:00; Follow-up Days after 2nd Dose: 200					
Gastrointestinal disorders/ Small intestinal obstruction/ SBO (SMALL BOWEL OBSTRUCTION)	2021-01-30 (12)/ Ongoing	Yes/ Yes/ No	3 2021-02-02)	Yes/3 (2021-01-31/ NR	NR/ DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
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Subject ID: US3432380; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.0; Weight (kg): 82.8; BMI (kg/m²): 27.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:10:59:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 01OCT2020:09:53:00; Follow-up Days after 2nd Dose: 177

Infections and infestations/ COVID-19/ COVID-19	2021-01-08 (9) / 2021-02-01 (33)	Yes/ Yes/ No	3	Yes/3 (2021-01-09/ 2021-01-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
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Subject ID: US3442074; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL/SC/D; Height (cm): 175.3; Weight (kg): 62.5; BMI (kg/m²): 20.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25AUG2020:09:35:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 22SEP2020:09:24:00; Follow-up Days after 2nd Dose: 197

Nervous system disorders/ Cerebrovascular accident/ ISCHEMIC CEREBROVASCULAR ACCIDENT (CVA) (HCC)	2021-04-02 (40) / 2021-04-06 (44)	Yes/ Yes/ No	5	Yes/1/3 (2021-04-02/ 2021-04-06)	NR/ NR	NOT APPLICABLE/ NONE	FATAL
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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3462364; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 167.6; Weight (kg): 90.7; BMI (kg/m ²): 32.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 27AUG2020:12:33:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: 24SEP2020:10:27:00; Follow-up Days after 2nd Dose: 184					
Renal and urinary disorders/ Nephrolithiasis/ KIDNEY STONES	2021-02-06 (20)/ 2021-02-08 (22)	Yes/ Yes/ No	4 2021-02-09)	Yes/3 (2021-02-07/ NR 2021-02-09)	NR/ DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED
Subject ID: US3462421; Age (years): 28; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.0; Weight (kg): 70.0; BMI (kg/m ²): 23.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:16:34:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:16:10:00; Follow-up Days after 2nd Dose: 171					
Pregnancy, puerperium and perinatal conditions/ Pregnancy/ PREGNANCY ON THE STUDY	2021-01-21 (9)/ 2021-01-23 (11)	Yes/ No/ No	1 2021-01-23 (11)	Yes/6 NR/ NR NONE	DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3462421; Age (years): 28; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.0; Weight (kg): 70.0; BMI (kg/m ²): 23.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:16:34:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:16:10:00; Follow-up Days after 2nd Dose: 171					
Pregnancy, puerperium and perinatal conditions/ Abortion spontaneous/ MISCARRIAGE	2021-01-23 (11)/ 2021-01-23 (11)	Yes/ No/ No	2 Yes/6	R/ NR	DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED
Subject ID: US3512082; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 94.1; BMI (kg/m ²): 28.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:15:08:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:13:49:00; Follow-up Days after 2nd Dose: 197					
Renal and urinary disorders/ Urinary retention/ ACUTE URINARY RETENTION	2021-01-26 (5)/ 2021-03-07 (45)	Yes/ Yes/ No	4 Yes/3 (2021-02-02/ 2021-02-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED WITH SEQUELAE: CHRONIC URINARY RETENTION - MODERATE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3512082; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 94.1; BMI (kg/m ²): 28.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:15:08:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:13:49:00; Follow-up Days after 2nd Dose: 197					
Renal and urinary disorders/ Haematuria/ HEMATURIA	2021-01-27 (6) / 2021-03-08 (46)	Yes/ Yes/ No	2 	Yes/3 (2021-02-02/ 2021-02-04)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3512248; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 105.2; BMI (kg/m ²): 32.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:12:51:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 08OCT2020:11:49:00; Follow-up Days after 2nd Dose: 170					
Infections and infestations/ Arthritis bacterial/ LEFT ELBOW SEPTIC ARTHRITIS	2021-02-24 (36)/ 2021-04-12 (83)	Yes/ Yes/ No	3 2021-02-25/ 2021-02-26)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT DISCONTINUED ALL ASSOCIATED MEDICATIONS BY 05MAR2021 AND AT LAST IN CLINIC VISIT IT WAS NOTED THAT THE REDNESS HAD RESOLVED AND THE SWELLING AND TENDERNESS WAS MOVING TOWARDS RESOLUTION.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3522128; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC/D Height (cm): 177.8; Weight (kg): 109.1; BMI (kg/m²): 34.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:10:26:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:13:34:00; Follow-up Days after 2nd Dose: 197					
Cardiac disorders/ Atrial fibrillation/ RECURRENT PAROXYSMAL ATRIAL FIBRILLATION STATUS POST MULTIPLE FAILED ABLATIONS AND MEDICAL/DIRECT CARDIOVERSIONS	2021-04-01 (30)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-04-01/ 2021-04-04)/6	NR/ NR APPLICABLE/ NONE UNKNOWN

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3522274; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 71.8; BMI (kg/m ²): 24.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 26AUG2020:10:40:00; Follow-up Days after 1st Dose: 213; Dose 2 Date/Time: 23SEP2020:12:20:00; Follow-up Days after 2nd Dose: 185					
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2021-02-10 (23)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2021-02-16/ 2021-03-23)	NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ NEW ONSET SHORTNESS OF BREATH	2021-02-17 (30)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-02-16/ 2021-03-23)	NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3522274; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 71.8; BMI (kg/m²): 24.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 26AUG2020:10:40:00; Follow-up Days after 1st Dose: 213; Dose 2 Date/Time: 23SEP2020:12:20:00; Follow-up Days after 2nd Dose: 185						
Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ PLEURAL EFFUSION	2021-03-10 (51) / Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-02-16/ 2021-03-23)	NR/ NR DOSE DELAYED/ CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
Vascular disorders/ Deep vein thrombosis/ BILATERAL DEEP VEIN THROMBOSIS	2021-03-10 (51) / Ongoing	Yes/ Yes/ No	4	Yes/2/3 (2021-02-16/ 2021-03-23)	NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3522696; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 200.7; Weight (kg): 144.0; BMI (kg/m ²): 35.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 16SEP2020:14:25:00; Follow-up Days after 1st Dose: 192; Dose 2 Date/Time: 14OCT2020:12:20:00; Follow-up Days after 2nd Dose: 164						
Infections and infestations/ Staphylococcal sepsis/ SEPSIS SECONDARY TO METHICILLIN SUSCEPTIBLE STAPHYLOCOCCUS AUREUS	2021-02-04 (25) / 2021-03-08 (57)	Yes/ Yes/ No	3	Yes/3 (2021-02-05/ 2021-02-11)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Deep vein thrombosis/ RIGHT LOWER EXTREMITY DVT	2021-02-04 (25) / 2021-03-09 (58)	Yes/ Yes/ No	3	Yes/3 (2021-02-05/ 2021-02-11)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3522709; Age (years): 25; Sex: M; Race: ASIAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 69.0; BMI (kg/m ²): 21.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 18SEP2020:13:45:00; Follow-up Days after 1st Dose: 190; Dose 2 Date/Time: 23OCT2020:14:12:00; Follow-up Days after 2nd Dose: 155					
Infections and infestations/ Appendicitis/ APPENDICITIS	2021-02-08 (13)/ 2021-02-11 (16)	Yes/ Yes/ No	3 Yes/3 (2021-02-10/ 2021-02-11)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 152.0; Weight (kg): 97.8; BMI (kg/m ²): 42.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 27AUG2020:11:16:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Infections and infestations/ Wound infection/ WOUND INFECTION LEFT BUTTOCK	2021-02-17 (16)/ 2021-03-09 (36)	Yes/ Yes/ No	4 Yes/3 (2021-02-19/ 2021-02-24)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3532170; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 152.0; Weight (kg): 97.8; BMI (kg/m ²): 42.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 27AUG2020:11:16:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Infections and infestations/ Sepsis/ SEPSIS	2021-02-19 (18)/ 2021-02-24 (23)	Yes/ Yes/ No	4 Yes/3 (2021-02-19/ 2021-02-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3532276; Age (years): 77; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 157.4; Weight (kg): 82.0; BMI (kg/m ²): 33.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:11:41:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 08OCT2020:09:56:00; Follow-up Days after 2nd Dose: 170					
Respiratory, thoracic and mediastinal disorders/ Asthma/ ASTHMA EXACERBATION	2021-02-04 08:00 (1)/ 2021-02-10 08:00 (7)	Yes/ Yes/ No	4 Yes/3 (2021-02-08/ 2021-02-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3542030; Age (years): 56; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 165.1; Weight (kg): 131.4; BMI (kg/m ²): 48.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:13:06:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 24SEP2020:10:40:00; Follow-up Days after 2nd Dose: 184					
Metabolism and nutrition disorders/ Obesity/ MORBID OBESITY	2021-04-22 (74)/ Ongoing	Yes/ Yes/ No	3 	Yes/3 (2021-04-22/ 2021-04-23)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Gastrointestinal disorders/ Hiatus hernia/ HIATAL HERNIA	2021-04-22 (74)/ 2021-04-23 (75)	Yes/ Yes/ No	3 	Yes/3 (2021-04-22/ 2021-04-23)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3542053; Age (years): 59; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 148.6; Weight (kg): 54.5; BMI (kg/m ²): 24.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25AUG2020:10:59:00; Follow-up Days after 1st Dose: 214; Dose 2 Date/Time: 21SEP2020:10:04:00; Follow-up Days after 2nd Dose: 187					
Cardiac disorders/ Atrial flutter/ ATRIAL FLUTTER	2021-02-04 (28)/ 2021-02-08 (32)	Yes/ Yes/ No	3 2021-02-08)	Yes/3 (2021-02-04/ 2021-02-08)	NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3542061; Age (years): 69; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 188.0; Weight (kg): 89.1; BMI (kg/m ²): 25.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 26AUG2020:10:20:00; Follow-up Days after 1st Dose: 213; Dose 2 Date/Time: 23SEP2020:08:24:00; Follow-up Days after 2nd Dose: 185					
Gastrointestinal disorders/ Pancreatitis acute/ ACUTE PANCREATITIS	2021-04-06 (62)/ 2021-04-16 (72)	Yes/ Yes/ No	2 2021-04-16)	Yes/3 (2021-04-08/ 2021-04-16)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3552005; Age (years): 65; Sex: M; Race: MULTIPLE: White, Black or African American, American Indian or Alaska Native; Risk Factors for Severe COVID-19[4]: D; Height (cm): 174.0; Weight (kg): 99.1; BMI (kg/m ²): 32.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:11:40:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 07SEP2020:08:48:00; Follow-up Days after 2nd Dose: 201					
Blood and lymphatic system disorders/ Anaemia/ SEVERE ANEMIA	2021-03-07 (14)/ 2021-03-12 (19)	Yes/ Yes/ No	4 	Yes/3 (2021-03-08/ 2021-03-12)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3552232; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 174.0; Weight (kg): 82.3; BMI (kg/m ²): 27.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29AUG2020:10:40:00; Follow-up Days after 1st Dose: 210; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Cardiac disorders/ Cardiac failure congestive/ CONGESTIVE HEART FAILURE	2021-04-04 (11)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-04-05/ 2021-04-07)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3552240; Age (years): 39; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 196.9; Weight (kg): 126.8; BMI (kg/m ²): 32.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29AUG2020:14:31:00; Follow-up Days after 1st Dose: 210; Dose 2 Date/Time: 01OCT2020:12:36:00; Follow-up Days after 2nd Dose: 177					
Endocrine disorders/ Autoimmune thyroiditis/ HASHIMOTO'S DISEASE	2021-02-02 (27)/ Ongoing	Yes/ Yes/ No	2 	Yes/6 	R/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Subject ID: US3552386; Age (years): 57; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 68.4; BMI (kg/m ²): 23.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:15:33:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 13OCT2020:15:37:00; Follow-up Days after 2nd Dose: 165					
Eye disorders/ Retinal tear/ RIGHT EYE RETINAL TEAR	2021-03-29 (50)/ Ongoing	Yes/ Yes/ No	4 	Yes/6 	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3562228; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 166.4; Weight (kg): 89.5; BMI (kg/m ²): 32.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14OCT2020:10:45:00; Follow-up Days after 1st Dose: 164; Dose 2 Date/Time: 11NOV2020:14:23:00; Follow-up Days after 2nd Dose: 136					
Infections and infestations/ Pneumonia/ BILATERAL PNEUMONIA	2021-03-12 (16) / 2021-03-25 (29)	Yes/ Yes/ No	3 	Yes/3 (2021-03-22/ 2021-03-23)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE
Subject ID: US3562229; Age (years): 55; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 166.4; Weight (kg): 107.3; BMI (kg/m ²): 38.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15OCT2020:12:18:00; Follow-up Days after 1st Dose: 163; Dose 2 Date/Time: 12NOV2020:11:00:00; Follow-up Days after 2nd Dose: 135					
Nervous system disorders/ Paraesthesia/ MILD WEEKNESS OF RIGHT SIDE PARESTHESIA	2021-04-16 (65) / 2021-04-18 (67)	Yes/ Yes/ No	4 	Yes/3 (2021-04-16/ 2021-04-18)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3572076; Age (years): 19; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.6; Weight (kg): 54.0; BMI (kg/m ²): 20.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24AUG2020:12:31:00; Follow-up Days after 1st Dose: 215; Dose 2 Date/Time: 22SEP2020:12:13:00; Follow-up Days after 2nd Dose: 186					
Pregnancy, puerperium and perinatal conditions/ Pregnancy/ PREGNANCY	2021-04-08 (43)/ 2021-04-16 (51)	Yes/ No/ No	Yes/6	NR/ NR	DOSE DELAYED/ NONE
Subject ID: US3572170; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 88.6; BMI (kg/m ²): 27.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:08:27:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 08OCT2020:10:27:00; Follow-up Days after 2nd Dose: 170					
Gastrointestinal disorders/ Gastroesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2021-03-29 (39)/ Ongoing	Yes/ No/ No	4 Yes/3 (2021-04-12/ 2021-04-14)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE
					NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3572170; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 88.6; BMI (kg/m ²): 27.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:08:27:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 08OCT2020:10:27:00; Follow-up Days after 2nd Dose: 170					
Cardiac disorders/ Acute myocardial infarction/ NSTEMI	2021-04-10 (51)/ 2021-04-10 (51)	Yes/ Yes/ No	4 2021-04-14)	Yes/3 (2021-04-10/ 2021-04-14)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3582102; Age (years): 77; Sex: M; Race: MULTIPLE: White, American Indian or Alaska Native; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 174.8; Weight (kg): 83.5; BMI (kg/m ²): 27.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:14:09:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 01OCT2020:11:33:00; Follow-up Days after 2nd Dose: 177					
Nervous system disorders/ Cerebrovascular accident/ ACUTE LEFT MIDDLE CEREBRAL ARTERY STROKE	2021-02-21 (14)/ 2021-02-21 (14)	Yes/ Yes/ No	3 2021-02-22)	Yes/3 (2021-02-21/ 2021-02-22)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3592061; Age (years): 44; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.0; Weight (kg): 105.8; BMI (kg/m ²): 36.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08AUG2020:09:42:00; Follow-up Days after 1st Dose: 231; Dose 2 Date/Time: 05SEP2020:08:51:00; Follow-up Days after 2nd Dose: 203					
Psychiatric disorders/ Suicidal ideation/ SUICIDAL IDEATIONS	2021-03-25 (44)/ 2021-03-28 (47)	Yes/ Yes/ No	2 2021-03-28)	Yes/3 (2021-03-25/ 2021-03-28)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3602123; Age (years): 46; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 165.1; Weight (kg): 68.6; BMI (kg/m ²): 25.2; Baseline SARS-CoV-2 Status: Positive; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Positive; Dose 1 Date/Time: 02OCT2020:15:32:00; Follow-up Days after 1st Dose: 176; Dose 2 Date/Time: 27OCT2020:10:14:00; Follow-up Days after 2nd Dose: 151					
Blood and lymphatic system disorders/ Immune thrombocytopenia/ WORSENING OF IMMUNE THROMBOCYTOPENIA	2021-02-12 (4)/ 2021-02-15 (7)	Yes/ Yes/ No	3 	Yes/6 	NR/ NR NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3602123; Age (years): 46; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 165.1; Weight (kg): 68.6; BMI (kg/m ²): 25.2; Baseline SARS-CoV-2 Status: Positive; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Positive; Dose 1 Date/Time: 02OCT2020:15:32:00; Follow-up Days after 1st Dose: 176; Dose 2 Date/Time: 27OCT2020:10:14:00; Follow-up Days after 2nd Dose: 151					
Investigations/ Platelet count decreased/ SIGNIFICANT DROP OF THE PLATELET COUNT	2021-02-12 (4) / 2021-02-15 (7)	Yes/ Yes/ No	3	Yes/6 NR/ NR NONE	NOT APPLICABLE/ RESOLVED
Subject ID: US3602154; Age (years): 42; Sex: M; Race: OTHER: ASIAN (INDIA); Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 110.5; BMI (kg/m ²): 34.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15OCT2020:16:00:00; Follow-up Days after 1st Dose: 163; Dose 2 Date/Time: 12NOV2020:14:40:00; Follow-up Days after 2nd Dose: 135					
General disorders and administration site conditions/ Non-cardiac chest pain/ NON - CARDIAC CHEST PAIN	2021-02-26 (18) / 2021-02-27 (19)	Yes/ Yes/ No	3	Yes/3 (2021-02-26/ 2021-02-27)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3612005; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 180.3; Weight (kg): 84.0; BMI (kg/m ²): 25.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:10:58:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 29SEP2020:10:21:00; Follow-up Days after 2nd Dose: 179					
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2021-04-13 (71)/ 2021-04-17 (75)	Yes/ Yes/ No	4 Yes/2/3 (2021-04-13/ 2021-04-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3612060; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 174.0; Weight (kg): 83.6; BMI (kg/m ²): 27.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 30SEP2020:11:05:00; Follow-up Days after 1st Dose: 178; Dose 2 Date/Time: 28OCT2020:09:38:00; Follow-up Days after 2nd Dose: 150					
Surgical and medical procedures/ Shoulder arthroplasty/ TOTAL SHOULDER ARTHROPLASTY	2021-03-31 (58)/ 2021-04-02 (60)	Yes/ Yes/ No	3 Yes/3 (2021-03-31/ 2021-04-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3622142; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 158.8; Weight (kg): 79.5; BMI (kg/m²): 31.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:12:02:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 01OCT2020:10:08:00; Follow-up Days after 2nd Dose: 177						
Infections and infestations/ COVID-19/ COVID-19	2021-01-26 (12)/ 2021-02-15 (32)	Yes/ Yes/ No	4 2021-01-29/ 2021-01-31)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SHORTNESS OF BREATH ON EXERTION

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3622142; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 158.8; Weight (kg): 79.5; BMI (kg/m ²): 31.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:12:02:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 01OCT2020:10:08:00; Follow-up Days after 2nd Dose: 177					
Respiratory, thoracic and mediastinal disorders/ Acute respiratory failure/ ACUTE HYPOXEMIC RESPIRATORY FAILURE SECONDARY TO COVID-19	2021-02-06 (23)/ 2021-02-09 (26)	Yes/ Yes/ No	4	Yes/3 (2021-02-06/ 2021-02-09)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: SHORTNESS OF BREATH ON EXERTION

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3622206; Age (years): 45; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D; Height (cm): 193.0; Weight (kg): 83.6; BMI (kg/m ²): 22.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19SEP2020:09:17:00; Follow-up Days after 1st Dose: 189; Dose 2 Date/Time: 16OCT2020:08:30:00; Follow-up Days after 2nd Dose: 162					
Infections and infestations/ Osteomyelitis bacterial/ OSTEOMYELITIS WITH GAS GANGRENE DISTAL RIGHT MIDDLE PHALANX 2ND DIGIT	2021-03-11 (31)/ 2021-03-16 (36)	Yes/ Yes/ No	4 	Yes/3 (2021-03-11/ 2021-03-16)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3622282; Age (years): 51; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/H; Height (cm): 157.5; Weight (kg): 84.1; BMI (kg/m ²): 33.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21OCT2020:10:52:00; Follow-up Days after 1st Dose: 157; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Infections and infestations/ Osteomyelitis/ BONE INFECTION	2021-02-25 (17)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-02-25/)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3632075; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 163.8; Weight (kg): 84.5; BMI (kg/m ²): 31.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11SEP2020:16:18:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 13OCT2020:16:43:00; Follow-up Days after 2nd Dose: 165					
Cardiac disorders/ Cardiac failure/ WORSENING HEART FAILURE	2021-02-12 (9) / 2021-03-03 (28)	Yes/ Yes/ No	3 2021-03-03)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED WITH SEQUELAE: NEW BASELINE EF OF 15% (WAS PREVIOUSLY HIGHER PER RECORDS)

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3632075; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 163.8; Weight (kg): 84.5; BMI (kg/m ²): 31.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11SEP2020:16:18:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 13OCT2020:16:43:00; Follow-up Days after 2nd Dose: 165					
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2021-02-12 (9) / 2021-03-03 (28)	Yes/ Yes/ No	4 2021-03-03) /4	NR/ NR 2021-03-03) /4	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
					RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Other Action Taken	Outcome
Subject ID: US3632075; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 163.8; Weight (kg): 84.5; BMI (kg/m ²): 31.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11SEP2020:16:18:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 13OCT2020:16:43:00; Follow-up Days after 2nd Dose: 165						
Renal and urinary disorders/ Renal failure/ WORSENING RENAL FAILURE	2021-02-14 (11)/ 2021-03-03 (28)	Yes/ Yes/ No	4 2021-03-03)/6	Yes/2/3 (2021-02-12/ 2021-03-03)/6	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: ACUTE RENAL FAILURE IMPROVED, NOW WITH NEW BASELINE RENAL FUNCTION

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
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Subject ID: US3642076; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 189.5; Weight (kg): 123.5; BMI (kg/m²): 34.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:17:34:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 30SEP2020:14:35:00; Follow-up Days after 2nd Dose: 178

Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Metastases to lung/ POSSIBLE RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS	2021-02-22 (33)/ Ongoing	Yes/ Yes/ No	3	Yes/2/3 (2021-02-22/ 2021-02-24)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERING/ RESOLVING
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Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3642081; Age (years): 68; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 165.0; Weight (kg): 62.1; BMI (kg/m ²): 22.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 02SEP2020:15:39:00; Follow-up Days after 1st Dose: 206; Dose 2 Date/Time: 01OCT2020:16:25:00; Follow-up Days after 2nd Dose: 177					
Gastrointestinal disorders/ Abdominal pain upper/ EPIGASTRIC PAIN	2021-03-28 (44) / 2021-03-29 (45)	Yes/ Yes/ No	3 3	Yes/3 (2021-03-28/ 2021-03-29)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3662032; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 173.5; Weight (kg): 107.0; BMI (kg/m ²): 35.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:09:58:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 29SEP2020:09:15:00; Follow-up Days after 2nd Dose: 179					
Infections and infestations/ Medical device site joint infection/ INFECTION/INFLAMMATION REACTION DUE TO INTERNAL LEFT HIP PROSTHESIS	2021-04-08 (50) / Ongoing	Yes/ Yes/ No	3 3	Yes/3 (2021-04-08/ 2021-04-13)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3672187; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.0; Weight (kg): 105.7; BMI (kg/m ²): 36.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:11:06:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Infections and infestations/ Pneumonia/ PNEUMONIA RIGHT LUNG	2021-03-06 (2) / 2021-03-09 (5)	Yes/ Yes/ No	3 	Yes/3 (2021-03-06/ 2021-03-09)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3702040; Age (years): 58; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 168.0; Weight (kg): 85.4; BMI (kg/m ²): 30.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21SEP2020:11:29:00; Follow-up Days after 1st Dose: 187; Dose 2 Date/Time: 20OCT2020:10:05:00; Follow-up Days after 2nd Dose: 158					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2021-01-26 (16) / Ongoing	Yes/ Yes/ No	4 	Yes/2 	NR/ NR CONCOMITANT MEDICATION

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3712096; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 159.4; Weight (kg): 132.6; BMI (kg/m ²): 52.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17SEP2020:12:02:00; Follow-up Days after 1st Dose: 191; Dose 2 Date/Time: 15OCT2020:12:07:00; Follow-up Days after 2nd Dose: 163					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Oesophageal adenocarcinoma/ ESOPHAGEAL ADENOCARCINOMA	2021-03-20 (23)/ Ongoing	Yes/ Yes/ No	3 Yes/2	NR/ NR	NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3712096; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 159.4; Weight (kg): 132.6; BMI (kg/m ²): 52.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17SEP2020:12:02:00; Follow-up Days after 1st Dose: 191; Dose 2 Date/Time: 15OCT2020:12:07:00; Follow-up Days after 2nd Dose: 163					
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLI	2021-04-15 (25)/ Ongoing	Yes/ Yes/ No	3 2021-04-20)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION
					RECOVERING/ RESOLVING

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3712174; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 177.6; Weight (kg): 121.0; BMI (kg/m ²): 38.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15OCT2020:10:58:00; Follow-up Days after 1st Dose: 163; Dose 2 Date/Time: 11NOV2020:09:44:00; Follow-up Days after 2nd Dose: 136					
Musculoskeletal and connective tissue disorders/ Intervertebral disc degeneration/ WORSENING OF DEGENERATIVE DISC DISEASE	2021-02-11 (17) / 2021-02-13 (19)	Yes/ Yes/ No	3 Yes/3 (2021-02-11/ 2021-02-13)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3742225; Age (years): 22; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 166.4; Weight (kg): 78.4; BMI (kg/m ²): 28.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:09:25:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 30SEP2020:09:52:00; Follow-up Days after 2nd Dose: 178					
Congenital, familial and genetic disorders/ Arnold-Chiari malformation/ ARNOLD CHIARI SYNDROME	2021-04-14 (65)/ 2021-04-17 (68)	Yes/ Yes/ No	2 Yes/3 (2021-04-14/ 2021-04-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3742301; Age (years): 45; Sex: F; Race: NOT REPORTED; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 160.0; Weight (kg): 121.6; BMI (kg/m ²): 47.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:16:10:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 08OCT2020:16:13:00; Follow-up Days after 2nd Dose: 170					
Gastrointestinal disorders/ Internal hernia/ INTERNAL HERNIA	2021-01-16 (3)/ 2021-01-22 (9)	Yes/ Yes/ No	3 Yes/3 (2021-01-16/ 2021-01-22)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3742384; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 163.8; Weight (kg): 109.5; BMI (kg/m ²): 40.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 16SEP2020:09:53:00; Follow-up Days after 1st Dose: 192; Dose 2 Date/Time: 13OCT2020:08:19:00; Follow-up Days after 2nd Dose: 165					
Surgical and medical procedures/ Colostomy/ REVERSAL OF OSTOMY - S/P HARTMANN'S PROCEDURE	2021-04-05 (50) / Ongoing	Yes/ Yes/ No	3 	Yes/3 (2021-04-05/ 2021-04-09)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3752184; Age (years): 81; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 168.9; Weight (kg): 78.7; BMI (kg/m ²): 27.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:14:30:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 21SEP2020:11:22:00; Follow-up Days after 2nd Dose: 187					
Infections and infestations/ Diverticulitis/ ACUTE DIVERTICULITIS	2021-03-31 (34) / 2021-04-10 (44)	Yes/ Yes/ No	3 	Yes/3 (2021-03-31/ 2021-04-02)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3762023; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 188.0; Weight (kg): 110.0; BMI (kg/m ²): 31.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21AUG2020:16:05:00; Follow-up Days after 1st Dose: 218; Dose 2 Date/Time: 17SEP2020:14:26:00; Follow-up Days after 2nd Dose: 191					
Cardiac disorders/ Aortic valve incompetence/ AORTIC VALVE FAILURE	2021-01-26 (16) / 2021-01-30 (20)	Yes/ Yes/ No	4 Yes/3 (2021-01-26/ 2021-01-30)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3772252; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 195.0; Weight (kg): 112.0; BMI (kg/m ²): 29.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11SEP2020:09:54:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 21OCT2020:15:05:00; Follow-up Days after 2nd Dose: 157					
Infections and infestations/ COVID-19 pneumonia/ COVID-19 PNEUMONIA	2021-02-02 (21) / 2021-02-07 (26)	Yes/ Yes/ No	3 Yes/3 (2021-02-01/ 2021-02-04)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3782014; Age (years): 64; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 176.0; Weight (kg): 158.2; BMI (kg/m ²): 51.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:16:04:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 10SEP2020:14:12:00; Follow-up Days after 2nd Dose: 198					
Skin and subcutaneous tissue disorders/ Drug eruption/ DRUG RASH	2021-03-06 (30)/ 2021-03-18 (42)	Yes/ Yes/ No	4 	Yes/3 (2021-03-08/ 2021-03-12)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Gastrointestinal disorders/ Duodenal ulcer perforation/ PERFORATED DUODENAL ULCER	2021-03-17 (41)/ 2021-03-30 (54)	Yes/ Yes/ No	4 	Yes/3 (2021-03-17/ 2021-04-02)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3802168; Age (years): 41; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 181.6; Weight (kg): 112.3; BMI (kg/m ²): 34.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08SEP2020:11:15:00; Follow-up Days after 1st Dose: 200; Dose 2 Date/Time: 09OCT2020:13:18:00; Follow-up Days after 2nd Dose: 169					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Castleman's disease/ EXCISION OF PERIHEPATIC MASS, CASTLEMAN'S DISEASE	2021-03-30 (58)/ 2021-03-30 (58)	Yes/ Yes/ No	3 	Yes/3 (2021-03-30/ 2021-04-03)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3812229; Age (years): 81; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 165.1; Weight (kg): 86.5; BMI (kg/m ²): 31.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21AUG2020:09:38:00; Follow-up Days after 1st Dose: 218; Dose 2 Date/Time: 18SEP2020:10:43:00; Follow-up Days after 2nd Dose: 190					
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2021-02-25 (15)/ 2021-02-25 (15)	Yes/ Yes/ No	4 2021-02-27)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
					RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3822342; Age (years): 77; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): ; Weight (kg): ; BMI (kg/m ²): ; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:13:27:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 08OCT2020:10:56:00; Follow-up Days after 2nd Dose: 170					
Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ RIGHT PLEURAL EFFUSION	2021-02-05 (32)/ 2021-02-08 (35)	Yes/ Yes/ No	3 Yes/3 (2021-02-05/ 2021-02-07)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED WITH SEQUELAE: PER MEDICAL RECORD RIGHT PLEURAL EFFUSION STILL ONGOING.
Subject ID: US3832176; Age (years): 74; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 165.1; Weight (kg): 95.5; BMI (kg/m ²): 35.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:12:13:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 09SEP2020:11:40:00; Follow-up Days after 2nd Dose: 199					
Gastrointestinal disorders/ Hiatus hernia/ WORSENING OF PARAOESOPHAGEAL HERNIA	2021-03-02 (30)/ 2021-03-03 (31)	Yes/ Yes/ No	4 Yes/3 (2021-03-02/ 2021-03-08)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3832176; Age (years): 74; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 165.1; Weight (kg): 95.5; BMI (kg/m ²): 35.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:12:13:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 09SEP2020:11:40:00; Follow-up Days after 2nd Dose: 199					
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2021-04-22 (81) / Ongoing	Yes/ Yes/ No	4 Yes/3 (2021-04-23 / 2021-04-25)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3852015; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 157.5; Weight (kg): 63.3; BMI (kg/m ²): 25.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24AUG2020:13:47:00; Follow-up Days after 1st Dose: 215; Dose 2 Date/Time: 21SEP2020:10:04:00; Follow-up Days after 2nd Dose: 187					
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING BACK PAIN	2021-03-28 (40) / 2021-03-31 (43)	Yes/ Yes/ No	3 Yes/3 (2021-03-28 / 2021-03-31) /6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3862020; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 176.5; Weight (kg): 93.6; BMI (kg/m ²): 30.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17AUG2020:14:46:00; Follow-up Days after 1st Dose: 222; Dose 2 Date/Time: 16SEP2020:10:41:00; Follow-up Days after 2nd Dose: 192					
Blood and lymphatic system disorders/ Anaemia/ SEVERE ANEMIA	2021-04-28 (58)/ Ongoing	Yes/ Yes/ No	3)	Yes/3 (2021-04-28/ NR	NR/ NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING
Subject ID: US3862099; Age (years): 51; Sex: M; Race: NOT REPORTED; Risk Factors for Severe COVID-19[4]: L/H; Height (cm): 186.7; Weight (kg): 115.5; BMI (kg/m ²): 33.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:16:23:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:16:03:00; Follow-up Days after 2nd Dose: 180					
Renal and urinary disorders/ Ureterolithiasis/ LEFT PROXIMAL AND DISTAL URETERAL CALCULI	2021-03-13 (30)/ 2021-03-14 (31)	Yes/ Yes/ No	3)	Yes/3 (2021-03-14/ 2021-03-15) NR	NR/ NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3862099; Age (years): 51; Sex: M; Race: NOT REPORTED; Risk Factors for Severe COVID-19[4]: L/H; Height (cm): 186.7; Weight (kg): 115.5; BMI (kg/m ²): 33.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:16:23:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:16:03:00; Follow-up Days after 2nd Dose: 180					
Renal and urinary disorders/ Nephrolithiasis/ NON OBSTRUCTING LEFT NEPHROLITHIASIS	2021-03-13 (30)/ 2021-04-11 (59)	Yes/ Yes/ No	3 	Yes/3 (2021-03-14/ 2021-03-15)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3862144; Age (years): 53; Sex: M; Race: MULTIPLE: White, Black or African American; Risk Factors for Severe COVID-19[4]: H; Height (cm): 170.2; Weight (kg): 106.6; BMI (kg/m ²): 36.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08SEP2020:15:37:00; Follow-up Days after 1st Dose: 200; Dose 2 Date/Time: 07OCT2020:09:53:00; Follow-up Days after 2nd Dose: 171					
Gastrointestinal disorders/ Intestinal obstruction/ PARTIAL BOWEL OBSTRUCTION	2021-02-19 (26)/ 2021-02-24 (31)	Yes/ Yes/ No	3 	Yes/3 (2021-02-21/ 2021-02-24)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Other Action Taken	Outcome
Subject ID: US3872187; Age (years): 64; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 182.9; Weight (kg): 90.9; BMI (kg/m ²): 27.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:10:53:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 18SEP2020:10:42:00; Follow-up Days after 2nd Dose: 190						
Infections and infestations/ Appendicitis/ APPENDICITIS	2021-03-07 (33)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-03-23/ 2021-03-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
						RECOVERING/ RESOLVING

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Other Action Taken	Outcome
Subject ID: US3872187; Age (years): 64; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 182.9; Weight (kg): 90.9; BMI (kg/m ²): 27.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:10:53:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 18SEP2020:10:42:00; Follow-up Days after 2nd Dose: 190						
Infections and infestations/ Appendicitis perforated/ PERFORATED APPENDIX	2021-03-18 (44)/ 2021-03-24 (50)	Yes/ Yes/ No	3 2021-03-23/ 2021-03-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: NO SURGICAL INTERVENTION AT THIS TIME, BUT PATIENT IS BEING MONITORED. SUBJECT DISCHARGED NEXT DAY WITH ANTIBIOTICS TO ADMINISTER AT HOME.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3872187; Age (years): 64; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 182.9; Weight (kg): 90.9; BMI (kg/m ²): 27.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:10:53:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 18SEP2020:10:42:00; Follow-up Days after 2nd Dose: 190					
Infections and infestations/ Appendiceal abscess/ PERI-APPENDICEAL ABSCESS	2021-03-23 (49) / 2021-03-24 (50)	Yes/ Yes/ No	3 Yes/3 (2021-03-23/ 2021-03-24)	NR/ NR	NOT APPLICABLE/ NONE RECOVERED/ RESOLVED WITH SEQUELAE: NO SURGICAL INTERVENTION AT THIS TIME, BUT PATIENT IS BEING MONITORED. SUBJECT DISCHARGED NEXT DAY WITH ANTIBIOTICS TO ADMINISTER AT HOME.

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3892032; Age (years): 64; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 161.0; Weight (kg): 109.4; BMI (kg/m ²): 42.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:12:02:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:11:52:00; Follow-up Days after 2nd Dose: 180					
Injury, poisoning and procedural complications/ Stress fracture/ STRESS FRACTURE LEFT FOOT	2021-03-22 (11)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-04-22/ 2021-04-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE NOT RECOVERED/ NOT RESOLVED
Subject ID: US3912046; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 177.8; Weight (kg): 105.0; BMI (kg/m ²): 33.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:13:22:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:11:07:00; Follow-up Days after 2nd Dose: 180					
Nervous system disorders/ Brain stem infarction/ ACUTE PONTINE INFARCT	2021-03-22 (25)/ 2021-03-30 (33)	Yes/ Yes/ No	3 Yes/2/3 (2021-03-22/ 2021-03-30)	NR/ NR	DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED WITH SEQUELAE: LEFT HEMIPARESIS; DYSPHAGIA

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3912076; Age (years): 51; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 151.1; Weight (kg): 89.5; BMI (kg/m ²): 39.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 02SEP2020:12:14:00; Follow-up Days after 1st Dose: 206; Dose 2 Date/Time: 30SEP2020:11:00:00; Follow-up Days after 2nd Dose: 178					
Immune system disorders/ Anaphylactic reaction/ ACUTE ANAPHYLAXIS	2021-01-31 (19)/ 2021-01-31 (19)	Yes/ Yes/ No	3 	Yes/2 	NR/ NR DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-with IP/ ship to Other Action IP/SP [3]	Action Taken Taken	Outcome
Subject ID: US3942072; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 172.4; Weight (kg): 75.9; BMI (kg/m ²): 25.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:10:19:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 08OCT2020:10:08:00; Follow-up Days after 2nd Dose: 170						
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE	2021-03-23 (48)/ 2021-03-29 (54)	Yes/ Yes/ No	3 2021-03-28)	Yes/3 (2021-03-23/ 2021-03-28)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT HAS REACHED A NEW BASELINE AND MEDICATIONS FOR ONGOING STABILIZATION ARE IN PLACE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3942151; Age (years): 54; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 172.6; Weight (kg): 107.5; BMI (kg/m ²): 36.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12OCT2020:11:58:00; Follow-up Days after 1st Dose: 166; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Injury, poisoning and procedural complications/ Anaemia postoperative/ ACUTE BLOOD LOSS ANEMIA POST OP	2021-04-19 (61)/ 2021-04-19 (61)	Yes/ Yes/ No	2 2020-10-22)	Yes/3 (2020-10-17/ 2020-10-22)	NR/ NR CONCOMITANT PROCEDURE
Subject ID: US3952173; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.3; Weight (kg): 85.9; BMI (kg/m ²): 28.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29SEP2020:14:32:00; Follow-up Days after 1st Dose: 179; Dose 2 Date/Time: 29OCT2020:10:56:00; Follow-up Days after 2nd Dose: 149					
Eye disorders/ Retinal artery occlusion/ (L) EYE RETINAL ARTERY OCCLUSION	2021-03-24 (16)/ 2021-03-31 (23)	Yes/ Yes/ No	3 2021-03-31)	Yes/3 (2021-03-29/ 2021-03-31)	NR/ NR CONCOMITANT MEDICATION

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3952173; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.3; Weight (kg): 85.9; BMI (kg/m ²): 28.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29SEP2020:14:32:00; Follow-up Days after 1st Dose: 179; Dose 2 Date/Time: 29OCT2020:10:56:00; Follow-up Days after 2nd Dose: 149					
Musculoskeletal and connective tissue disorders/ Chondrocalcinosis pyrophosphate/ OLIGOARTHRITIS SECONDARY TO PSEUDOGOUT FLARE	2021-04-08 (31)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-04-09/ 2021-04-12)	NR/ NR NONE	NOT APPLICABLE/ RESOLVING

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3982013; Age (years): 73; Sex: F; Race: ASIAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 156.0; Weight (kg): 56.2; BMI (kg/m ²): 23.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 26AUG2020:12:40:00; Follow-up Days after 1st Dose: 213; Dose 2 Date/Time: 24SEP2020:12:03:00; Follow-up Days after 2nd Dose: 184					
Musculoskeletal and connective tissue disorders/ Arthralgia/ JOINT PAIN MULTIPLE SITES	2021-04-11 (59)/ Ongoing	Yes/ Yes/ Yes	2 Yes/3 (2021-04-11/ 2021-04-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3982028; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 176.0; Weight (kg): 114.9; BMI (kg/m ²): 37.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:11:32:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 01OCT2020:12:14:00; Follow-up Days after 2nd Dose: 177					
Injury, poisoning and procedural complications/ Post procedural hypotension/ ORTHOSTATIC HYPOTENSION, POST OPERATIVE	2021-01-21 (9)/ 2021-01-24 (12)	Yes/ Yes/ No	2 Yes/3 (2021-01-20/ 2021-01-24)	NR/ NR	DOSE NOT CHANGED/ NONE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3982169; Age (years): 81; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.1; Weight (kg): 77.5; BMI (kg/m ²): 25.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14SEP2020:15:21:00; Follow-up Days after 1st Dose: 194; Dose 2 Date/Time: 09OCT2020:13:08:00; Follow-up Days after 2nd Dose: 169					
Renal and urinary disorders/ Nephrolithiasis/ WORSENING OF RENAL STONES	2021-02-03 17:00 (1)/ 2021-02-06 00:00 (3)	Yes/ Yes/ No	3 2	Yes/3 (2021-02-05/ 2021-02-06)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED
Subject ID: US3982269; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL/SO/D; Height (cm): 169.6; Weight (kg): 129.0; BMI (kg/m ²): 44.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09OCT2020:16:16:00; Follow-up Days after 1st Dose: 169; Dose 2 Date/Time: 06NOV2020:11:15:00; Follow-up Days after 2nd Dose: 141					
General disorders and administration site conditions/ Gait disturbance/ GAIT BALANCE AND MOTILITY DYSFUNCTION	2021-03-03 (15)/ 2021-03-22 (34)	Yes/ Yes/ No	2	Yes/4	NR/ NR DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
Subject ID: US3982269; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL/SO/D; Height (cm): 169.6; Weight (kg): 129.0; BMI (kg/m ²): 44.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09OCT2020:16:16:00; Follow-up Days after 1st Dose: 169; Dose 2 Date/Time: 06NOV2020:11:15:00; Follow-up Days after 2nd Dose: 141					
Infections and infestations/ Pneumonia/ BILATERAL PERIHILAR PNEUMONIA	2021-03-03 (15) / 2021-03-22 (34)	Yes/ Yes/ No	2	Yes/3 (2021-03-03/ 2021-03-08)	NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION
Infections and infestations/ Cystitis/ ACUTE CYSTITIS	2021-03-18 (30) / 2021-03-22 (34)	Yes/ Yes/ No	2	Yes/3 (2021-03-18/ 2021-03-22)	NR/ NR DOSE NOT CHANGED/ NONE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3992037; Age (years): 23; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 165.1; Weight (kg): 56.8; BMI (kg/m ²): 20.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 26SEP2020:11:47:00; Follow-up Days after 1st Dose: 182; Dose 2 Date/Time: 30OCT2020:09:20:00; Follow-up Days after 2nd Dose: 148					
Infections and infestations/ Appendicitis/ ACUTE APPENDICITIS	2021-01-10 (5)/ 2021-01-13 (8)	Yes/ Yes/ No	3 	Yes/3 (2021-01-13/ 2021-01-14)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3002149; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 193.0; Weight (kg): 129.0; BMI (kg/m ²): 34.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:12:37:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 09SEP2020:11:08:00; Follow-up Days after 2nd Dose: 199					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Oesophageal carcinoma/ ESOPHAGEAL CANCER	2021-04-09 (213)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3012171; Age (years): 64; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 168.9; Weight (kg): 111.4; BMI (kg/m ²): 39.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 18AUG2020:16:06:00; Follow-up Days after 1st Dose: 221; Dose 2 Date/Time: 15SEP2020:11:01:00; Follow-up Days after 2nd Dose: 193					
Blood and lymphatic system disorders/ Leukocytosis/ LEUKOCYTOSIS	2021-03-12 (179)/ 2021-04-13 (211)	Yes/ Yes/ No	1	Yes/3 (2021-03-12/ 2021-03-17)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [2]	Action Taken Other Action Taken	Outcome
Subject ID: US3012171; Age (years): 64; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 168.9; Weight (kg): 111.4; BMI (kg/m²): 39.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 18AUG2020:16:06:00; Follow-up Days after 1st Dose: 221; Dose 2 Date/Time: 15SEP2020:11:01:00; Follow-up Days after 2nd Dose: 193						
Infections and infestations/ Epididymitis/ EPIDIDYMITIS	2021-03-12 (179) / 2021-04-13 (211)	Yes/ Yes/ No	2	Yes/3 (2021-03-12/ 2021-03-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2021-03-12 (179) / 2021-04-13 (211)	Yes/ Yes/ No	1	Yes/3 (2021-03-12/ 2021-03-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3022167; Age (years): 21; Sex: F; Race: OTHER: HISPANIC; Risk Factors for Severe COVID-19[4]:; Height (cm): 156.7; Weight (kg): 51.9; BMI (kg/m ²): 21.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17AUG2020:18:59:00; Follow-up Days after 1st Dose: 222; Dose 2 Date/Time: 14SEP2020:16:35:00; Follow-up Days after 2nd Dose: 194					
Metabolism and nutrition disorders/ Dehydration/ DEHYDRATION	2021-03-19 (187) / 2021-03-22 (190)	Yes/ Yes/ No	4 2021-03-22)	NR/ NR NONE	NOT APPLICABLE/ RESOLVED
Subject ID: US3042262; Age (years): 22; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SO; Height (cm): 185.4; Weight (kg): 140.5; BMI (kg/m ²): 40.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:15:16:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 17SEP2020:16:08:00; Follow-up Days after 2nd Dose: 191					
Psychiatric disorders/ Intentional self-injury/ ACT OF SELF-HARM	2021-02-24 (161) / 2021-02-24 (161)	Yes/ Yes/ No	2 2021-03-22)	NR/ NR NONE	NOT APPLICABLE/ CONCOMITANT MEDICATION

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3052005; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 190.5; Weight (kg): 87.3; BMI (kg/m²): 24.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 30JUL2020:11:22:00; Follow-up Days after 1st Dose: 240; Dose 2 Date/Time: 26AUG2020:11:27:00; Follow-up Days after 2nd Dose: 213					
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ RIGHT HIP JOINT REPLACEMENT (WORSENING OF OSTEOARTHRITIS)	2021-02-24 (183)/ 2021-02-25 (184)	Yes/ Yes/ No	3 Yes/3 (2021-02-24/ 2021-02-25)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3052028; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/D; Height (cm): 163.8; Weight (kg): 68.2; BMI (kg/m ²): 25.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 30JUL2020:18:01:00; Follow-up Days after 1st Dose: 240; Dose 2 Date/Time: 25AUG2020:16:26:00; Follow-up Days after 2nd Dose: 214					
Musculoskeletal and connective tissue disorders/ Musculoskeletal chest pain/ MUSCULOSKELETAL CHEST PAIN	2021-04-03 (222)/ 2021-04-04 (223)	Yes/ Yes/ No	3 Yes/3 (2021-04-03/ 2021-04-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED
Subject ID: US3062079; Age (years): 40; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 163.0; Weight (kg): 99.6; BMI (kg/m ²): 37.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04AUG2020:18:31:00; Follow-up Days after 1st Dose: 235; Dose 2 Date/Time: 04SEP2020:14:19:00; Follow-up Days after 2nd Dose: 204					
Renal and urinary disorders/ Nephrolithiasis/ WORSENING OF RECURRENT NEPHROLITHIASIS	2021-04-19 (228)/ Ongoing	Yes/ Yes/ No	4 Yes/3 (2021-04-19/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3112043; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 115.7; BMI (kg/m ²): 40.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31JUL2020:10:48:00; Follow-up Days after 1st Dose: 239; Dose 2 Date/Time: 26AUG2020:12:45:00; Follow-up Days after 2nd Dose: 213					
Infections and infestations/ Diverticulitis/ DIVERTICULITIS WITH SPONTANEOUS RESOLUTION	2021-03-09 (196)/ 2021-03-13 (200)	Yes/ Yes/ No	3 Yes/3 (2021-03-09/ 2021-03-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3112113; Age (years): 61; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 170.2; Weight (kg): 148.2; BMI (kg/m ²): 51.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:14:58:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 02SEP2020:13:47:00; Follow-up Days after 2nd Dose: 206					
Renal and urinary disorders/ Haematuria/ INTERMITTENT HEMATURIA	2021-03-02 (182)/ Ongoing	Yes/ Yes/ No	2 Yes/3 (2021-04-23/ 2021-04-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3112113; Age (years): 61; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 170.2; Weight (kg): 148.2; BMI (kg/m ²): 51.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:14:58:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 02SEP2020:13:47:00; Follow-up Days after 2nd Dose: 206					
Injury, poisoning and procedural complications/ Tendon rupture/ FULL THICKNESS TEAR OF SUPRASPINATUS TENDON	2021-03-23 (203)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-03-25/ 2021-03-27)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3132004; Age (years): 52; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 182.9; Weight (kg): 83.2; BMI (kg/m ²): 24.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:10:31:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 31AUG2020:08:35:00; Follow-up Days after 2nd Dose: 208					
Nervous system disorders/ Sciatica/ WORSENING SCIATICA	2021-04-26 (239)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-04-26/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3132149; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 160.0; Weight (kg): 68.2; BMI (kg/m ²): 26.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21OCT2020:12:35:00; Follow-up Days after 1st Dose: 157; Dose 2 Date/Time: 18NOV2020:11:41:00; Follow-up Days after 2nd Dose: 129					
Injury, poisoning and procedural complications/ Poisoning/ INTOXICATION	2021-04-09 (143)/ 2021-04-13 (147)	Yes/ Yes/ No	2 Yes/3 (2021-04-09/ 2021-04-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3152162; Age (years): 46; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 160.7; Weight (kg): 95.5; BMI (kg/m ²): 37.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:13:02:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 10SEP2020:16:33:00; Follow-up Days after 2nd Dose: 198					
Nervous system disorders/ Cerebrovascular accident/ ACUTE CEREBROVASCULAR ACCIDENT	2021-04-01 (204)/ 2021-04-01 (204)	Yes/ Yes/ No	4 Yes/2/3 (2021-04-01/ 2021-04-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3152413; Age (years): 48; Sex: F; Race: OTHER: HISPANIC; Risk Factors for Severe COVID-19[4]:; Height (cm): 165.0; Weight (kg): 103.7; BMI (kg/m ²): 38.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29SEP2020:10:18:00; Follow-up Days after 1st Dose: 179; Dose 2 Date/Time: 27OCT2020:14:37:00; Follow-up Days after 2nd Dose: 151					
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2021-04-06 (162) / 2021-04-08 (164)	Yes/ Yes/ No	3 (2021-04-08/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE
Subject ID: US3162290; Age (years): 42; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 72.6; BMI (kg/m ²): 25.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19OCT2020:18:23:00; Follow-up Days after 1st Dose: 159; Dose 2 Date/Time: 16NOV2020:15:51:00; Follow-up Days after 2nd Dose: 131					
Infections and infestations/ Orchitis/ ACUTE LEFT EPIDIDYMO-ORCHITIS	2021-03-06 (111) / 2021-04-09 (145)	Yes/ Yes/ No	4 (2021-03-10/ 2021-03-11)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3172040; Age (years): 77; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.8; Weight (kg): 71.3; BMI (kg/m ²): 26.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:14:08:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:11:33:00; Follow-up Days after 2nd Dose: 200					
Metabolism and nutrition disorders/ Gout/ ACUTE EXACERBATION OF GOUT	2021-02-21 (167)/ 2021-02-22 (168)	Yes/ Yes/ No	2 	Yes/3 (2021-02-21/ 2021-02-22)	NR/ NR NONE RECOVERED/ RESOLVED
Subject ID: US3172406; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 150.1; Weight (kg): 83.0; BMI (kg/m ²): 36.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19OCT2020:15:22:00; Follow-up Days after 1st Dose: 159; Dose 2 Date/Time: 16NOV2020:16:25:00; Follow-up Days after 2nd Dose: 131					
Injury, poisoning and procedural complications/ Patella fracture/ LEFT KNEE PATELLA FRACTURE	2021-01-31 (77)/ Ongoing	Yes/ Yes/ No	3 	Yes/3 (2021-02-09/ 2021-02-12)	NR/ NR NOT RECOVERED/ NOT RESOLVED CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3172469; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 174.0; Weight (kg): 76.5; BMI (kg/m ²): 25.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21OCT2020:16:29:00; Follow-up Days after 1st Dose: 157; Dose 2 Date/Time: 18NOV2020:11:04:00; Follow-up Days after 2nd Dose: 129					
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT THIGH PAIN WORSENING	2021-03-22 (125)/ 2021-04-12 (146)	Yes/ Yes/ No	3 Yes/3 (2021-03-22/ 2021-04-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3202025; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 170.8; Weight (kg): 98.7; BMI (kg/m ²): 33.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:10:26:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:12:19:00; Follow-up Days after 2nd Dose: 205					
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF BACK PAIN	2021-04-28 (238)/ Ongoing	Yes/ Yes/ No	2 Yes/3 (2021-04-28/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3202042; Age (years): 49; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 164.9; Weight (kg): 58.3; BMI (kg/m²): 21.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:16:13:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 10SEP2020:15:42:00; Follow-up Days after 2nd Dose: 198						
Vascular disorders/ Jugular vein thrombosis/ DEEP VEIN THROMBOSIS LEFT INTERNAL JUGULAR - PARTIALLY OCCLUSIVE	2021-01-06 (119) / 2021-01-11 (124)	Yes/ Yes/ No	3	Yes/3 (2021-01-07/ 2021-01-11)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Subclavian vein thrombosis/ DVT- OCCLUSIVE LEFT SUBCLAVIAN VEIN	2021-01-06 (119) / 2021-01-11 (124)	Yes/ Yes/ No	3	Yes/3 (2021-01-07/ 2021-01-11)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3202197; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 179.0; Weight (kg): 122.2; BMI (kg/m ²): 38.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15AUG2020:09:31:00; Follow-up Days after 1st Dose: 224; Dose 2 Date/Time: 14SEP2020:15:06:00; Follow-up Days after 2nd Dose: 194					
Nervous system disorders/ Carotid artery stenosis/ LEFT CAROTID STENOSIS	2021-01-19 (128)/ 2021-01-19 (128)	Yes/ Yes/ No	2 2021-01-20)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
					RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3202366; Age (years): 30; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 173.7; Weight (kg): 108.9; BMI (kg/m ²): 36.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:14:25:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:11:15:00; Follow-up Days after 2nd Dose: 180					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Uterine leiomyoma/ WORSENING OF UTERINE FIBROID	2021-04-01 (186)/ 2021-04-03 (188)	Yes/ Yes/ No	2 2021-04-01/ 2021-04-03)	NR/ NR	NOT APPLICABLE/ NONE
					RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3202375; Age (years): 56; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 164.0; Weight (kg): 69.9; BMI (kg/m ²): 26.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:10:54:00; Follow-up Days after 1st Dose: 216; Dose 2 Date/Time: 05OCT2020:09:31:00; Follow-up Days after 2nd Dose: 182					
General disorders and administration site conditions/ Sudden death/ SUDDEN DEATH (UNKNOWN CAUSE)	2021-04-04 (182)/ 2021-04-04 (182)	Yes/ Yes/ No	5 Yes/1	NR/ NR	NOT APPLICABLE/ NONE FATAL
Subject ID: US3212049; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 190.5; Weight (kg): 133.2; BMI (kg/m ²): 36.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:13:16:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 09SEP2020:12:32:00; Follow-up Days after 2nd Dose: 199					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2021-02-01 (146)/ Ongoing	Yes/ Yes/ No	3 Yes/6	NR/ NR	NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3212250; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 157.5; Weight (kg): 96.5; BMI (kg/m²): 38.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:15:32:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 16SEP2020:13:17:00; Follow-up Days after 2nd Dose: 192					
Gastrointestinal disorders/ Enterovesical fistula/ COLOVESICIAL FISTULA	2021-02-11 (149) / 2021-04-05 (202)	Yes/ Yes/ No	3	Yes/3 (2021-02-11/ 2021-02-12)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Gastrointestinal disorders/ Enterovesical fistula/ COLOVESICULAR FISTULA (SIGMOID COLECTOMY SURGERY)	2021-04-05 (202) / Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-04-05/ 2021-04-08)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
					RECOVERED/ RESOLVED RECOVERING/ RESOLVING

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3222017; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/L; Height (cm): 162.5; Weight (kg): 104.3; BMI (kg/m ²): 39.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:16:01:00; Follow-up Days after 1st Dose: 183; Dose 2 Date/Time: 03SEP2020:15:45:00; Follow-up Days after 2nd Dose: 155					
Cardiac disorders/ Cardiac arrest/ CARDIAC ARREST	2021-02-04 (155) / 2021-02-04 (155)	Yes/ No/ No	5 Yes/1	NR/ NR	DOSE NOT CHANGED/ NONE
Subject ID: US3232050; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 174.0; Weight (kg): 99.6; BMI (kg/m ²): 32.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:12:05:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:10:58:00; Follow-up Days after 2nd Dose: 197					
Gastrointestinal disorders/ Gastrointestinal haemorrhage/ GASTROINTESTINAL BLEED	2021-03-04 (175) / 2021-03-05 (176)	Yes/ Yes/ No	3 Yes/3 (2021-03-04/ 2021-03-06)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3232050; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 174.0; Weight (kg): 99.6; BMI (kg/m ²): 32.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:12:05:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:10:58:00; Follow-up Days after 2nd Dose: 197					
Vascular disorders/ Hypotension/ HYPOTENSION	2021-03-04 (175) / 2021-03-06 (177)	Yes/ Yes/ No	3 2021-03-06)	Yes/3 (2021-03-04/ 2021-03-06)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3232162; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.0; Weight (kg): 126.0; BMI (kg/m ²): 38.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11SEP2020:10:40:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 09OCT2020:10:08:00; Follow-up Days after 2nd Dose: 169					
Cardiac disorders/ Cardiac failure congestive/ ACUTE EXACERBATION OF CONGESTIVE HEART FAILURE	2021-01-29 (113) / 2021-02-02 (117)	Yes/ Yes/ No	3 2021-02-02)	Yes/3 (2021-01-31/ 2021-02-02)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3242081; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 185.4; Weight (kg): 75.9; BMI (kg/m ²): 22.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:16:12:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 11SEP2020:16:44:00; Follow-up Days after 2nd Dose: 197					
Infections and infestations/ Sepsis/ SEVERE SEPSIS	2021-04-01 (203)/ 2021-04-03 (205)	Yes/ Yes/ No	4 	Yes/3 (2021-04-01/ 2021-04-03)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3242102; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 81.8; BMI (kg/m ²): 28.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15AUG2020:10:44:00; Follow-up Days after 1st Dose: 224; Dose 2 Date/Time: 14SEP2020:09:43:00; Follow-up Days after 2nd Dose: 194					
Cardiac disorders/ Acute left ventricular failure/ ACUTE DIASTOLIC CONGESTIVE HEART FAILURE	2021-04-04 (203)/ 2021-04-14 (213)	Yes/ Yes/ No	4 	Yes/3 (2021-04-04/ 2021-04-07)	NR/ NR NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3252624; Age (years): 33; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 167.6; Weight (kg): 149.1; BMI (kg/m ²): 53.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05OCT2020:16:57:00; Follow-up Days after 1st Dose: 173; Dose 2 Date/Time: 04NOV2020:10:23:00; Follow-up Days after 2nd Dose: 143					
Infections and infestations/ Pneumonia bacterial/ BACTERIAL PNEUMONIA	2021-04-12 (160) / 2021-04-17 (165)	Yes/ Yes/ No	3 	Yes/3 (2020-04-12/ 2021-04-17)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3262027; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 157.5; Weight (kg): 69.2; BMI (kg/m ²): 27.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28JUL2020:17:02:00; Follow-up Days after 1st Dose: 242; Dose 2 Date/Time: 21SEP2020:10:11:00; Follow-up Days after 2nd Dose: 187					
Infections and infestations/ Pneumonia/ PNEUMONIA	2021-04-08 (200) / 2021-04-11 (203)	Yes/ Yes/ No	3 	Yes/3 (2021-04-08/ 2021-04-11)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3262115; Age (years): 57; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.3; Weight (kg): 102.7; BMI (kg/m ²): 33.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:12:15:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:13:50:00; Follow-up Days after 2nd Dose: 205					
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2021-04-03 (213) / 2021-04-06 (216)	Yes/ Yes/ No	3 Yes/3 (2021-04-03 / 2021-04-06)	NR/ NR	DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED
Subject ID: US3262133; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 157.5; Weight (kg): 78.2; BMI (kg/m ²): 31.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:15:29:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 05SEP2020:11:15:00; Follow-up Days after 2nd Dose: 203					
Hepatobiliary disorders/ Biliary colic/ EPIGASTRIC PAIN DUE TO RECURRENT BILIARY COLIC	2021-03-08 (185) / 2021-03-10 (187)	Yes/ Yes/ No	3 Yes/3 (2021-03-08 / 2021-03-10) /6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3272060; Age (years): 22; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 178.0; Weight (kg): 86.1; BMI (kg/m²): 27.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:12:01:00; Follow-up Days after 1st Dose: 233; Dose 2 Date/Time: 03SEP2020:10:54:00; Follow-up Days after 2nd Dose: 205						
Psychiatric disorders/ Suicide attempt/ SUICIDE ATTEMPT	2021-02-21 (172) / 2021-02-21 (172)	Yes/ Yes/ No	3	Yes/2 NR/	NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED
Subject ID: US3272078; Age (years): 39; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.0; Weight (kg): 74.3; BMI (kg/m²): 25.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:11:22:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 04SEP2020:09:55:00; Follow-up Days after 2nd Dose: 204						
Injury, poisoning and procedural complications/ Post procedural haematoma/ POSTOPERATIVE HEMATOMA OF BREAST, LEFT	2021-03-25 (203) / 2021-03-28 (206)	Yes/ Yes/ No	4	Yes/2/3 (2021-03-25/ 2021-03-28)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3292158; Age (years): 58; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC/D; Height (cm): 171.5; Weight (kg): 89.8; BMI (kg/m ²): 30.5; Baseline SARS-CoV-2 Status: ; Baseline RT-PCR: ; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: ; Dose 1 Date/Time: 13AUG2020:15:16:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 12SEP2020:13:29:00; Follow-up Days after 2nd Dose: 196						
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ EXACERBATION OF COPD	2021-03-26 (196)/ 2021-03-29 (199)	Yes/ Yes/ No	3	Yes/3 (2021-03-28/ 2021-03-29)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Respiratory, thoracic and mediastinal disorders/ Chronic obstructive pulmonary disease/ EXACERBATION OF COPD	2021-04-07 (208)/ 2021-04-09 (210)	Yes/ Yes/ No	3	Yes/3 (2021-04-07/ 2021-04-09)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3292172; Age (years): 53; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 161.6; Weight (kg): 93.9; BMI (kg/m ²): 36.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:17:20:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 10SEP2020:09:22:00; Follow-up Days after 2nd Dose: 198					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Uterine cancer/ UTERINE CANCER	2021-02-19 (163)/ 2021-04-07 (210)	Yes/ Yes/ No	3 	Yes/6 	NR/ NR DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED
Subject ID: US3302105; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 79.5; BMI (kg/m ²): 27.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:16:26:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 04SEP2020:08:37:00; Follow-up Days after 2nd Dose: 204					
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2021-02-19 (169)/ 2021-02-19 (169)	Yes/ Yes/ No	3 	Yes/3 (2021-02-19/ 2021-02-22)	NR/ NR NOT APPLICABLE/ NONE RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3302465; Age (years): 69; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL/D; Height (cm): 179.1; Weight (kg): 93.2; BMI (kg/m ²): 29.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29SEP2020:15:06:00; Follow-up Days after 1st Dose: 123; Dose 2 Date/Time: 27OCT2020:10:40:00; Follow-up Days after 2nd Dose: 95					
Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	2021-01-29 (95)/ 2021-01-29 (95)	Yes/ Yes/ No	5 	Yes/1 	NR/ NR NOT APPLICABLE/ NONE FATAL
Subject ID: US3312006; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 75.0; BMI (kg/m ²): 23.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10AUG2020:12:54:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: 07SEP2020:10:36:00; Follow-up Days after 2nd Dose: 184					
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARCTION	2021-03-09 (184)/ 2021-03-09 (184)	Yes/ No/ No	5 	Yes/1 	NR/ NR NOT APPLICABLE/ NONE FATAL

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
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Subject ID: US3312008; Age (years): 86; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 154.9; Weight (kg): 70.4; BMI (kg/m²): 29.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10AUG2020:13:47:00; Follow-up Days after 1st Dose: 229; Dose 2 Date/Time: 07SEP2020:13:48:00; Follow-up Days after 2nd Dose: 201

Cardiac disorders/ Coronary artery insufficiency/ CORONARY ARTERY INSUFFICIENCY (INVOLVING THE LEFT ANTERIOR DESCENDING AND LEFT CIRCUMFLEX CORONARY ARTERIES)	2021-02-15 (162) / Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-04-15/ 2021-04-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [2]	Action Taken Other Action Taken	Outcome	
Subject ID: US3312379; Age (years): 27; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 177.8; Weight (kg): 112.3; BMI (kg/m²): 35.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28AUG2020:16:36:00; Follow-up Days after 1st Dose: 211; Dose 2 Date/Time: 25SEP2020:14:56:00; Follow-up Days after 2nd Dose: 183							
Reproductive system and breast disorders/ Endometriosis/ ENDOMETRIOSIS	2021-01-18 (116) / Ongoing	Yes/ Yes/ No	2	Yes/3 (2021-04-11/ 2021-04-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	NOT RECOVERED/ NOT RESOLVED
Reproductive system and breast disorders/ Ovarian cyst/ RIGHT OVARIAN CYST	2021-03-13 (170) / 2021-03-23 (180)	Yes/ Yes/ No	3	Yes/3 (2021-03-16/ 2021-03-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3312465; Age (years): 18; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 188.0; Weight (kg): 114.9; BMI (kg/m ²): 32.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 02SEP2020:15:29:00; Follow-up Days after 1st Dose: 206; Dose 2 Date/Time: 30SEP2020:13:52:00; Follow-up Days after 2nd Dose: 178					
Psychiatric disorders/ Suicide attempt/ SUICIDE ATTEMPT	2021-03-02 (154) / 2021-03-02 (154)	Yes/ Yes/ No	3 Yes/3 (2021-03-02/ 2021-03-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3322314; Age (years): 46; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 170.2; Weight (kg): 86.5; BMI (kg/m ²): 29.9; Baseline SARS-CoV-2 Status: Positive; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Positive; Dose 1 Date/Time: 11SEP2020:10:50:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 09OCT2020:11:25:00; Follow-up Days after 2nd Dose: 169					
Nervous system disorders/ Transient ischaemic attack/ TRANSIENT ISCHEMIC ATTACK	2021-04-05 (179) / 2021-04-06 (180)	Yes/ Yes/ No	3 Yes/3 (2021-04-05/ 2021-04-06) /6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3332033; Age (years): 77; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 175.3; Weight (kg): 85.1; BMI (kg/m ²): 27.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10AUG2020:10:06:00; Follow-up Days after 1st Dose: 229; Dose 2 Date/Time: 11SEP2020:09:08:00; Follow-up Days after 2nd Dose: 197						
Cardiac disorders/ Acute myocardial infarction/ NON-ST ELEVATION ACUTE MYOCARDIAL INFARCTION	2021-02-25 (168) / 2021-03-05 (176)	Yes/ Yes/ No	4	Yes/3 (2021-02-26/ 2021-02-27)	NR/ NR CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED
Cardiac disorders/ Coronary artery disease/ WORSENING OF CORONARY ARTERY DISEASE	2021-02-25 (168) / 2021-03-05 (176)	Yes/ Yes/ No	4	Yes/2/3 (2021-02-28/ 2021-03-05)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3332059; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 157.0; Weight (kg): 55.6; BMI (kg/m ²): 22.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24AUG2020:15:02:00; Follow-up Days after 1st Dose: 215; Dose 2 Date/Time: 18SEP2020:14:42:00; Follow-up Days after 2nd Dose: 190						
Injury, poisoning and procedural complications/ Acetabulum fracture/ RIGHT ACETABULAR FRACTURE	2021-04-22 (217)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-04-22/)/4	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Fractured sacrum/ CLOSED SACRAL FRACTURE	2021-04-22 (217)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-04-22/)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3332059; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 157.0; Weight (kg): 55.6; BMI (kg/m ²): 22.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24AUG2020:15:02:00; Follow-up Days after 1st Dose: 215; Dose 2 Date/Time: 18SEP2020:14:42:00; Follow-up Days after 2nd Dose: 190						
Injury, poisoning and procedural complications/ Pelvic fracture/ MULTIPLE PELVIC FRACTURES	2021-04-22 (217)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-04-22/)/4	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Injury, poisoning and procedural complications/ Rib fracture/ RIGHT RIBS #4-8 FRACTURES	2021-04-22 (217)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-04-22/)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3342127; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 182.0; Weight (kg): 79.6; BMI (kg/m ²): 24.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:12:19:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 21SEP2020:12:12:00; Follow-up Days after 2nd Dose: 187					
Cardiac disorders/ Cardiac failure congestive/ WORSENING OF CONGESTIVE HEART FAILURE	2021-03-01 (162) / Ongoing	Yes/ Yes/ No	4	Yes/3 (2021-03-06/ 2021-03-22)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM RIGHT LUNG	2021-04-11 (203) / Ongoing	Yes/ Yes/ No	4	Yes/2/3 (2021-04-16/ 2021-04-18)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3352015; Age (years): 41; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 176.1; Weight (kg): 107.3; BMI (kg/m ²): 34.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04AUG2020:16:26:00; Follow-up Days after 1st Dose: 235; Dose 2 Date/Time: 03SEP2020:15:10:00; Follow-up Days after 2nd Dose: 205					
Hepatobiliary disorders/ Cholecystitis acute/ ACUTE CHOLECYSTITIS	2021-03-21 (200)/ 2021-03-28 (207)	Yes/ Yes/ No	4 	Yes/3 (2021-03-26/ 2021-03-28)	NR/ NR CONCOMITANT PROCEDURE
Subject ID: US3352070; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.0; Weight (kg): 76.0; BMI (kg/m ²): 23.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:12:46:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 08SEP2020:12:41:00; Follow-up Days after 2nd Dose: 200					
Infections and infestations/ Sepsis/ SEPSIS	2021-03-10 (184)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-03-10/)	NR/ NR CONCOMITANT MEDICATION

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Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3352070; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.0; Weight (kg): 76.0; BMI (kg/m²): 23.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:12:46:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 08SEP2020:12:41:00; Follow-up Days after 2nd Dose: 200					
Injury, poisoning and procedural complications/ Tibia fracture/ WORSENING OF LEFT DISTAL TIBIA FRACTURE	2021-03-10 (184)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-03-10/)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Vascular disorders/ Deep vein thrombosis/ LEFT POPLITEAL DEEP VEIN THROMBOSIS	2021-03-10 (184)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-03-10/)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3352070; Age (years): 54; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.0; Weight (kg): 76.0; BMI (kg/m ²): 23.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:12:46:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 08SEP2020:12:41:00; Follow-up Days after 2nd Dose: 200					
Infections and infestations/ Cellulitis/ CELLULITIS OF LEFT LEG	2021-04-05 (210) / Ongoing	Yes/ Yes/ No	4 (2021-03-10/)	Yes/3 NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3362071; Age (years): 52; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 181.0; Weight (kg): 140.0; BMI (kg/m ²): 42.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:10:21:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 04SEP2020:09:20:00; Follow-up Days after 2nd Dose: 204					
Vascular disorders/ Aortic dissection/ DISSECTING AORTA	2021-03-05 (183) / 2021-03-10 (188)	Yes/ Yes/ No	3 (2021-03-05/ 2021-03-10)	Yes/3 NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3362116; Age (years): 56; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 175.6; Weight (kg): 92.8; BMI (kg/m ²): 30.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:11:39:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 18SEP2020:11:40:00; Follow-up Days after 2nd Dose: 190					
Infections and infestations/ Cellulitis/ CELLULITIS OF LEFT ABDOMEN	2021-01-30 (135)/ 2021-02-08 (144)	Yes/ Yes/ No	4 Yes/3 (2021-01-30/ 2021-02-02)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3392112; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 147.3; Weight (kg): 76.8; BMI (kg/m ²): 35.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28AUG2020:15:40:00; Follow-up Days after 1st Dose: 211; Dose 2 Date/Time: 22SEP2020:13:29:00; Follow-up Days after 2nd Dose: 186					
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2021-02-26 (158)/ 2021-03-01 (161)	Yes/ Yes/ No	2 Yes/3 (2021-02-26/ 2021-03-01)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3392133; Age (years): 45; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 185.4; Weight (kg): 90.9; BMI (kg/m ²): 26.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:10:21:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 28SEP2020:09:28:00; Follow-up Days after 2nd Dose: 180					
Cardiac disorders/ Atrial flutter/ ATRIAL FLUTTER	2021-03-09 (163) / 2021-03-12 (166)	Yes/ Yes/ No	3 	Yes/3 (2021-03-09/ 2021-03-12)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3392287; Age (years): 65; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/SO; Height (cm): 157.5; Weight (kg): 113.6; BMI (kg/m ²): 45.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 16SEP2020:12:04:00; Follow-up Days after 1st Dose: 192; Dose 2 Date/Time: 12OCT2020:10:33:00; Follow-up Days after 2nd Dose: 166					
Cardiac disorders/ Atrial fibrillation/ WORSENING CHRONIC ATRIAL FIBRILLATION	2021-02-08 (120) / 2021-02-09 (121)	Yes/ Yes/ No	3 	Yes/3 (2021-02-08/ 2021-02-09)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3402082; Age (years): 58; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 182.8; Weight (kg): 92.6; BMI (kg/m ²): 27.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29JUL2020:13:21:00; Follow-up Days after 1st Dose: 241; Dose 2 Date/Time: 26AUG2020:11:35:00; Follow-up Days after 2nd Dose: 213					
Nervous system disorders/ Balance disorder/ UNSTABLE BALANCE	2021-02-01 (160)/ 2021-02-03 (162)	Yes/ Yes/ No	2 2021-02-03)	Yes/3 (2021-02-01/ 2021-02-03)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3402232; Age (years): 33; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 198.1; Weight (kg): 106.6; BMI (kg/m ²): 27.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05AUG2020:08:41:00; Follow-up Days after 1st Dose: 234; Dose 2 Date/Time: 02SEP2020:08:25:00; Follow-up Days after 2nd Dose: 206					
Infections and infestations/ COVID-19/ SARS COVID 2	2021-03-18 (198)/ 2021-03-26 (206)	Yes/ Yes/ No	1 2021-03-26)	Yes/6 2021-03-26)	NR/ NR NOT APPLICABLE/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3412059; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.5; Weight (kg): 81.3; BMI (kg/m²): 28.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31JUL2020:10:10:00; Follow-up Days after 1st Dose: 239; Dose 2 Date/Time: 28AUG2020:17:20:00; Follow-up Days after 2nd Dose: 211						
Cardiac disorders/ Ischaemic cardiomyopathy/ ISCHEMIC CARDIOMYOPATHY	2021-03-06 (191)/ Ongoing	Yes/ Yes/ No	4	Yes/3 (2021-03-06/ 2021-03-08)	NR/ NR NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Cardiac disorders/ Acute myocardial infarction/ ACUTE MYOCARDIAL INFARCTION	2021-03-06 (191)/ 2021-03-06 (191)	Yes/ Yes/ No	4	Yes/2/3 (2021-03-06/ 2021-03-08)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
Subject ID: US3412059; Age (years): 68; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.5; Weight (kg): 81.3; BMI (kg/m²): 28.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31JUL2020:10:10:00; Follow-up Days after 1st Dose: 239; Dose 2 Date/Time: 28AUG2020:17:20:00; Follow-up Days after 2nd Dose: 211					
General disorders and administration site conditions/ Chest pain/ PRECORDIAL CHEST PAIN	2021-03-06 (191) / 2021-03-06 (191)	Yes/ Yes/ No	4	Yes/3 (2021-03-06/ 2021-03-08)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Cardiac disorders/ Acute left ventricular failure/ ACUTE SYSTOLIC FAILURE	2021-03-06 (191) / 2021-03-08 (193)	Yes/ Yes/ No	4	Yes/3 (2021-03-06/ 2021-03-08)	NR/ NR NOT APPLICABLE/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3412151; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.5; Weight (kg): 114.0; BMI (kg/m²): 38.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 06AUG2020:10:35:00; Follow-up Days after 1st Dose: 240; Dose 2 Date/Time: 03SEP2020:08:03:00; Follow-up Days after 2nd Dose: 212						
Vascular disorders/ Aortic stenosis/ WORSENING OF AORTIC STENOSIS	2021-02-05 (156) / Ongoing	Yes/ Yes/ No	2 	Yes/3 (2021-03-31/) /6	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE	NOT RECOVERED/ NOT RESOLVED
Nervous system disorders/ Cerebrovascular accident/ STROKE	2021-03-31 (210) / 2021-04-02 (212)	Yes/ Yes/ No	5 	Yes/1/3 (2021-03-31/) /4/6	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION	FATAL

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3412200; Age (years): 31; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 161.5; Weight (kg): 69.9; BMI (kg/m²): 26.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:11:25:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:08:50:00; Follow-up Days after 2nd Dose: 200						
Psychiatric disorders/ Depression/ SEVERE DEPRESSION	2021-04-06 (211) / Ongoing	Yes/ Yes/ No	4	Yes/3 (2021-04-06/ 2021-04-14)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Psychiatric disorders/ Post-traumatic stress disorder/ POST TRAUMATIC STRESS DISORDER	2021-04-06 (211) / Ongoing	Yes/ Yes/ No	4	Yes/3 (2021-04-06/ 2021-04-14)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERING/ RESOLVING

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3412246; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.0; Weight (kg): 65.9; BMI (kg/m ²): 22.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14AUG2020:13:15:00; Follow-up Days after 1st Dose: 225; Dose 2 Date/Time: 11SEP2020:13:10:00; Follow-up Days after 2nd Dose: 197					
Injury, poisoning and procedural complications/ Cervical vertebral fracture/ ANTERIOR OSTEOPHYTE AVULSIAN FRACTURE C6	2021-03-02 (173)/ Ongoing	Yes/ Yes/ No	4 Yes/3 (2021-03-02/ 2021-03-04)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3412262; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 182.7; Weight (kg): 84.4; BMI (kg/m ²): 25.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17AUG2020:16:05:00; Follow-up Days after 1st Dose: 222; Dose 2 Date/Time: 14SEP2020:11:40:00; Follow-up Days after 2nd Dose: 194					
Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING L HIP OA	2021-04-01 (200)/ 2021-04-21 (220)	Yes/ Yes/ No	4 Yes/3 (2021-04-21/ 2021-04-24)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3412337; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 157.7; Weight (kg): 73.0; BMI (kg/m ²): 29.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:11:55:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:11:30:00; Follow-up Days after 2nd Dose: 180					
Injury, poisoning and procedural complications/ Hip fracture/ LEFT HIP FRACTURE	2021-02-22 (148)/ 2021-02-23 (149)	Yes/ Yes/ No	4 Yes/3 (2021-02-22/ 2021-02-25)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3422101; Age (years): 35; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 177.8; Weight (kg): 75.0; BMI (kg/m ²): 23.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25AUG2020:09:52:00; Follow-up Days after 1st Dose: 214; Dose 2 Date/Time: 22SEP2020:08:39:00; Follow-up Days after 2nd Dose: 186					
Gastrointestinal disorders/ Ileus/ ILEUS	2021-02-13 (145)/ 2021-02-15 (147)	Yes/ Yes/ No	2 Yes/3 (2021-02-13/ 2021-02-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3432094; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 174.0; Weight (kg): 90.6; BMI (kg/m ²): 29.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:15:22:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 10SEP2020:10:05:00; Follow-up Days after 2nd Dose: 198					
Gastrointestinal disorders/ Haematochezia/ HEMATOCHEZIA	2021-01-30 (143)/ 2021-02-06 (150)	Yes/ Yes/ No	3 Yes/3 (2021-02-02/ 2021-02-05)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3432240; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 176.0; Weight (kg): 106.7; BMI (kg/m ²): 34.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 22AUG2020:11:23:00; Follow-up Days after 1st Dose: 217; Dose 2 Date/Time: 25SEP2020:11:13:00; Follow-up Days after 2nd Dose: 183					
Infections and infestations/ Arthritis bacterial/ L SHOULDER SEPTIC ARTHRITIS	2021-03-08 (165)/ 2021-04-19 (207)	Yes/ Yes/ No	3 Yes/3 (2021-03-08/ 2021-03-12)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3432497; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 159.0; Weight (kg): 47.2; BMI (kg/m ²): 18.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 14SEP2020:08:28:00; Follow-up Days after 1st Dose: 194; Dose 2 Date/Time: 14OCT2020:16:50:00; Follow-up Days after 2nd Dose: 164					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Breast cancer/ BREAST CANCER (L BREAST)	2021-04-12 (181)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR NOT RECOVERED/ NOT RESOLVED CONCOMITANT PROCEDURE
Subject ID: US3442087; Age (years): 43; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 182.9; Weight (kg): 109.1; BMI (kg/m ²): 32.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25AUG2020:17:35:00; Follow-up Days after 1st Dose: 214; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Thyroid cancer/ THYROID CANCER	2021-04-22 (88)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-04-22/ 2021-04-23)	NR/ NR NOT RECOVERED/ NOT RESOLVED CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3462097; Age (years): 64; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 176.0; Weight (kg): 90.2; BMI (kg/m ²): 29.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10AUG2020:12:58:00; Follow-up Days after 1st Dose: 229; Dose 2 Date/Time: 14SEP2020:12:43:00; Follow-up Days after 2nd Dose: 194					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2021-02-28 (168)/ Ongoing	Yes/ Yes/ No	3 Yes/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE NOT RECOVERED/ NOT RESOLVED
Subject ID: US3462244; Age (years): 27; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 158.0; Weight (kg): 45.0; BMI (kg/m ²): 18.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:11:21:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 16SEP2020:11:50:00; Follow-up Days after 2nd Dose: 192					
Pregnancy, puerperium and perinatal conditions/ Pregnancy/ PREGNANCY ON STUDY	2021-04-12 (209)/ Ongoing	Yes/ Yes/ No	1 Yes/6	NR/ NR	NOT APPLICABLE/ NONE UNKNOWN

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [2]	Action Taken Other Action Taken	Outcome	
Subject ID: US3482240; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 158.8; Weight (kg): 79.1; BMI (kg/m²): 31.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04SEP2020:16:39:00; Follow-up Days after 1st Dose: 204; Dose 2 Date/Time: 29SEP2020:15:23:00; Follow-up Days after 2nd Dose: 179							
Musculoskeletal and connective tissue disorders/ Pain in extremity/ LEFT ARM PAIN	2021-01-07 (101)/ 2021-02-15 (140)	Yes/ Yes/ No	3	Yes/3 (2021-01-19/ 2021-01-23)	NR/ R	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2021-01-19 (113)/ 2021-01-23 (117)	Yes/ Yes/ No	3	Yes/3 (2021-01-19/ 2021-01-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3492078; Age (years): 93; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 187.9; Weight (kg): 82.5; BMI (kg/m ²): 23.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05SEP2020:15:59:00; Follow-up Days after 1st Dose: 203; Dose 2 Date/Time: 02OCT2020:14:53:00; Follow-up Days after 2nd Dose: 176					
Respiratory, thoracic and mediastinal disorders/ Pleural effusion/ RIGHT LUNG PLEURAL EFFUSION	2021-04-24 (205)/ Ongoing	Yes/ Yes/ No	4 (2021-04-24/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERING/ RESOLVING
Subject ID: US3492107; Age (years): 75; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 169.1; Weight (kg): 83.6; BMI (kg/m ²): 29.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:13:02:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:12:50:00; Follow-up Days after 2nd Dose: 171					
Cardiac disorders/ Coronary artery disease/ WORSENING OF EXISTING CORONARY ARTERY DISEASE	2021-01-08 (94)/ 2021-01-11 (97)	Yes/ Yes/ No	4 (2021-01-08/ 2021-01-15)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED WITH SEQUELAE: REQUIRED CARDIAC REHAB POST SURGERY

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3492273; Age (years): 65; Sex: M; Race: OTHER: LATINO; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 180.0; Weight (kg): 113.0; BMI (kg/m ²): 34.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 30SEP2020:10:30:00; Follow-up Days after 1st Dose: 178; Dose 2 Date/Time: 28OCT2020:10:33:00; Follow-up Days after 2nd Dose: 150					
Infections and infestations/ Appendicitis/ APPENDICITIS	2021-01-30 (95) / 2021-02-05 (101)	Yes/ Yes/ No	4	Yes/3 (2021-01-30/ 2021-02-05)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Infections and infestations/ Streptococcal infection/ STREPTOCOCCAL ANGINOSUS BLOOD STREAM INFECTION	2021-01-30 (95) / 2021-02-05 (101)	Yes/ Yes/ No	4	Yes/3 (2021-01-30/ 2021-02-05)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3502125; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 159.8; Weight (kg): 47.5; BMI (kg/m ²): 18.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:14:49:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:14:37:00; Follow-up Days after 2nd Dose: 171					
Nervous system disorders/ Transient global amnesia/ TRANSIENT GLOBAL AMNESIA	2021-04-09 (185)/ Ongoing	Yes/ Yes/ No	3 2021-04-10)	Yes/3 (2021-04-09/ NR	NR/ NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3522082; Age (years): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 168.9; Weight (kg): 70.8; BMI (kg/m ²): 24.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:14:57:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:15:20:00; Follow-up Days after 2nd Dose: 200					
Respiratory, thoracic and mediastinal disorders/ Respiratory tract congestion/ CHEST CONGESTION	2021-03-01 (175)/ Ongoing	Yes/ Yes/ No	2 2021-03-02)	Yes/3 (2021-03-01/ NR	NR/ NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3522112; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 152.4; Weight (kg): 104.5; BMI (kg/m ²): 45.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:11:34:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 10SEP2020:10:54:00; Follow-up Days after 2nd Dose: 198					
Respiratory, thoracic and mediastinal disorders/ Dyspnoea exertional/ EXERTIONAL DYSPNEA	2021-04-13 (216) / 2021-04-19 (222)	Yes/ Yes/ No	2 Yes/3 (2021-04-13/ 2021-04-14)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: NEW DIAGNOSIS OF CONGESTIVE HEART FAILURE
Cardiac disorders/ Cardiac failure congestive/ NEW DIAGNOSIS OF CONGESTIVE HEART FAILURE	2021-04-15 (218) / Ongoing	Yes/ Yes/ No	2 Yes/4	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERING/ RESOLVING

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-with IP/ ship to Other Action IP/SP [3]	Action Taken Taken	Outcome
Subject ID: US3522173; Age (years): 42; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 165.1; Weight (kg): 148.5; BMI (kg/m ²): 54.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 18AUG2020:09:45:00; Follow-up Days after 1st Dose: 221; Dose 2 Date/Time: 15SEP2020:10:10:00; Follow-up Days after 2nd Dose: 193						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Borderline mucinous tumour of ovary/ STAGE 1A MUCINOUS BORDERLINE TUMOR OF THE OVARY WITH INTRAEPITHELIAL CARCINOMA	2021-02-19 (158)/ 2021-03-16 (183)	Yes/ Yes/ No	4 Yes/3 (2021-03-16/ 2021-03-18)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3522299; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 157.5; Weight (kg): 112.7; BMI (kg/m ²): 45.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24AUG2020:09:15:00; Follow-up Days after 1st Dose: 215; Dose 2 Date/Time: 21SEP2020:08:50:00; Follow-up Days after 2nd Dose: 187					
General disorders and administration site conditions/ Incarcerated hernia/ VENTRAL HERNIA WITH INCARCERATED SMALL BOWEL	2021-03-23 (184)/ 2021-03-25 (186)	Yes/ Yes/ No	3 Yes/3 (2021-03-24/ 2021-03-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3522666; Age (years): 76; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/SO/D; Height (cm): 178.1; Weight (kg): 134.3; BMI (kg/m ²): 42.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11SEP2020:13:44:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 12OCT2020:10:02:00; Follow-up Days after 2nd Dose: 166					
Cardiac disorders/ Coronary artery disease/ WORSENING OF CORONARY ARTERY DISEASE	2021-03-16 (156)/ 2021-03-26 (166)	Yes/ Yes/ No	4 Yes/2/3 (2021-03-12/ 2021-03-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3542029; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 168.0; Weight (kg): 132.7; BMI (kg/m ²): 47.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 20AUG2020:11:15:00; Follow-up Days after 1st Dose: 219; Dose 2 Date/Time: 17SEP2020:09:44:00; Follow-up Days after 2nd Dose: 191					
Metabolism and nutrition disorders/ Hyperkalaemia/ HYPERKALEMIA DUE TO ACUTE KIDNEY INJURY OF UNKNOWN ETIOLOGY	2021-02-18 (155)/ 2021-02-20 (157)	Yes/ Yes/ No	3 	Yes/3 (2021-02-18/ 2021-02-22)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3542131; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 154.9; Weight (kg): 48.2; BMI (kg/m ²): 20.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 02SEP2020:14:20:00; Follow-up Days after 1st Dose: 206; Dose 2 Date/Time: 07OCT2020:11:36:00; Follow-up Days after 2nd Dose: 171					
Gastrointestinal disorders/ Ileus/ ILEUS	2021-04-05 (181)/ 2021-04-10 (186)	Yes/ Yes/ No	3 	Yes/3 (2021-04-08/ 2021-04-10)	NR/ NR CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3542332; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 187.0; Weight (kg): 93.2; BMI (kg/m ²): 26.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09OCT2020:12:16:00; Follow-up Days after 1st Dose: 169; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Nervous system disorders/ Seizure/ WORSENING OF SEIZURE DISORDER	2021-04-12 (68)/ 2021-04-13 (69)	Yes/ Yes/ No	3 Yes/3 (2021-04-12/ 2021-04-13)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3552010; Age (years): 65; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 88.3; BMI (kg/m ²): 30.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:11:22:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 07SEP2020:09:43:00; Follow-up Days after 2nd Dose: 201					
Endocrine disorders/ Goitre/ THYROID GOITER	2021-03-16 (191)/ 2021-04-01 (207)	Yes/ Yes/ No	4 Yes/3 (2021-03-16/ 2021-03-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3552355; Age (years): 53; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.3; Weight (kg): 68.2; BMI (kg/m ²): 22.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08SEP2020:09:35:00; Follow-up Days after 1st Dose: 200; Dose 2 Date/Time: 05OCT2020:12:52:00; Follow-up Days after 2nd Dose: 173					
Injury, poisoning and procedural complications/ Lower limb fracture/ OPEN FRACTURE OF RIGHT FIBULA WITH DISPLACED FRACTURE OF RIGHT TIBIA	2021-03-25 (172)/ Ongoing	Yes/ Yes/ No	4 Yes/3 (2021-03-25/ 2021-03-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERING/ RESOLVING
Subject ID: US3572251; Age (years): 41; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 172.7; Weight (kg): 100.9; BMI (kg/m ²): 33.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:12:16:00; Follow-up Days after 1st Dose: 206; Dose 2 Date/Time: 06OCT2020:13:23:00; Follow-up Days after 2nd Dose: 180					
Injury, poisoning and procedural complications/ Head injury/ HEAD TRAUMA DUE TO FALL	2021-04-03 (180)/ 2021-04-03 (180)	Yes/ Yes/ No	5 Yes/1	NR/ NR	NOT APPLICABLE/ NONE FATAL

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3572330; Age (years): 38; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 177.8; Weight (kg): 122.7; BMI (kg/m ²): 38.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21SEP2020:11:22:00; Follow-up Days after 1st Dose: 187; Dose 2 Date/Time: 26OCT2020:09:38:00; Follow-up Days after 2nd Dose: 152					
Surgical and medical procedures/ Gastric bypass/ ELECTIVE GASTRIC BYPASS	2021-01-16 (83)/ 2021-01-18 (85)	Yes/ No/ No	1 2021-01-16/ 2021-01-18)	NR/ NR NONE	NOT APPLICABLE/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3592238; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 181.0; Weight (kg): 152.4; BMI (kg/m ²): 46.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29AUG2020:10:21:00; Follow-up Days after 1st Dose: 210; Dose 2 Date/Time: 26SEP2020:09:39:00; Follow-up Days after 2nd Dose: 182					
Metabolism and nutrition disorders/ Hyperglycaemia/ HYPERGLYCEMIA	2021-03-23 (179)/ 2021-03-26 (182)	Yes/ Yes/ No	2 2021-03-23/ 2021-03-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT REPORTED DURING TC WITH RESEARCH ASSISTANT ON 05-APR-2021 AT 1503 THAT ON 23MAR2021 HE WAS EXPERIENCING BLURRED VISION AND DROVE HIMSELF TO THE EMERGENCY ROOM AT WESLEY MEDICAL CENTER.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
Subject ID: US3622160; Age (years): 51; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL/SC/D/H; Height (cm): 139.7; Weight (kg): 70.9; BMI (kg/m ²): 36.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 05SEP2020:12:54:00; Follow-up Days after 1st Dose: 203; Dose 2 Date/Time: 03OCT2020:11:49:00; Follow-up Days after 2nd Dose: 175					
General disorders and administration site conditions/ Chest pain/ CHEST PAIN	2021-04-04 (184)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-04-05/ NR	NR/ NR NOT APPLICABLE/ NOT RECOVERED/ NOT RESOLVED
Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	2021-04-04 (184)/ Ongoing	Yes/ Yes/ No	4 	Yes/3 (2021-04-05/ NR	NR/ NR NOT APPLICABLE/ NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3632052; Age (years): 61; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 176.0; Weight (kg): 95.0; BMI (kg/m²): 30.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08SEP2020:11:02:00; Follow-up Days after 1st Dose: 200; Dose 2 Date/Time: 06OCT2020:11:33:00; Follow-up Days after 2nd Dose: 172						
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Prostate cancer/ PROSTATE CANCER	2021-03-22 (168)/ Ongoing	Yes/ Yes/ No	3	Yes/6	NR/ NR NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3642217; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC/D; Height (cm): 155.0; Weight (kg): 67.2; BMI (kg/m²): 28.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15SEP2020:15:53:00; Follow-up Days after 1st Dose: 193; Dose 2 Date/Time: 13OCT2020:15:56:00; Follow-up Days after 2nd Dose: 165						
Vascular disorders/ Intermittent claudication/ INTERMITTENT CLAUDICATION	2021-02-01 (112)/ 2021-02-16 (127)	Yes/ Yes/ No	3	Yes/3 (2020-02-16/ 2020-02-17)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3642217; Age (years): 72; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC/D; Height (cm): 155.0; Weight (kg): 67.2; BMI (kg/m ²): 28.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 15SEP2020:15:53:00; Follow-up Days after 1st Dose: 193; Dose 2 Date/Time: 13OCT2020:15:56:00; Follow-up Days after 2nd Dose: 165					
Vascular disorders/ Peripheral arterial occlusive disease/ ATHEROSCLEROSIS OF BILATERAL LEGS	2021-02-01 (112)/ 2021-02-16 (127)	Yes/ Yes/ No	3 Yes/3 (2021-02-16/ 2021-02-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3662049; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: H; Height (cm): 164.5; Weight (kg): 83.1; BMI (kg/m ²): 30.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:15:43:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 30SEP2020:12:49:00; Follow-up Days after 2nd Dose: 178					
Nervous system disorders/ Presyncope/ HYPOTENSION WITH NEAR SYNCOPE	2021-04-09 (192)/ 2021-04-09 (192)	Yes/ Yes/ No	3 Yes/3 (2021-04-09/ 2021-04-10)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3662101; Age (years): 65; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 177.8; Weight (kg): 87.0; BMI (kg/m ²): 27.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 16SEP2020:09:45:00; Follow-up Days after 1st Dose: 192; Dose 2 Date/Time: 14OCT2020:08:46:00; Follow-up Days after 2nd Dose: 164					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Salivary gland cancer stage IV/ MALIGNANT NEOPLASM OF PAROTID GLAND STAGE IVA	2021-02-17 (127)/ Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-04-08/ 2021-04-11)/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
					NOT RECOVERED/ NOT RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3662116; Age (years): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 153.0; Weight (kg): 119.3; BMI (kg/m ²): 51.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 18SEP2020:10:17:00; Follow-up Days after 1st Dose: 190; Dose 2 Date/Time: 16OCT2020:10:35:00; Follow-up Days after 2nd Dose: 162					
Gastrointestinal disorders/ Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	2021-02-10 (118) / 2021-02-16 (124)	Yes/ Yes/ No	3 2021-02-16)	Yes/3 (2021-02-11/ 2021-02-16)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3672255; Age (years): 32; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 173.6; Weight (kg): 146.4; BMI (kg/m ²): 48.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 21AUG2020:14:56:00; Follow-up Days after 1st Dose: 218; Dose 2 Date/Time: 22SEP2020:16:06:00; Follow-up Days after 2nd Dose: 186					
Psychiatric disorders/ Suicidal ideation/ SUICIDAL IDEATION	2021-03-27 (187) / 2021-04-02 (193)	Yes/ Yes/ No	4 2021-04-02)	Yes/2/3 (2021-03-27/ 2021-04-02)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3682134; Age (years): 46; Sex: M; Race: OTHER: HISPANIC; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 170.2; Weight (kg): 128.6; BMI (kg/m²): 44.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17SEP2020:14:51:00; Follow-up Days after 1st Dose: 191; Dose 2 Date/Time: 15OCT2020:14:39:00; Follow-up Days after 2nd Dose: 163						
Metabolism and nutrition disorders/ Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2021-03-02 (139) / 2021-03-09 (146)	Yes/ Yes/ No	3	Yes/3 (2021-03-03/ 2021-03-09)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Osteomyelitis/ OSTEOMYELITIS OF LEFT FOOT	2021-03-02 (139) / 2021-04-13 (181)	Yes/ Yes/ No	3	Yes/3 (2021-03-03/ 2021-03-09)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [2]	Action Taken Other Action Taken	Outcome
Subject ID: US3682163; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 167.6; Weight (kg): 113.6; BMI (kg/m²): 40.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24SEP2020:13:36:00; Follow-up Days after 1st Dose: 184; Dose 2 Date/Time: 22OCT2020:15:07:00; Follow-up Days after 2nd Dose: 156						
Renal and urinary disorders/ Nephritis/ RIGHT NEPHRITIS	2021-02-02 (104) / 2021-02-11 (113)	Yes/ Yes/ No	3	Yes/3 (2021-02-02 / 2021-02-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Renal and urinary disorders/ Ureterolithiasis/ RIGHT URETERAL STONES	2021-02-02 (104) / 2021-03-22 (152)	Yes/ Yes/ No	3	Yes/3 (2021-02-02 / 2021-02-03)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3682163; Age (years): 60; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 167.6; Weight (kg): 113.6; BMI (kg/m ²): 40.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24SEP2020:13:36:00; Follow-up Days after 1st Dose: 184; Dose 2 Date/Time: 22OCT2020:15:07:00; Follow-up Days after 2nd Dose: 156					
Renal and urinary disorders/ Ureterolithiasis/ RIGHT URETERAL STONES	2021-02-02 (104)/ 2021-03-22 (152)	Yes/ Yes/ No	3 Yes/3 (2021-03-15/ 2021-03-17)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3702046; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 180.7; Weight (kg): 144.3; BMI (kg/m ²): 44.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25SEP2020:10:34:00; Follow-up Days after 1st Dose: 166; Dose 2 Date/Time: 23OCT2020:10:08:00; Follow-up Days after 2nd Dose: 138					
Psychiatric disorders/ Bipolar I disorder/ BIPOLAR DISORDER WITH PSYCHOSIS	2021-02-26 (127)/ 2021-03-09 (138)	Yes/ Yes/ No	3 Yes/3 (2021-02-26/ 2021-03-09)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
Subject ID: US3702046; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 180.7; Weight (kg): 144.3; BMI (kg/m ²): 44.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25SEP2020:10:34:00; Follow-up Days after 1st Dose: 166; Dose 2 Date/Time: 23OCT2020:10:08:00; Follow-up Days after 2nd Dose: 138					
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ PULMONARY EMBOLISM	2021-03-01 (130) / 2021-03-09 (138)	Yes/ Yes/ No	5	Yes/1/2/3 (2021-02-26/ 2021-03-09)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION
Cardiac disorders/ Pulseless electrical activity/ PULSELESS ELECTRICAL ACTIVITY	2021-03-09 (138) / 2021-03-09 (138)	Yes/ Yes/ No	5	Yes/1/2	NR/ NR NOT APPLICABLE/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3702046; Age (years): 49; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 180.7; Weight (kg): 144.3; BMI (kg/m ²): 44.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25SEP2020:10:34:00; Follow-up Days after 1st Dose: 166; Dose 2 Date/Time: 23OCT2020:10:08:00; Follow-up Days after 2nd Dose: 138					
Gastrointestinal disorders/	2021-03-09 (138) /	Yes/	5	Yes/1/2/3 (2021-02-26/	NR/ NOT FATAL
Gastrointestinal haemorrhage/	2021-03-09 (138)	No		2021-03-09)	NR APPLICABLE/ NONE
GASTROINTESTINAL BLEED					
Subject ID: US3722158; Age (years): 45; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 166.4; Weight (kg): 126.2; BMI (kg/m ²): 45.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:16:53:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 08SEP2020:11:02:00; Follow-up Days after 2nd Dose: 200					
Infections and infestations/	2021-02-25 (171) /	Yes/	3	Yes/3 (2021-02-25/	NR/ NOT RECOVERED/
Perirectal abscess/	2021-03-05	Yes/		2021-02-28)	NR APPLICABLE/ RESOLVED
PERIRECTAL ABSCESS	(179)	No			CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3722215; Age (years): 63; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 159.3; Weight (kg): 63.8; BMI (kg/m ²): 25.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:15:06:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 08SEP2020:14:27:00; Follow-up Days after 2nd Dose: 200					
Musculoskeletal and connective tissue disorders/ Spondylolisthesis/ L3-L4 SPONDYLOLISTHESIS	2021-03-11 (185)/ 2021-03-14 (188)	Yes/ Yes/ No	3 	Yes/3 (2021-03-11/ 2021-03-14)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3732023; Age (years): 71; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 158.3; Weight (kg): 69.8; BMI (kg/m ²): 27.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:12:06:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 04SEP2020:11:25:00; Follow-up Days after 2nd Dose: 204					
Injury, poisoning and procedural complications/ Hip fracture/ BROKEN HIP	2021-04-22 (231)/ Ongoing	Yes/ Yes/ No	3 	Yes/3 (2021-04-23/)	NA/ NA NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3742034; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 164.3; Weight (kg): 71.6; BMI (kg/m ²): 26.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 25AUG2020:20:00:00; Follow-up Days after 1st Dose: 214; Dose 2 Date/Time: 22SEP2020:16:42:00; Follow-up Days after 2nd Dose: 186					
Infections and infestations/ Appendicitis perforated/ RUPTURED APPENDIX	2021-02-09 (141) / 2021-02-26 (158)	Yes/ Yes/ No	4 Yes/2/3 (2021-02-09/ 2021-02-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE
Subject ID: US3742137; Age (years): 40; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.6; Weight (kg): 77.3; BMI (kg/m ²): 29.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28AUG2020:13:41:00; Follow-up Days after 1st Dose: 211; Dose 2 Date/Time: 25SEP2020:12:04:00; Follow-up Days after 2nd Dose: 183					
Immune system disorders/ Anaphylactic reaction/ ANAPHYLAXIS	2021-02-09 (138) / 2021-02-09 (138)	Yes/ Yes/ No	3 Yes/2	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3742148; Age (years): 24; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 59.1; BMI (kg/m ²): 20.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 28AUG2020:17:13:00; Follow-up Days after 1st Dose: 211; Dose 2 Date/Time: 25SEP2020:16:22:00; Follow-up Days after 2nd Dose: 183					
Pregnancy, puerperium and perinatal conditions/ Abortion spontaneous/ SPONTANEOUS ABORTION	2021-01-29 (127) / 2021-01-29 (127)	Yes/ Yes/ No	3 Yes/6	NR/ NR	NOT APPLICABLE/ NONE RECOVERED/ RESOLVED
Subject ID: US3742153; Age (years): 51; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 174.0; Weight (kg): 109.3; BMI (kg/m ²): 36.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29AUG2020:12:28:00; Follow-up Days after 1st Dose: 210; Dose 2 Date/Time: 26SEP2020:11:38:00; Follow-up Days after 2nd Dose: 182					
Hepatobiliary disorders/ Cholelithiasis obstructive/ CHOLELITHIASIS WITH OBSTRUCTION	2021-04-16 (203) / Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-04-16/ 2021-04-19)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3742229; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 156.2; Weight (kg): 59.1; BMI (kg/m²): 24.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:11:18:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 30SEP2020:12:06:00; Follow-up Days after 2nd Dose: 178						
Psychiatric disorders/ Major depression/ SEVERE MAJOR DEPRESSION WITH PSYCHOTIC FEATURES	2021-04-04 (187) / Ongoing	Yes/ Yes/ No	3)	Yes/3 (2021-04-04/ NR	NR/ NOT APPLICABLE/ NONE	RECOVERING/ RESOLVING
Subject ID: US3752010; Age (years): 67; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 164.0; Weight (kg): 80.5; BMI (kg/m²): 29.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:15:26:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 08SEP2020:13:30:00; Follow-up Days after 2nd Dose: 200						
Hepatobiliary disorders/ Cholecystitis/ CHOLECYSTITIS	2021-01-21 (136) / 2021-01-23 (138)	Yes/ Yes/ No	2)	Yes/3 (2021-01-21/ 2021-01-23)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3752402; Age (years): 70; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.0; Weight (kg): 76.4; BMI (kg/m²): 24.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04SEP2020:10:40:00; Follow-up Days after 1st Dose: 204; Dose 2 Date/Time: 01OCT2020:09:09:00; Follow-up Days after 2nd Dose: 177					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ High-grade B-cell lymphoma/ HIGH GRADE B-CELL LYMPHOMA	2021-02-05 (128)/ 2021-02-26 (149)	Yes/ Yes/ No	4 Yes/2/3 (2021-02-25/ 2021-02-26)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED WITH SEQUELAE: NEW BASELINE ESTABLISHED WITH DIAGNOSIS OF LYMPHOMA. SUBJECT WILL BE GOING THROUGH 6 ROUNDS OF CHEMOTHERAPY.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3762120; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 172.5; Weight (kg): 80.0; BMI (kg/m²): 26.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:16:18:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:14:43:00; Follow-up Days after 2nd Dose: 180						
Infections and infestations/ Staphylococcal bacteraemia/ METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS BACTEREMIA	2021-02-21 (147) / 2021-02-25 (151)	Yes/ Yes/ No	2	Yes/3 (2021-02-21/ 2021-02-25)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Urinary tract infection/ COMPLICATED URINARY TRACT INFECTION	2021-02-21 (147) / 2021-02-25 (151)	Yes/ Yes/ No	2	Yes/3 (2021-02-21/ 2021-02-25)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3762120; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 172.5; Weight (kg): 80.0; BMI (kg/m²): 26.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:16:18:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:14:43:00; Follow-up Days after 2nd Dose: 180					
Renal and urinary disorders/ Nephrolithiasis/ NEPHROLITHIASIS	2021-02-21 (147)/ 2021-03-16 (170)	Yes/ Yes/ No	3 2021-02-25)	Yes/3 (2021-02-21/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
					RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3762120; Age (years): 79; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 172.5; Weight (kg): 80.0; BMI (kg/m²): 26.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:16:18:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:14:43:00; Follow-up Days after 2nd Dose: 180						
Infections and infestations/ Staphylococcal bacteraemia/ METHICILLIN-SUSCEPTIBLE STAPHYLOCOCCUS AUREUS BACTEREMIA	2021-03-13 (167) / 2021-03-17 (171)	Yes/ Yes/ No	3	Yes/3 (2021-03-14/ 2021-03-17)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Infections and infestations/ Escherichia urinary tract infection/ E. COLI UTI	2021-03-14 (168) / 2021-03-29 (183)	Yes/ Yes/ No	2	Yes/3 (2021-03-14/ 2021-03-17)	NR/ NR CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [2]	Action Taken Other Action Taken	Outcome
Subject ID: US3762131; Age (years): 48; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 90.9; BMI (kg/m²): 31.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:10:41:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 29SEP2020:09:54:00; Follow-up Days after 2nd Dose: 179						
Injury, poisoning and procedural complications/ Fibula fracture/ COMMINUTED DISTAL FIBULAR FRACTURE	2021-03-20 (173) / 2021-03-23 (176)	Yes/ Yes/ No	3	Yes/3 (2021-03-20/ 2021-03-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Injury, poisoning and procedural complications/ Fracture displacement/ CLOSED DISPLACED PILON FRACTURE OF RIGHT TIBIA	2021-03-20 (173) / 2021-03-23 (176)	Yes/ Yes/ No	3	Yes/3 (2021-03-20/ 2021-03-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3772041; Age (years): 87; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 149.0; Weight (kg): 49.5; BMI (kg/m ²): 22.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:11:23:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 08SEP2020:12:00:00; Follow-up Days after 2nd Dose: 200					
Vascular disorders/ Hypertension/ EXACERBATION OF HYPERTENSION	2021-02-15 (161) / 2021-02-16 (162)	Yes/ Yes/ No	3 Yes/3 (2021-02-15/ 2021-02-16)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
Subject ID: US3782028; Age (years): 66; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 174.0; Weight (kg): 106.7; BMI (kg/m ²): 35.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:08:29:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 16SEP2020:08:02:00; Follow-up Days after 2nd Dose: 192					
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ BILATERAL PULMONARY EMBOLUS	2021-02-21 (159) / 2021-02-25 (163)	Yes/ Yes/ No	4 Yes/3 (2021-02-22/ 2021-02-25)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
					RECOVERED/ RESOLVED WITH SEQUELAE: NO NEW DIAGNOSTIC EVIDENCE OF RESOLUTION BUT ONGOING NEED FOR ELIQUIS

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3782162; Age (years): 78; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 161.5; Weight (kg): 76.9; BMI (kg/m ²): 29.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08SEP2020:13:43:00; Follow-up Days after 1st Dose: 200; Dose 2 Date/Time: 09OCT2020:12:50:00; Follow-up Days after 2nd Dose: 169					
Cardiac disorders/ Angina pectoris/ CARDIAC CHEST PAIN	2021-01-21 (105) / 2021-01-21 (105)	Yes/ Yes/ No	4 2021-01-23)	Yes/3 (2021-01-22/ 2021-01-23)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3792012; Age (years): 71; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 170.2; Weight (kg): 96.4; BMI (kg/m ²): 33.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:10:43:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 09SEP2020:09:44:00; Follow-up Days after 2nd Dose: 199					
Musculoskeletal and connective tissue disorders/ Back pain/ WORSENING OF CHRONIC BACK PAIN	2021-01-10 (124) / 2021-02-19 (164)	Yes/ Yes/ No	3 2021-02-19)	Yes/3 (2021-02-17/ 2021-02-19)	NR/ NR NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3792016; Age (years): 64; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.3; Weight (kg): 121.1; BMI (kg/m ²): 39.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 12AUG2020:15:39:00; Follow-up Days after 1st Dose: 227; Dose 2 Date/Time: 09SEP2020:11:18:00; Follow-up Days after 2nd Dose: 199					
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2021-04-10 (214) / 2021-04-19 (223)	Yes/ Yes/ No	3 3	Yes/3 (2021-04-13/ 2021-04-19)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3802074; Age (years): 69; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 181.0; Weight (kg): 99.1; BMI (kg/m ²): 30.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:09:45:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 28SEP2020:09:26:00; Follow-up Days after 2nd Dose: 180					
Hepatobiliary disorders/ Cholecystitis acute/ ACUTE CHOLECYSTITIS	2021-03-27 (181) / 2021-03-29 (183)	Yes/ Yes/ No	3 3	Yes/3 (2021-03-27/ 2021-03-29)	NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3812081; Age (years): 47; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 184.2; Weight (kg): 105.9; BMI (kg/m ²): 31.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:17:12:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 02SEP2020:17:20:00; Follow-up Days after 2nd Dose: 206					
Infections and infestations/ Appendicitis/ ACUTE APPENDICITIS	2021-03-29 (209)/ 2021-04-01 (212)	Yes/ Yes/ No	4 	Yes/3 (2021-03-31/ 2021-04-01)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3822088; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 180.3; Weight (kg): 117.3; BMI (kg/m ²): 36.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:17:06:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 09SEP2020:11:56:00; Follow-up Days after 2nd Dose: 199					
Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	2021-03-09 (182)/ 2021-04-05 (209)	Yes/ Yes/ No	3 	Yes/3 (2021-03-20/ 2021-03-26)	NR/ NR NOT APPLICABLE/ NONE

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3822181; Age (years): 25; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 185.7; Weight (kg): 105.1; BMI (kg/m ²): 30.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:08:26:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 24SEP2020:07:53:00; Follow-up Days after 2nd Dose: 184					
Infections and infestations/ Appendicitis/ APPENDICITIS	2021-03-03 (161)/ 2021-03-04 (162)	Yes/ Yes/ No	2 	Yes/3 (2021-03-03/ 2021-03-04)	NR/ NR NOT APPLICABLE/ CONCOMITANT PROCEDURE
Subject ID: US3822465; Age (years): 41; Sex: M; Race: UNKNOWN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 179.1; Weight (kg): 139.0; BMI (kg/m ²): 43.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 23OCT2020:12:25:00; Follow-up Days after 1st Dose: 155; Dose 2 Date/Time: 23NOV2020:12:30:00; Follow-up Days after 2nd Dose: 124					
Infections and infestations/ Sepsis/ SEPSIS	2021-04-11 (140)/ 2021-04-14 (143)	Yes/ Yes/ No	3 	Yes/3 (2021-04-11/ 2021-04-14)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3832071; Age (years): 58; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL; Height (cm): 172.0; Weight (kg): 84.4; BMI (kg/m ²): 28.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04AUG2020:11:34:00; Follow-up Days after 1st Dose: 235; Dose 2 Date/Time: 01SEP2020:09:57:00; Follow-up Days after 2nd Dose: 207					
Infections and infestations/ Appendicitis perforated/ RUPTURED APPENDIX	2021-03-21 (202) / 2021-03-27 (208)	Yes/ Yes/ No	4 Yes/3 (2021-03-26/ 2021-03-31)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3852177; Age (years): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: CL/SO; Height (cm): 182.9; Weight (kg): 137.3; BMI (kg/m ²): 41.0; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11SEP2020:15:06:00; Follow-up Days after 1st Dose: 197; Dose 2 Date/Time: 06OCT2020:14:01:00; Follow-up Days after 2nd Dose: 172					
Infections and infestations/ Pneumonia/ PNEUMONIA	2021-04-13 (190) / Ongoing	Yes/ Yes/ No	3 Yes/3 (2021-04-16/ 2021-04-19)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3862007; Age (years): 65; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 162.6; Weight (kg): 102.1; BMI (kg/m ²): 38.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 13AUG2020:12:29:00; Follow-up Days after 1st Dose: 226; Dose 2 Date/Time: 10SEP2020:16:48:00; Follow-up Days after 2nd Dose: 198					
Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY	2021-03-11 (183)/ 2021-03-14 (186)	Yes/ Yes/ No	3 Yes/3 (2021-03-11/ 2021-03-14)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3862110; Age (years): 60; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D/H; Height (cm): 177.8; Weight (kg): 104.1; BMI (kg/m ²): 32.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 02SEP2020:11:57:00; Follow-up Days after 1st Dose: 206; Dose 2 Date/Time: 30SEP2020:11:20:00; Follow-up Days after 2nd Dose: 178					
Nervous system disorders/ Cerebrovascular accident/ CEREBROVASCULAR ACCIDENT	2021-03-29 (181)/ 2021-03-31 (183)	Yes/ Yes/ No	3 Yes/2/3 (2021-03-29/ 2021-03-31)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION
					RECOVERED/ RESOLVED WITH SEQUELAE: LEFT SIDED HEMIPARESIS

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3862128; Age (years): 69; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 166.3; Weight (kg): 76.8; BMI (kg/m ²): 27.8; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04SEP2020:11:37:00; Follow-up Days after 1st Dose: 204; Dose 2 Date/Time: 02OCT2020:12:45:00; Follow-up Days after 2nd Dose: 176					
Infections and infestations/ Diverticulitis/ DIVERTICULITIS	2021-04-25 (206)/ Ongoing	Yes/ Yes/ No	3 (2021-04-27/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3872083; Age (years): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 180.3; Weight (kg): 98.2; BMI (kg/m ²): 30.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 07AUG2020:09:07:00; Follow-up Days after 1st Dose: 232; Dose 2 Date/Time: 04SEP2020:08:19:00; Follow-up Days after 2nd Dose: 204					
Ear and labyrinth disorders/ Vertigo/ VERTIGO	2021-01-25 (144)/ Ongoing	Yes/ Yes/ No	3 (2021-01-28/ 2021-01-30)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3892042; Age (years): 44; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 201.0; Weight (kg): 92.4; BMI (kg/m²): 22.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 01SEP2020:12:53:00; Follow-up Days after 1st Dose: 207; Dose 2 Date/Time: 28SEP2020:08:14:00; Follow-up Days after 2nd Dose: 180					
Injury, poisoning and procedural complications/ Thoracic vertebral fracture/ SPINAL FRACTURE ON T11 AND T12	2021-02-20 (146)/ 2021-02-23 (149)	Yes/ Yes/ No	3	Yes/3 (2021-02-20/ NR 2021-02-23)	NR/ NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED WITH SEQUELAE: PAIN, PHYSICAL IMPAIRMENT AND SURGICAL CHANGES
Subject ID: US3892054; Age (years): 41; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 163.5; Weight (kg): 51.3; BMI (kg/m²): 19.2; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04SEP2020:14:18:00; Follow-up Days after 1st Dose: 204; Dose 2 Date/Time: 02OCT2020:13:37:00; Follow-up Days after 2nd Dose: 176					
Psychiatric disorders/ Depression/ WORSENING OF DEPRESSION	2021-02-01 (123)/ 2021-03-25 (175)	Yes/ Yes/ No	2	Yes/3 (2021-03-20/ NR 2021-03-25)	NR/ NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3902051; Age (years): 66; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: CL/SC/D; Height (cm): 188.0; Weight (kg): 129.5; BMI (kg/m ²): 36.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:12:40:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:10:41:00; Follow-up Days after 2nd Dose: 171					
Infections and infestations/ Respiratory syncytial virus infection/ RESPIRATORY SYNCYTIAL VIRUS	2021-03-19 (164)/ Ongoing	Yes/ Yes/ No	3 (2021-03-21/)	NR/ NR	NOT APPLICABLE/ NONE RECOVERING/ RESOLVING
Subject ID: US3902060; Age (years): 61; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC/D; Height (cm): 167.6; Weight (kg): 80.0; BMI (kg/m ²): 28.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:12:12:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 14OCT2020:11:20:00; Follow-up Days after 2nd Dose: 164					
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2021-03-02 (140)/ Ongoing	Yes/ Yes/ No	3 (2021-03-02/)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
Subject ID: US3922043; Age (years): 60; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: D; Height (cm): 175.3; Weight (kg): 86.4; BMI (kg/m ²): 28.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 27AUG2020:16:29:00; Follow-up Days after 1st Dose: 212; Dose 2 Date/Time: 28SEP2020:11:49:00; Follow-up Days after 2nd Dose: 180					
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2021-04-09 (194)/ Ongoing	Yes/ Yes/ No	2 Yes/3 (2021-04-09/ 2021-04-14)	NR/ NR NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3922088; Age (years): 63; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 162.6; Weight (kg): 73.0; BMI (kg/m ²): 27.6; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08SEP2020:13:20:00; Follow-up Days after 1st Dose: 200; Dose 2 Date/Time: 13OCT2020:11:59:00; Follow-up Days after 2nd Dose: 165					
Endocrine disorders/ Adrenal mass/ ADRENAL MASS	2021-03-10 (149)/ 2021-03-24 (163)	Yes/ Yes/ No	2 Yes/3 (2021-03-11/)	NR/ NR CONCOMITANT MEDICATION	NOT RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3942064; Age (years): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]:; Height (cm): 172.9; Weight (kg): 66.6; BMI (kg/m ²): 22.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 03SEP2020:16:39:00; Follow-up Days after 1st Dose: 205; Dose 2 Date/Time: 01OCT2020:12:32:00; Follow-up Days after 2nd Dose: 177					
Neoplasms benign, malignant and unspecified (incl cysts and polyps) / Pheochromocytoma/ RIGHT PHEOCHROMOCYTOMA	2021-02-07 (130) / 2021-03-16 (167)	Yes/ Yes/ No	3 Yes/3 (2021-02-08/ 2021-02-19)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE
Subject ID: US3942121; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Risk Factors for Severe COVID-19[4]: SO; Height (cm): 162.6; Weight (kg): 154.3; BMI (kg/m ²): 58.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 24SEP2020:09:23:00; Follow-up Days after 1st Dose: 184; Dose 2 Date/Time: ; Follow-up Days after 2nd Dose: NA					
Social circumstances/ Physical assault/ PHYSICAL ASSAULT	2021-03-07 (48) / 2021-03-07 (48)	Yes/ Yes/ No	3 Yes/2/6	NR/ NR	NOT APPLICABLE/ CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3]	Action Taken Taken	Outcome
Subject ID: US3952052; Age (years): 74; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]: D; Height (cm): 165.1; Weight (kg): 91.4; BMI (kg/m²): 33.5; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 08SEP2020:11:15:00; Follow-up Days after 1st Dose: 200; Dose 2 Date/Time: 13OCT2020:15:06:00; Follow-up Days after 2nd Dose: 165						
Respiratory, thoracic and mediastinal disorders/ Pulmonary embolism/ (R) PULMONARY EMBOLISM	2021-03-06 (145)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-03-06/ 2021-03-08)/6	NR/ NR CONCOMITANT MEDICATION	RECOVERING/ RESOLVING
Subject ID: US3962005; Age (years): 62; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 191.7; Weight (kg): 115.3; BMI (kg/m²): 31.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:10:16:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 16SEP2020:08:28:00; Follow-up Days after 2nd Dose: 192						
General disorders and administration site conditions/ Chest discomfort/ CHEST TIGHTNESS	2021-04-20 (217)/ Ongoing	Yes/ Yes/ No	3	Yes/3 (2021-04-23/)	NR/ NR NONE	NOT RECOVERED/ NOT RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome	
Subject ID: US3972064; Age (years): 69; Sex: F; Race: MULTIPLE: Black or African American, American Indian or Alaska Native; Risk Factors for Severe COVID-19[4]: CL/SC; Height (cm): 174.0; Weight (kg): 64.7; BMI (kg/m²): 21.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 31AUG2020:13:30:00; Follow-up Days after 1st Dose: 208; Dose 2 Date/Time: 30SEP2020:10:27:00; Follow-up Days after 2nd Dose: 178						
Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ SHORTNESS OF BREATH	2021-04-23 (206)/ Ongoing	Yes/ Yes/ No	3)	Yes/3 (2021-04-23/ NR	DOSE NOT CHANGED/ NONE	NOT RECOVERED/ NOT RESOLVED
Subject ID: US3972186; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 176.5; Weight (kg): 82.2; BMI (kg/m²): 26.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17SEP2020:10:25:00; Follow-up Days after 1st Dose: 191; Dose 2 Date/Time: 15OCT2020:09:09:00; Follow-up Days after 2nd Dose: 163						
Metabolism and nutrition disorders/ Lactic acidosis/ LACTIC ACIDOSIS	2021-01-21 (99)/ 2021-01-21 (99)	Yes/ Yes/ No	3)	Yes/3 (2021-01-21/ 2021-01-23) NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [1]	Relation-ship to IP/SP [3]	Action Taken Other Action Taken	Outcome
Subject ID: US3972186; Age (years): 75; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 176.5; Weight (kg): 82.2; BMI (kg/m ²): 26.4; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17SEP2020:10:25:00; Follow-up Days after 1st Dose: 191; Dose 2 Date/Time: 15OCT2020:09:09:00; Follow-up Days after 2nd Dose: 163						
Nervous system disorders/ Syncope/ SYNCOPE	2021-01-21 (99) / 2021-01-21 (99)	Yes/ Yes/ No	3 Yes/3 (2021-01-21/ 2021-01-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED
Vascular disorders/ Hypotension/ EXACERBATION OF HYPOTENSION	2021-01-21 (99) / 2021-01-21 (99)	Yes/ Yes/ No	3 Yes/3 (2021-01-21/ 2021-01-23)	NR/ NR	NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3982014; Age (years): 72; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SC; Height (cm): 175.2; Weight (kg): 73.5; BMI (kg/m ²): 23.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 26AUG2020:13:57:00; Follow-up Days after 1st Dose: 213; Dose 2 Date/Time: 23SEP2020:12:07:00; Follow-up Days after 2nd Dose: 185					
Cardiac disorders/ Atrial flutter/ ATRIAL FLUTTER	2021-03-14 (173)/ 2021-03-15 (174)	Yes/ Yes/ No	3 2021-03-15)	Yes/3 (2021-03-14/ 2021-03-15)	NR/ NR CONCOMITANT MEDICATION
Subject ID: US3982112; Age (years): 73; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.0; Weight (kg): 91.5; BMI (kg/m ²): 31.3; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 04SEP2020:16:20:00; Follow-up Days after 1st Dose: 204; Dose 2 Date/Time: 09OCT2020:13:12:00; Follow-up Days after 2nd Dose: 169					
Cardiac disorders/ Coronary artery disease/ CORONARY ARTERY DISEASE, WORSENING	2021-01-28 (112)/ 2021-02-12 (127)	Yes/ Yes/ No	3 2021-02-12)	Yes/3 (2021-01-28/ 2021-02-12)	NR/ NR CONCOMITANT PROCEDURE

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome	
Subject ID: US3982147; Age (years): 52; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]: SO/D; Height (cm): 183.5; Weight (kg): 148.6; BMI (kg/m²): 44.1; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 10SEP2020:12:46:00; Follow-up Days after 1st Dose: 198; Dose 2 Date/Time: 13OCT2020:09:53:00; Follow-up Days after 2nd Dose: 165						
Psychiatric disorders/ Substance use disorder/ WORSENING OF SUBSTANCE USE DISORDER	2021-03-11 (150) / 2021-03-18 (157)	Yes/ Yes/ No	2	Yes/3 (2021-03-11/ 2021-03-18)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION	RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WAS DISCHARGED ON SUBOXONE, OFF OF MORPHINE AND OXYCODONE, AND LORAZEPAM.
Gastrointestinal disorders/ Pancreatitis/ PANCREATITIS	2021-03-15 (154) / 2021-03-16 (155)	Yes/ Yes/ No	1	Yes/3 (2021-03-15/ 2021-03-16)	NR/ NR NOT APPLICABLE/ NONE	RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day) / End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3982194; Age (years): 59; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 185.0; Weight (kg): 105.1; BMI (kg/m ²): 30.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 17SEP2020:12:58:00; Follow-up Days after 1st Dose: 191; Dose 2 Date/Time: 14OCT2020:09:21:00; Follow-up Days after 2nd Dose: 164					
Cardiac disorders/ Bradycardia/ SYMPTOMATIC BRADYCARDIA	2021-04-06 (175) / 2021-04-08 (177)	Yes/ Yes/ No	2 	Yes/3 (2021-04-06/ 2021-04-08)	NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT WAS ADMITTED TO THE HOSPITAL WITH SYMPTOMS OF WEAKNESS, FATIGUE, AND DIZZINESS. SEQUELAE WOULD BE HYPOTHYROIDISM NEEDING TREATMENT WITH LEVOTHYROXINE REPLACEMENT

Note: Footnotes are listed on the last page.

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Listing 16.2.7.9.3
Serious Adverse Events in Open-Label Phase
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.

Relative day is defined as days from the most recent injection date.

MedDRA version 23.0.

[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4, 5 = Grade 5.

[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.

[3] R = Related, NR = Not Related, NA = Not Applicable.

[4] CL = Chronic Lung Disease, SC = Significant Cardiac Disease, SO = Severe Obesity, D = Diabetes, L = Liver Disease, H = Human Immunodeficiency Virus Infection.

Listing 16.2.7.10.3
Serious Treatment-Related Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
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There are no observations for this section.

Note: Footnotes are listed on the last page.

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Listing 16.2.7.10.3
Serious Treatment-Related Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3142236; Age (years): 41; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.5; Weight (kg): 116.7; BMI (kg/m ²): 39.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 19AUG2020:12:50:00; Follow-up Days after 1st Dose: 220; Dose 2 Date/Time: 16SEP2020:15:31:00; Follow-up Days after 2nd Dose: 192					
Nervous system disorders/ Paraesthesia/ LEFT ARM PARESTHESIA	2021-01-20 (9)/ 2021-01-22 (11)	Yes/ Yes/ No	3 2021-01-21)	Yes/3 (2021-01-21/ 2021-01-21)	R/ R NONE DOSE DELAYED/ RECOVERED/ RESOLVED
Subject ID: US3372089; Age (years): 74; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 175.5; Weight (kg): 98.1; BMI (kg/m ²): 31.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 11AUG2020:16:11:00; Follow-up Days after 1st Dose: 228; Dose 2 Date/Time: 09SEP2020:15:19:00; Follow-up Days after 2nd Dose: 199					
Musculoskeletal and connective tissue disorders/ Muscular weakness/ MUSCLE WEAKNESS LOWER EXTREMITIES	2021-02-16 02:50 (1)/ 2021-02-17 11:57 (3)	Yes/ Yes/ No	3 2021-02-17)	Yes/3 (2021-02-16/ 2021-02-17)	R/ R NONE NOT APPLICABLE/ RECOVERED/ RESOLVED

Note: Footnotes are listed on the last page.

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Listing 16.2.7.10.3
Serious Treatment-Related Adverse Events in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ Criteria [2]	Relation-with IP/ ship to Other Action IP/SP [3] Taken	Action Taken Outcome
Subject ID: US3462421; Age (years): 28; Sex: F; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 171.0; Weight (kg): 70.0; BMI (kg/m ²): 23.9; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 09SEP2020:16:34:00; Follow-up Days after 1st Dose: 199; Dose 2 Date/Time: 07OCT2020:16:10:00; Follow-up Days after 2nd Dose: 171					
Pregnancy, puerperium and perinatal conditions/	2021-01-23 (11)/	Yes/No/	2	Yes/6	R/ NR
Abortion spontaneous/	2021-01-23 (11)	No			DOSE NOT CHANGED/ NONE
MISCARRIAGE					RECOVERED/ RESOLVED
Subject ID: US3552240; Age (years): 39; Sex: M; Race: WHITE; Risk Factors for Severe COVID-19[4]:; Height (cm): 196.9; Weight (kg): 126.8; BMI (kg/m ²): 32.7; Baseline SARS-CoV-2 Status: Negative; Baseline RT-PCR: Negative; Baseline Elecsys SARS-CoV-2 Nucleocapsid bAb: Negative; Dose 1 Date/Time: 29AUG2020:14:31:00; Follow-up Days after 1st Dose: 210; Dose 2 Date/Time: 01OCT2020:12:36:00; Follow-up Days after 2nd Dose: 177					
Endocrine disorders/	2021-02-02 (27)/	Yes/	2	Yes/6	R/ NR
Autoimmune thyroiditis/		Yes/			DOSE NOT CHANGED/
HASHIMOTO'S DISEASE	Ongoing	No			CONCOMITANT MEDICATION
					RECOVERING/ RESOLVING

Note: Footnotes are listed on the last page.

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Listing 16.2.7.10.3
Serious Treatment-Related Adverse Events in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

System Organ Class/ Preferred Term/ Verbatim	Start Date and Time (Relative Day)/ End Date and Time (Relative Day)	TEAE/ MAAE/ Solicited AR	Sev. SAE/ [1] Criteria [2]	Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken	Outcome
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There are no observations for this section.

Note: Footnotes are listed on the last page.

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Listing 16.2.7.10.3
Serious Treatment-Related Adverse Events in Open-Label Phase
Safety Set

TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.

Relative day is defined as days from the most recent injection date.

MedDRA version 23.0.

[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4, 5 = Grade 5.

[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.

[3] R = Related, NR = Not Related, NA = Not Applicable.

[4] CL = Chronic Lung Disease, SC = Significant Cardiac Disease, SO = Severe Obesity, D = Diabetes, L = Liver Disease, H = Human Immunodeficiency Virus Infection.

Listing 16.2.12.3
Death Listing in Open-Label Phase
Safety Set

Treatment Group: Placebo

Subject ID	Age (years)	Sex	Race	Ethnicity	BMI (kg/m ²)	Risk Factors for Severe COVID-19	Baseline SARS-CoV-2 Status	Date of Death	Main Cause of Death/ Cause Specified	Was Autopsy Performed?
US3932147	84	F	WHITE	NOT HISPANIC OR LATINO	35.0	Chronic Lung Disease	Negative	2021-01-21	ADVERSE EVENT	UNK

Listing 16.2.12.3
Death Listing in Open-Label Phase
Safety Set

Treatment Group: Placebo-mRNA-1273

Subject ID	Age (years)	Sex	Race	Ethnicity	BMI (kg/m ²)	Risk Factors for Severe COVID-19	Baseline SARS-CoV-2 Status	Date of Death	Main Cause of Death/ Cause Specified	Was Autopsy Performed?
US3222524	79	M	WHITE	NOT HISPANIC OR LATINO	43.7	Significant Cardiac Disease, Severe Obesity		2021-03-12	ADVERSE EVENT	N
US3242089	30	F	WHITE	NOT HISPANIC OR LATINO	37.2		Negative	2021-03-04	ADVERSE EVENT	Y
US3442074	61	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	20.3	Chronic Lung Disease, Significant Cardiac Disease, Diabetes	Negative	2021-04-06	ADVERSE EVENT	UNK

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Listing 16.2.12.3
Death Listing in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

Subject ID	Age (years)	Sex	Race	Ethnicity	BMI (kg/m ²)	Risk Factors for Severe COVID-19	Baseline SARS-CoV-2 Status	Date of Death	Main Cause of Death/ Cause Specified	Was Autopsy Performed?
US3202375	56	F	WHITE	NOT HISPANIC OR LATINO	26.0		Negative	2021-04-04	ADVERSE EVENT	N
US3222017	72	F	WHITE	NOT HISPANIC OR LATINO	39.5	Significant Cardiac Disease, Liver Disease	Negative	2021-02-04	ADVERSE EVENT	N
US3302465	69	M	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	29.1	Chronic Lung Disease, Diabetes	Negative	2021-01-29	ADVERSE EVENT	UNK
US3312006	62	M	WHITE	NOT HISPANIC OR LATINO	23.1		Negative	2021-03-09	ADVERSE EVENT	Y
US3412151	71	M	WHITE	NOT HISPANIC OR LATINO	38.8		Negative	2021-04-02	ADVERSE EVENT	N
US3572251	41	M	WHITE	HISPANIC OR LATINO	33.8	Diabetes	Negative	2021-04-03	ADVERSE EVENT	Y
US3702046	49	M	BLACK OR AFRICAN AMERICAN	HISPANIC OR LATINO	44.2	Severe Obesity	Negative	2021-03-09	ADVERSE EVENT	

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Listing 16.2.12.3
Death Listing in Open-Label Phase
Safety Set

Treatment Group: mRNA-1273

Subject ID	Age (years)	Sex	Race	Ethnicity	BMI (kg/m ²)	Risk Factors for Severe COVID-19	Baseline SARS-CoV-2 Status	Date of Death	Main Cause of Death/ Cause Specified	Was Autopsy Performed?
US3822443	75	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	19.7	Chronic Lung Disease, Significant Cardiac Disease	Negative	2021-02-11	ADVERSE EVENT	N

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