

## 16.2.2 Protocol Deviations

- Listing 16.2.2.1      Inclusion and Exclusion Criteria Deviations Subjects Randomized but did not meet Eligibility Criteria
- Listing 16.2.2.2      Major Protocol Deviations Randomized Set
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Listing 16.2.2.1

Inclusion and Exclusion Criteria Deviations

Subjects Randomized but did not meet Eligibility Criteria

Cohort 1 (Age  $\geq$  18 and age  $<$  55); Vaccination Group: Placebo

Subject ID	Criteria Type	Description
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There are no observations for this section.

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mRNA-1273-P201

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Primary Analysis (Extraction Date: 06NOV2020)

Listing 16.2.2.1

Inclusion and Exclusion Criteria Deviations

Subjects Randomized but did not meet Eligibility Criteria

Cohort 1 (Age  $\geq$  18 and age  $<$  55); Vaccination Group: mRNA-1273 50  $\mu$ g

Subject ID	Criteria Type	Description
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There are no observations for this section.

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Primary Analysis (Extraction Date: 06NOV2020)

Listing 16.2.2.1

Inclusion and Exclusion Criteria Deviations

Subjects Randomized but did not meet Eligibility Criteria

Cohort 1 (Age  $\geq$  18 and age  $<$  55); Vaccination Group: mRNA-1273 100  $\mu$ g

Subject ID	Criteria Type	Description
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There are no observations for this section.

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Listing 16.2.2.1

Inclusion and Exclusion Criteria Deviations

Subjects Randomized but did not meet Eligibility Criteria

Cohort 2 (Age >= 55); Vaccination Group: Placebo

Subject ID	Criteria Type	Description
US2071092	INCLUSION	Body mass index (BMI) of 18 kg/m2 to 30 kg/m2 (inclusive) at the Screening Visit (Day 0)
US2081104	EXCLUSION	Grade 1 or higher toxicity on clinical safety laboratory testing at the Screening Visit (Day 0)

Listing 16.2.2.1

Inclusion and Exclusion Criteria Deviations

Subjects Randomized but did not meet Eligibility Criteria

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Criteria Type	Description
US2071099	EXCLUSION	Grade 1 or higher toxicity on clinical safety laboratory testing at the Screening Visit (Day 0)

Listing 16.2.2.1

Inclusion and Exclusion Criteria Deviations

Subjects Randomized but did not meet Eligibility Criteria

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Criteria Type	Description
US2081016	EXCLUSION	Grade 1 or higher toxicity on clinical safety laboratory testing at the Screening Visit (Day 0)
US2081108	EXCLUSION	Grade 1 or higher toxicity on clinical safety laboratory testing at the Screening Visit (Day 0)

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2011042	2020-07-13 (36)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2011067	2020-06-10 (8)	Visit Scheduling	P10: VISIT NOT PERFORMED (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS)
US2011070	2020-06-10 (6)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
	2020-06-12 (8)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2011088	2020-07-14 (41)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2021094	2020-07-06 (32)	Study Procedures/Assessments	P10: US2021094- VISIT 4 DAY 29 PROCEDURES AND ASSESSMENTS WERE MISSED DUE TO COVID-19 IMPACT. SUBJECT WAS AWAITING COVID TEST RESULTS.
	2020-07-17 (43)	Study Procedures/Assessments	P10: US2021094- VISIT 6 WERE COMPLETED OVER THE PHONE AND PROCEDURES AND ASSESSMENTS WERE MISSED DUE TO COVID-19 IMPACT.
	2020-08-06 (63)	Study Procedures/Assessments	P10: US2021094- VISIT 7 WERE COMPLETED OVER THE PHONE AND PROCEDURES AND ASSESSMENTS WERE MISSED DUE TO COVID-19 IMPACT.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2021135	2020-06-06 (2)	Missing Endpoint Assessments	P07: SUBJECT US2021135 DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING. EDIARY NOT COMPLETED AT D1 AFTER VACCINATION(6.5.2020), D2 (6.6.2020)
US2021137	2020-07-15 (38)	Study Procedures/Assessments	P10: US2021137- VISIT 5 WERE COMPLETED OVER THE PHONE AND PROCEDURES AND ASSESSMENTS WERE MISSED DUE TO COVID-19 IMPACT.
	2020-07-21 (44)	Study Procedures/Assessments	P10: US2021137 VISIT 6 WERE COMPLETED OVER THE PHONE AND PROCEDURES AND ASSESSMENTS WERE MISSED DUE TO COVID-19 IMPACT.
	2020-08-18 (72)	Study Procedures/Assessments	P10: US2021137- VISIT 7 PROCEDURES AND ASSESSMENTS WERE COMPLETED OUT OF WINDOW DUE TO COVID-19 IMPACT. CONVALESCENT VISIT OCCURRED ON 11AUG2020.
US2021144	2020-08-10 (67)	Study Procedures/Assessments	P10: US2021144- VISIT 7 WERE COMPLETED OVER THE PHONE AND PROCEDURES AND ASSESSMENTS WERE MISSED DUE TO COVID-19 IMPACT.
US2021162	2020-06-23 (16)	Study Procedures/Assessments	P10: US2021162 MISSED VISIT 3 DUE TO A FALSE POSITIVE COVID-19 LAB RESULT ON DAY 1 FROM CENTRAL LAB.
	2020-07-13 (36)	Study Procedures/Assessments	P10: US2021162 MISSED VISIT 4 DAY 29 VACCINATION 2 DUE TO A FALSE POSITIVE COVID-19 LAB RESULT ON DAY 1 FROM VIRACOR LAB.
US2041011	2020-08-17 (78)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2041019	2020-07-28 (57)	Visit Scheduling	P10_VISIT COMPLETED OUT OF WINDOW. (V7D57 OUT OF WINDOW)
US2041056	2020-06-30 (29)	Missing Endpoint Assessments	P07: SUBJECT DIARY NOT COMPLETED (IN ENTIRETY) FOR SAFETY DATA COLLECTION
US2041059	2020-07-06 (35)	Visit Scheduling	P10.3 SUBJECT 2041059 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 06JUL2020 WHICH INCLUDES THE +7 DAYS ALLOWED PER THE PROTOCOL. HOWEVER, DUE TO THE SITE NOT HAVING NEEDLES THE SUBJECT visit was not conducted within window. The subject visit has not yet been completed and/or scheduled per the site staff.
US2041078	2020-07-01 (29)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2051022	2020-07-29 (57)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051035	2020-07-17 (44) 2020-07-30 (57)	Visit Scheduling Visit Scheduling	P10 VISIT 6 COMPLETED OOW P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051044	2020-07-16 (42) 2020-07-28 (54)	Visit Scheduling Visit Scheduling	P10 VISIT 6 COMPLETED OOW P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2061021	2020-07-21 (48)	Visit Scheduling	21JUL2020 VISIT 6 WAS +2 DAYS OUT OF WINDOW.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2061025	2020-06-03 (1)	Study Treatment Admin/Dispense	VACCINATION IS NOT ACCORDING TO THE PROTOCOL - SUBJECT US206-1025 WAS RANDOMIZED TO PLACEBO TREATMENT ARM BUT RECEIVED 100 MCG DOSE AT DAY 1
US2061032	2020-08-05 (62)	Visit Scheduling	P07 D71 EDIARY ENTRY NOT COMPLETE, SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.
US2071012	2020-08-05 (64)	Informed Consent	RECONSENT NOT COLLECTED FOR NEW ICF
US2071017	2020-05-25 (-8) 2020-06-30 (29)	Exclusion Criteria Inv Record Keeping SourceCRF Entry Docs	EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED CRF ENTRY IS NOT SUPPORTED BY SOURCE DOCUMENTATION 24SEP: ROOT CAUSE ANALYSIS INDICATES THE MISSING SOURCE IS RELATED TO UNSUPERVISED SITE MANAGER REMOVING SOURCE DATA AND SUBJECT BINDERS IN ORDER TO remain up to date on EDC data entry. This issue and site processes to prevent recurrence are addressed in SPIP follow up
	2020-08-18 (78)	Visit Scheduling	VISIT NOT PERFORMED
US2071049	2020-08-06 (64)	Informed Consent	RECONSENT NOT COLLECTED FOR NEW ICF
US2071070	2020-06-15 (8)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2081033	2020-07-14 (43)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2081058	2020-06-22 (15)	Missing Endpoint Assessments	IMMUNOGENICITY RESULTS NOT AVAILABLE (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)
	2020-07-06 (29)	Study Treatment Admin/Dispense	SUBJECT DID NOT COMPLY WITH STUDY VACCINATION SCHEDULE (2ND VACCINATION NOT GIVEN )

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2011055	2020-07-07 (36)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2011087	2020-07-08 (36)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2041016	2020-07-06 (35)	Visit Scheduling	P10.3 SUBJECT 2041016 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 06JUL2020 WHICH INCLUDES THE +7 DAYS ALLOWED PER THE PROTOCOL.
US2041049	2020-07-08 (35)	Visit Scheduling	P10.3 SUBJECT 2041049 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 08JUL2020 WHICH INCLUDES THE +7 DAYS ALLOWED PER THE PROTOCOL. HOWEVER, DUE TO THE SITE NOT HAVING NEEDLES THE SUBJECT visit was not conducted within window. The subject visit has not yet been completed and/or scheduled per the site staff.
US2041055	2020-06-25 (23) 2020-07-07 (35)	Visit Scheduling Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW P10.3 SUBJECT 2041055 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 07JUL2020 WHICH INCLUDES THE +7 DAYS ALLOWED PER THE PROTOCOL. HOWEVER, DUE TO THE SITE NOT HAVING NEEDLES THE SUBJECT visit was not conducted within window. The subject visit has not yet been completed and/or scheduled per the site staff.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2041058	2020-07-07 (35)	Visit Scheduling	P10.3 SUBJECT 2041058 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 07JUL2020 WHICH INCLUDES THE +7 DAYS ALLOWED PER THE PROTOCOL. HOWEVER, DUE TO THE SITE NOT HAVING NEEDLES THE SUBJECT visit was not conducted within window. The subject visit has not yet been completed and/or scheduled per the site staff.
US2041064	2020-07-14 (37)	Visit Scheduling	P10: THE PI DID NOT ENSURE ADHERENCE TO PROTOCOL PROCEDURES AS FOLLOWS: SUBJECT US2041064 VISIT 1 WAS CONDUCTED ON 08JUN2020. VISIT 4 WAS CONDUCTED ON 14JUL2020, ONE DAY OUTSIDE OF THE ALLOWABLE visit window per Table 7 of the protocol. Alison Pierce, Unblinded Coordinator, explained the site did not have the appropriate gauge needle to complete the dosing. Per Ms. Pierce the needles had been ordered but had not yet arrived. Ms. Pierce requested to use a different size needle for the visit via an sPIP, but had not received a response in time to conduct the visit. Ms. Pierce explained she did not want to violate the protocol by using a different gauge needle than what was specified in the protocol.
US2041075	2020-07-21 (50)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2041077	2020-07-01 (29)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2041092	2020-07-13 (36)	Visit Scheduling	P10.3 SUBJECT 2041092 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 13JUL2020 WHICH INCLUDES THE +7 DAYS ALLOWED PER THE PROTOCOL. HOWEVER, DUE TO THE SITE NOT HAVING NEEDLES THE SUBJECT visit was not conducted within window. The subject visit was completed on 14Jul2020.
	2020-07-14 (37)	Visit Scheduling	P10: THE PI DID NOT ENSURE ADHERENCE TO PROTOCOL PROCEDURES AS FOLLOWS: SUBJECT 204-1092 THE SUBJECT RETURNED FOR VISIT 4 (SECOND DOSING VISIT) ON 14JUL2020 OUTSIDE THE ALLOWABLE WINDOW (>35 DAYS after the first dose).
US2051008	2020-06-11 (14)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2051011	2020-07-17 (45)	Visit Scheduling	P10 VISIT 6 COMPLETED OOW
	2020-07-30 (58)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051027	2020-07-31 (54)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051032	2020-06-25 (24)	Study Procedures/Assessments	P08_PROCEDURE PERFORMED OUT OF WINDOW

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2051033	2020-07-17 (44)	Visit Scheduling	P10 VISIT 6 COMPLETED OOW
	2020-07-28 (55)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051043	2020-06-11 (9)	Missing Endpoint Assessments	P07 SUBJECT DIARY NOT COMPLETED (IN ENTIRETY) FOR SAFETY DATA COLLECTION
US2061001	2020-07-10 (37)	Visit Scheduling	P10 VISIT 4 DATE IS > 35 DAYS AFTER DAY1 VISIT 1 VACCINATION
	2020-08-04 (62)	Visit Scheduling	P07 D71 EDIARY NOT DONE. , SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.
US2061006	2020-07-03 (31)	Missing Endpoint Assessments	3JUL2020 THE SUBJECT MISSED DAYS 3 TO5 OF DIARY ENTRY AFTER VACCINATION #2 VISIT 4 .
	2020-07-22 (50)	Visit Scheduling	P10_V6D43 WAS OOW
US2061009	2020-08-04 (63)	Visit Scheduling	P07 D71 EDIARY ENTRY NOT COMPLETE, SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2061011	2020-08-10 (69)	Visit Scheduling	P07 D71 EDIARY ENTRY NOT COMPLETE, SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.
US2061019	2020-07-21 (49)	Visit Scheduling	P10 V6 20JUL2020 IS +3 DAYS OUT OF WINDOW.
	2020-07-29 (57)	Visit Scheduling	P07 D71 EDIARY ENTRY NOT COMPLETE, SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.
US2061026	2020-08-04 (61)	Visit Scheduling	P07 D71 EDIARY ENTRY NOT COMPLETE, SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.
US2071004	2020-08-06 (64)	Informed Consent	RECONSENT NOT COLLECTED FOR NEW ICF
US2071029	2020-06-12 (8)	Inv Record Keeping SourceCRF Entry is not supported by source documentation Docs	24SEP: ROOT CAUSE ANALYSIS INDICATES THE MISSING SOURCE IS RELATED TO UNSUPERVISED SITE MANAGER REMOVING SOURCE DATA AND SUBJECT BINDERS IN ORDER TO remain up to date on EDC data entry. This issue and site processes to prevent recurrence are addressed in sPIP follow up

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2071029	2020-07-10 (36)	Study Treatment	VACCINATION IS NOT ACCORDING TO THE PROTOCOL UNKNOWN
		Admin/Dispense	ROUTE OF ADMIN; UNKNOWN IF IP WAS ACCEPTABLE FOR USE
	2020-08-05 (62)	Missing Endpoint Assessments	IMMUNOGENICITY RESULTS NOT AVAILABLE (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED AND PROCESSED AS OUTLINED IN LAB MANUAL)
		Visit Scheduling	MISSED DAY 71 DAIRY ENTRY
US2071030	2020-07-23 (51)	Inv Record Keeping Source Docs	CRF ENTRY IS NOT SUPPORTED BY SOURCE DOCUMENTATION. 24SEP: ROOT CAUSE ANALYSIS INDICATES THE MISSING SOURCE IS RELATED TO UNSUPERVISED SITE MANAGER REMOVING SOURCE DATA AND SUBJECT BINDERS IN ORDER to remain up to date on EDC data entry. This issue and site processes to prevent recurrence are addressed in sPIP follow up
	2020-08-11 (70)	Visit Scheduling	P10 VISIT PERFORMED OOW
US2071033	2020-07-07 (30)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
	2020-07-09 (32)	Study Treatment Admin/Dispense	VACCINATION IS NOT ACCORDING TO THE PROTOCOL UNKNOWN ROUTE OF ADMIN; UNKNOWN IF IP WAS ACCEPTABLE FOR USE
US2071067	2020-08-13 (70)	Visit Scheduling	P10 VISIT PERFORMED OOW
US2081036	2020-07-15 (42)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2081039	2020-06-26 (19)	Visit Scheduling	VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2011041	2020-06-10 (9)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
	2020-07-07 (36)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2011059	2020-06-30 (29)	Study Procedures/Assessments	P08 LAB SAMPLES NOT SHIPPED, COLLECTED AND/OR PROCESSED PER PROTOCOL, CFC OR LAB MANUAL. (EXPIRED TUBES, AMBIENT SHIPMENT, INCORRECT LAB KIT USED)
US2011103	2020-07-07 (30)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2021164	2020-08-07 (61)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED) VISIT 6 COMPLETED 19 DAYS AFTER VISIT 4
US2021182	2020-07-31 (54)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2041008	2020-08-11 (72)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2041060	2020-08-18 (78)	Visit Scheduling	P10_VISIT COMPLETED OUT OF WINDOW. (V7D57 OUT OF WINDOW)
US2041061	2020-08-13 (73)	Visit Scheduling	P10_VISIT COMPLETED OUT OF WINDOW. (V7D57 OUT OF WINDOW)
US2051001	2020-05-26 (-9)	ICF Process/Timing	I02.01_INCORRECT ICF SIGNED

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2051002	2020-05-26 (-7)	ICF Process/Timing	I02.01_INCORRECT ICF SIGNED
US2051003	2020-05-26 (-3) 2020-05-29 (1)	ICF Process/Timing Study Treatment Admin/Dispense	I02.01 INCORRECT ICF SIGNED VACCINATION IS NOT ACCORDING TO THE PROTOCOL - DAY 1 VISIT DOSING PROCEDURE WAS NOT PERFORMED ACCORDING TO THE PHARMACY MANUAL AND DOSING WORKSHEET INSTRUCTION. P07_SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
	2020-06-11 (14)	Missing Endpoint Assessments	
US2051017	2020-07-29 (55)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051024	2020-07-28 (57)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051025	2020-07-30 (56)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051026	2020-06-25 (24)	Study Procedures/Assessments	P08_PROCEDURE PERFORMED OUT OF WINDOW
US2051028	2020-07-02 (29)	Study Treatment Admin/Dispense	P05.04_SUBJECT DID NOT COMPLY WITH STUDY VACCINATION SCHEDULE (2ND VACCINATION NOT GIVEN)
US2051029	2020-07-30 (57)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2061010	2020-08-04 (63)	Visit Scheduling	P07 D71 EDIARY ENTRY NOT COMPLETE, SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.
US2061024	2020-06-03 (1)	Study Treatment Admin/Dispense	VACCINATION IS NOT ACCORDING TO THE PROTOCOL - SUBJECT WAS RANDOMIZED TO 100 MCG TREATMENT ARM AT DAY 1 BUT RECEIVED PLACEBO
	2020-08-04 (63)	Visit Scheduling	P07 D71 EDIARY ENTRY NOT COMPLETE, SUBJECT NON COMPLIANT WITH SAFETY DIARY ENTRIES. SITE FAILED TO FOLLOW UP VIA TELEPHONE, NO DOCUMENTATION TO NOTE AT LEAST 2 ATTEMPTS MADE TO CONTACT SUBJECT.
US2071002	2020-07-21 (51)	Study Procedures/Assessments	PROCEDURE NOT PERFORMED VITAL SIGNS
	2020-07-27 (57)	Study Procedures/Assessments	PROCEDURE NOT PERFORMED PHYSICAL EXAM
		Study Procedures/Assessments	PROCEDURE NOT PERFORMED VITAL SIGNS
US2071026	2020-06-08 (1)	Inv Record Keeping SourceCRF Entry Docs	IS NOT SUPPORTED BY SOURCE DOCUMENTATION 24SEP: ROOT CAUSE ANALYSIS INDICATES THE MISSING SOURCE IS RELATED TO UNSUPERVISED SITE MANAGER REMOVING SOURCE DATA AND SUBJECT BINDERS IN ORDER TO remain up to date on EDC data entry. This issue and site processes to prevent recurrence are addressed in sPIP follow up

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2071038	2020-07-13 (40)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 09JUL2020
US2071039	2020-07-13 (39)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 10JUL2020
US2071071	2020-06-05 (1)	Exclusion Criteria	SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18) (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
US2081023	2020-06-11 (9)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2081045	2020-06-01 (-3)	Exclusion Criteria	SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18) (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-06-11 (8)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
	2020-07-14 (41)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2081051	2020-07-08 (34)	Study Procedures/Assessments	PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS) (SAFETY FOLLOW UP CALLS)

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Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2081064	2020-07-10 (33)	Study Procedures/Assessments	PROCEDURE NOT PERFORMED (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS) (NASOPHARYNGEAL SWAB COLLECTIONS AT D1, D29, D57, UNS, MAAE)

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Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2011011	2020-05-29 (1)	Study Procedures/Assessments	P08: LAB SAMPLES NOT SHIPPED, COLLECTED AND/OR PROCESSED PER PROTOCOL, CFC OR LAB MANUAL. (EXPIRED TUBES, AMBIENT SHIPMENT, INCORRECT LAB KIT USED)
US2011124	2020-07-31 (36)	Missing Endpoint Assessments	P07 SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2021198	2020-08-18 (51)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 03AUG2020
US2021207	2020-08-06 (42)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 31JUL2020
US2041114	2020-08-03 (39)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 31JUL2020
US2051072	2020-09-09 (66)	Visit Scheduling	P10_VISIT NOT PERFORMED
US2061035	2020-07-20 (25)	Study Treatment Compliance	P10 23JUL2020BR:SUBJECT US2061035 WAS VACCINATED WITH V4D29 (20JUL20) VACCINATION 24 DAYS AFTER THE FIRST TREATMENT (26JUN20) INSTEAD OF AT LEAST 28 DAYS BETWEEN VACCINATIONS.
US2061051	2020-06-30 (1)	Informed Consent	P01 SUBJECT WAS NOT RECONSENTED TO V2.1_20200522 ICF AT THE NEXT SCHEDULED VISIT 30JUN2020 .

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2071086	2020-07-09 (14)	Inv Record Keeping SourceCRF ENTRY IS NOT SUPPORTED BY SOURCE DOCUMENTATION Docs	24SEP: ROOT CAUSE ANALYSIS INDICATES THE MISSING SOURCE IS RELATED TO UNSUPERVISED SITE MANAGER REMOVING SOURCE DATA AND SUBJECT BINDERS IN ORDER TO remain up to date on EDC data entry. This issue and site processes to prevent recurrence are addressed in sPIP follow up
US2071092	2020-06-19 (-7)	Inclusion Criteria	P02: SUBJECT 2071092 SCREENING BMI WAS 31.5 BUT RANDOMIZED TO TRIAL. PER SITE, THEY ARE UNSURE IF COLLECTION OF INCORRECT HEIGHT AT SCREENING VISIT WAS DUE TO SUBJECT HIGH HEEL SHOES OR BAD collection. CRA confirmed site documented protocol deviation
US2071094	2020-08-04 (30)	Study Procedures/Assessments Study Procedures/Assessments	PROCEDURE NOT PERFORMED PROCEDURE NOT PERFORMED (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS)
US2071098	2020-08-05 (36) 2020-08-24 (55)	Inv Record Keeping SourceDocs Exclusion Criteria	VISIT4 2ND VACCINE COMPLETED BY (b) (6) BUT SOURCE DOCUMENTS FOR THE VISIT WAS NOT FULLY COMPLETED. EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED
US2071103	2020-09-11 (72)	Visit Scheduling	P10 VISIT PERFORMED OOW

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo

Subject ID	Date Deviation (Day)	Deviation	Description
US2081065	2020-08-24 (60)	ICF Process/Timing	ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent
US2081066	2020-08-11 (47) 2020-08-25 (61)	Visit Scheduling ICF Process/Timing	VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS) ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent
US2081104	2020-06-23 (-9)	Exclusion Criteria	SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18) (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
US2081119	2020-08-11 (37)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 10AUG2020

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Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\_U\Primary Analysis\TLF\116020202.sas 19NOV2020 01:23 Database Lock Date: 05NOV2020

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2021018	2020-07-13 (46)	Visit Scheduling	P10: US2021018- VISIT 4 DAY 29 WAS DELAYED DUE TO COVID-19 IMPACT. SUBJECT WAS AWAITING COVID TEST RESULTS. UPON RECEIVING NEGATIVE TEST RESULTS, SUBJECT RESUMED VISIT 4 DAY 29 AND ALL ASSESSMENTS. Day 1 was to occur on 26Jun2020 and occurred on 13 Jul2020. This is within the 21 day window.
US2031107	2020-09-02 (66)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2041094	2020-08-11 (47)	Visit Scheduling	P10_VISIT COMPLETED OUT OF WINDOW. (V6D43 OUT OF WINDOW.)
US2041113	2020-07-05 (6)	Missing Endpoint Assessments	P07_DOSE DIARY 1- SUBJECT MISSED DAY 6-DAY 7 EDIARY ENTRY.
	2020-08-12 (44)	Missing Endpoint Assessments	P07_DOSE DIARY 2- SUBJECT MISSED DAY4-DAY 7 EDIARY ENTRY.
US2051059	2020-08-18 (54)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2051071	2020-08-24 (57)	Concomitant Medication	P09_ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION
US2061068	2020-08-25 (57)	Visit Scheduling	P10 V6D43 WAS NOT DONE;(IMMUNOGENECITY SAMPLES WERE NOT COLLECTED).

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2071099	2020-07-07 (1)	Exclusion Criteria	SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18) (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-08-11 (36)	Missing Endpoint Assessments	SUBJECT DIARY NOT COMPLETED (IN ENTIRETY) FOR SAFETY DATA COLLECTION
US2071101	2020-08-24 (57)	Exclusion Criteria	EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED
	2020-08-31 (64)	Study Treatment Admin/Dispense	VACCINATION IS NOT ACCORDING TO THE PROTOCOL UNKNOWN ROUTE OF ADMIN; UNKNOWN IF IP WAS ACCEPTABLE FOR USE
US2081003	2020-06-11 (14)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2081085	2020-08-11 (40)	Visit Scheduling	VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
	2020-08-26 (55)	ICF Process/Timing	ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent
US2081112	2020-08-11 (40)	Visit Scheduling	VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2081112	2020-08-26 (55)	ICF Process/Timing	ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent
US2081123	2020-08-11 (43)	Visit Scheduling	VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
	2020-08-25 (57)	ICF Process/Timing	ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent

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Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2011122	2020-08-21 (57)	Visit Scheduling	P07.01 IMMUNOGENICITY RESULTS NOT AVAILABLE (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)
US2011128	2020-06-30 (1)	Study Procedures/Assessments	P08 LAB SAMPLES NOT SHIPPED, COLLECTED AND/OR PROCESSED PER PROTOCOL, CFC OR LAB MANUAL. (EXPIRED TUBES, AMBIENT SHIPMENT, INCORRECT LAB KIT USED)
US2011162	2020-07-01 (-5)	Study Procedures/Assessments	P08 LAB SAMPLES NOT SHIPPED, COLLECTED AND/OR PROCESSED PER PROTOCOL, CFC OR LAB MANUAL. (EXPIRED TUBES, AMBIENT SHIPMENT, INCORRECT LAB KIT USED)
US2021208	2020-08-19 (50)	Study Procedures/Assessments	P10: US2021208 VISIT 6 WERE COMPLETED OVER THE PHONE AND PROCEDURES AND ASSESSMENTS WERE MISSED DUE TO COVID-19 IMPACT.
	2020-09-08 (70)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2021215	2020-09-08 (72)	Visit Scheduling	P10: (VISITS WHERE IMMUNOGENECITY SAMPLES ARE COLLECTED)
US2031101	2020-07-20 (22)	Visit Scheduling	(P10: VISIT SCHEDULING; VISIT PERFORMED OUT OF WINDOW)- SUBJECT US2031101- VISIT 3 DAY 15 PERFORMED OUT OF WINDOW (+/- 3 DAYS).
US2031112	2020-09-02 (69)	Study Procedures/Assessments	(P10 : VISIT SCHEDULING)- VISIT COMPLETED OUT OF WINDOW: V7/DAY57 VISIT FOR SUBJECT US2031112 WAS OUT OF WINDOW PER PROTOCOL (>35 DAYS FROM LAST VACCINATION).

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2041112	2020-08-18 (54)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW
US2041131	2020-08-10 (43)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 03AUG2020
US2051084	2020-08-10 (41)	Concomitant Medication	P09_ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION
US2051111	2020-08-24 (50)	Visit Scheduling	P10 VISIT 6 COMPLETED OOW
US2061045	2020-08-20 (53)	Visit Scheduling	P10_V7 DAY 57 WAS OOW
US2061063	2020-08-11 (43)	Visit Scheduling	P10_V6D43 WAS NOT DONE; (IMMUNOGENECITY SAMPLES WERE NOT COLLECTED) .
US2071006	2020-07-07 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2071013	2020-07-09 (38)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 07JUL2020
US2071087	2020-07-06 (11)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2071093	2020-06-29 (1)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2071096	2020-06-24 (-8)	Exclusion Criteria	SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18) (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-08-05 (35)	Inv Record Keeping Source Docs	VISIT4 2ND VACCINE COMPLETED BY (b) (6) BUT SOURCE DOCUMENTS FOR THE VISIT WAS NOT FULLY COMPLETED.
US2081016	2020-05-27 (-5)	Exclusion Criteria	SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18) (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-06-11 (11)	Missing Endpoint Assessments	SUBJECT DIARY HAS 2 OR MORE DAYS OF SOLICITED ENTRIES MISSING
US2081081	2020-08-27 (60)	ICF Process/Timing	ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent
US2081099	2020-08-26 (62)	ICF Process/Timing	ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent
US2081108	2020-06-23 (-10)	Exclusion Criteria	SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18) (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)

Day is defined as study day from first injection date.

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Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Date Deviation (Day)	Deviation	Description
US2081117	2020-08-11 (37)	Visit Scheduling	P10.3 VISIT 4 (VACCINE 2) SHOULD HAVE OCCURRED NO LATER THAN 10AUG2020
US2081120	2020-08-26 (57)	ICF Process/Timing	ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, LAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION resulted in an invalid consent
US2081129	2020-08-24 (54)	Visit Scheduling	VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)

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Day is defined as study day from first injection date.

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Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
US2021094	Day 29		2020-07-06 (32)	MISSED ASSESSMENT	Exposure to COVID-19
	Day 36	Vital Signs, Physical Examination	2020-07-15 (41)	MISSED ASSESSMENT	Exposure to COVID-19
	Day 43	Vital Signs, Central Laboratory - Antibody-Mediated Immunogenicity	2020-07-17 (43)	MISSED ASSESSMENT	Exposure to COVID-19
	Day 57	Vital Signs, Physical Examination, Central Laboratory - Nasal Swab and Blood Collection for SARS-CoV-2, Central Laboratory - Antibody-Mediated Immunogenicity	2020-08-06 (63)	MISSED ASSESSMENT	Exposure to COVID-19
US2021111	Day 29	Visit Date	2020-07-17 (40)	VISIT PERFORMED OUT OF WINDOW	Symptoms of COVID-19
US2021137	Day 36	Vital Signs, Physical Examination	2020-07-15 (38)	MISSED ASSESSMENT	Exposure to COVID-19
	Day 43	Vital Signs, Physical Examination, Central Laboratory - Antibody-Mediated Immunogenicity	2020-07-21 (44)	MISSED ASSESSMENT	Exposure to COVID-19

Day is defined as study day from first injection date.

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Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
US2021144	Day 57	Vital Signs, Physical Examination, Central Laboratory - Nasal Swab and Blood Collection for SARS-CoV-2, Central Laboratory - Antibody-Mediated Immunogenicity	2020-08-10 (67)	MISSED ASSESSMENT	Possible exposure to COVID-19
US2021162	Day 8	Vital Signs, Physical Examination	2020-06-16 (9)	MISSED ASSESSMENT	Presumption / confirmed COVID-19
	Day 15	Vital Signs, Physical Examination, Central Laboratory - Antibody-Mediated Immunogenicity	2020-06-23 (16)	MISSED ASSESSMENT	Presumption / confirmed COVID-19
	Day 29		2020-07-13 (36)	MISSED ASSESSMENT	Presumption / confirmed COVID-19
US2081058	Day 15	Vital Signs, Physical Examination, Central Laboratory - Antibody-Mediated Immunogenicity	2020-06-22 (15)	MISSED ASSESSMENT, VISIT WAS PERFORMED BY PHONE	Presumption / confirmed COVID-19

Day is defined as study day from first injection date.

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ModernaTX, Inc.  
mRNA-1273-P201

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Primary Analysis (Extraction Date: 06NOV2020)

Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
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There are no observations for this section.

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\_U\Primary Analysis\TLF\116020203.sas 19NOV2020 01:24 Database Lock Date: 05NOV2020

ModernaTX, Inc.  
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Primary Analysis (Extraction Date: 06NOV2020)

Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

Cohort 1 (Age  $\geq 18$  and age  $< 55$ ); Vaccination Group: mRNA-1273 100  $\mu\text{g}$

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
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There are no observations for this section.

Day is defined as study day from first injection date.

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Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
US2051072	Day 57	Visit Date	2020-09-21 (78)	VISIT PERFORMED OUT OF WINDOW	Quarantine due to COVID-19, Presumption / confirmed COVID-19, Symptoms of COVID-19

Day is defined as study day from first injection date.

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Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
US2021018	Day 29	Visit Date	2020-07-13 (46)	VISIT PERFORMED OUT OF WINDOW	Symptoms of COVID-19
US2071106	Day 15	All	2020-07-23 (18)	MISSED VISIT	Exposure to COVID-19
	Day 29	All	2020-07-13 (8)	STUDY TREATMENT NOT GIVEN, MISSED VISIT	Exposure to COVID-19
	Day 36	All	2020-07-15 (10)	MISSED VISIT	Symptoms of COVID-19

Day is defined as study day from first injection date.

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Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
US2021208	Day 36	Visit Date, Vital Signs, Physical Examination	2020-08-10 (41)	MISSED VISIT	Possible exposure to COVID-19
	Day 43	Vital Signs, Physical Examination, Central Laboratory, Central Laboratory - Antibody-Mediated Immunogenicity	2020-08-19 (50)	MISSED ASSESSMENT	Possible exposure to COVID-19

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\_U\Primary Analysis\TLF\116020203.sas 19NOV2020 01:24 Database Lock Date: 05NOV2020