

## 16.2.2 Protocol Deviations

[Listing 16.2.2.2](#)      [Major Protocol Deviations Randomized Set](#)

[Listing 16.2.2.3](#)      [COVID-19 Impact Safety Set](#)

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
US2011030	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011042	2020-07-13 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-12-21 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011043	2020-09-28 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011056	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011057	2020-12-17 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011060	2020-09-28 (119)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-17 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011064	2020-09-28 (119)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011067	2020-09-29 (119)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-10-27 (147)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-16 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011068	2020-12-18 (200)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011069	2020-10-01 (122)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-18 (200)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011070	2020-06-10 (6)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011070	2020-06-12 (8)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-09-03 (91)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011086	2021-01-09 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011088	2020-07-14 (41)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-09-02 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-01 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-28 (147)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-17 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-02 (244)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021082	2020-09-21 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-16 (167)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021089	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-23 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021096	2020-11-15 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021107	2021-01-27 (239)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021135	2020-06-06 (2)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021137	2020-08-18 (72)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-23 (169)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021138	2020-09-21 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021138	2020-10-09 (128)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (167)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021144	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021155	2020-09-13 (98)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021155	2020-09-27 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-22 (137)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-18 (194)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021161	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021175	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-20 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2031014	2020-10-14 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-18 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031022	2020-10-14 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031023	2020-10-14 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-18 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031029	2020-09-21 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2031029	2020-10-19 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-16 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-21 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031038	2021-01-22 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-02-19 (262)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031040	2020-09-18 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-13 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2031040	2021-01-20 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-02-17 (262)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041005	2021-02-19 (267)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041011	2020-08-17 (78)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
	2020-12-16 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-20 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-02-17 (262)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041014	2020-12-13 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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 (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-12-16 (198)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041022	2021-02-12 (253)	Concomitant Medication	P09.01 ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION (ANY INVESTIGATIONAL DRUG OR VACCINE OTHER THAN THE STUDY IP) (PROHIBITED CONCOMITANT MEDICATION OR VACCINE RECEIVED BY SUBJECT)
US2041029	2020-12-18 (201)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041034	2020-12-17 (200)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041056	2020-06-30 (29)	Missing Endpoint Assessments	P07: SUBJECT DIARY NOT COMPLETED (IN ENTIRETY) FOR SAFETY DATA COLLECTION (POST VACCINATION)
US2041059	2020-07-06 (35)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2041078	2020-07-01 (29)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041089	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041090	2020-12-17 (193)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2051022	2020-11-04 (155)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051035	2020-07-17 (44)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
	2020-07-30 (57)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051044	2020-07-17 (43)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
	2020-07-28 (54)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2061003	2020-08-25 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061003	2020-09-22 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (167)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-26 (237)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061015	2020-08-25 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-23 (113)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061015	2021-01-25 (237)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061018	2020-08-26 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-23 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-19 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061021	2020-07-21 (48)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
	2020-08-31 (89)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
	2020-08-19 (78)	Visit Scheduling	P10: SITE FAILS TO FOLLOW UP VIA TELEPHONE (AT LEAST 2 ATTEMPTS MUST BE DOCUMENTED) WITH SUBJECT WHO WHO ARE NON COMPLIANT WITH SAFETY DIARY ENTRIES (FOR DIARY ENTRIES DAY 71 AND BEYOND)
	2020-12-14 (195)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061032	2020-09-23 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-19 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2071012	2020-08-20 (79)	Informed Consent	P03.01: RECONSENT NOT COLLECTED FOR NEW ICF

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2071017	2020-06-30 (29)	Inv Record Keeping SourceI10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE Docs	DOCUMENTATION.
	2020-08-24 (84)	Exclusion Criteria	P03.01: EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED
US2071042	2020-07-21 (48)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2071049	2020-08-20 (78)	Informed Consent	P03.01: RECONSENT NOT COLLECTED FOR NEW ICF
US2071059	2020-07-07 (30)	Study Treatment Admin/Dispense	P05.01: VACCINATION IS NOT ACCORDING TO THE PROTOCOL , (IP (INCLUDING DILUENT AND SALINE) GIVEN THAT WAS NOT APPROPRIATE FOR USE (EXPIRED, TEMPERATURE DEVIATED UNREPORTED / QUARANTINED IP ETC), WRONG OR UNKNOWN ROUTE OF ADMINISTRATION, OR RECEIVED 2ND DOSE DESPITE CONTRAINDICATION); IP DETERMINED TO BE NOT ACCEPTABLE FOR USE
US2071064	2020-10-14 (132)	Inclusion Criteria	P02: SUBJECT DOES NOT MEET ENTRY CRITERIA (INC#) (INCLUSION CRITERIA NOT MET, BUT SUBJECT RANDOMIZED)
US2071070	2020-06-15 (8)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2081033	2020-07-14 (43)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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	2021-01-05 (218)	Inv Safety Reporting (CRF)	I11: UNREPORTED AE IN CRF
US2081046	2020-09-30 (115)	ICF Process/Timing	I02.01: 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
US2081058	2020-06-22 (15)	Missing Endpoint Assessments	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE, (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)
	2020-07-06 (29)	Visit Scheduling	P10: MISSED VISIT (DUE TO COVID-19) EVEN IF TELEPHONE VISIT CONDUCTED
		Study Treatment Admin/Dispense	P05.04: SUBJECT DID NOT COMPLY WITH STUDY VACCINATION SCHEDULE (2ND VACCINATION NOT GIVEN )

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011020	2020-09-30 (122)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011029	2020-09-28 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011048	2020-09-02 (94)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-22 (236)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-19 (264)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011051	2020-09-01 (92)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011051	2020-10-12 (133)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-01 (245)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011055	2020-07-07 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011061	2020-12-18 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011084	2021-01-09 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011087	2020-07-08 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-09-30 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011087	2020-10-26 (146)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-16 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011090	2020-09-30 (119)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-11 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011091	2020-09-30 (119)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-11 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011092	2020-09-01 (89)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-02 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011092	2020-12-18 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011093	2021-01-15 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-30 (237)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-27 (265)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011095	2020-10-01 (119)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-12 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011102	2020-10-02 (117)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-15 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2021058	2020-08-20 (77)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021058	2020-09-09 (97)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021064	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-23 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-24 (170)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021084	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-22 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021090	2020-09-21 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-18 (170)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021147	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2021147	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021166	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021167	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021167	2020-11-30 (176)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021179	2020-09-14 (99)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-29 (114)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-23 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-20 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2031002	2020-10-14 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-18 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031004	2020-10-15 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-18 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031011	2020-10-13 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-18 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031030	2020-08-29 (88)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2031056	2020-09-18 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-16 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-13 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031072	2020-08-23 (82)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-21 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-16 (167)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-22 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041003	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-04-01 (304)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041007	2020-12-15 (198)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041012	2020-10-22 (143)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-16 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041013	2020-10-13 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-10 (196)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041016	2020-07-06 (35)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041016	2020-10-20 (141)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-16 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041023	2020-12-15 (198)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041027	2020-12-18 (201)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041030	2020-12-18 (201)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041047	2020-12-16 (198)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041049	2020-07-08 (35)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-09-11 (100)	Visit Scheduling	P10: VISIT NOT PERFORMED (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041051	2020-12-17 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041055	2020-06-25 (23)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
	2020-07-07 (35)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2041058	2020-07-07 (35)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2041064	2020-07-13 (36)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2041071	2020-10-22 (143)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-18 (170)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041075	2020-07-21 (50)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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 CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2041088	2021-01-29 (236)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041091	2021-01-31 (236)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041092	2020-07-13 (36)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-08-28 (82)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-28 (113)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-24 (170)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2051008	2020-05-26 (-3)	ICF Process/Timing	I02.01: 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
	2020-06-11 (14)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2051009	2020-05-27 (-6)	ICF Process/Timing	I02.01: 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
US2051011	2020-07-17 (45)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
	2020-07-29 (57)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051027	2020-11-04 (150)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051033	2020-07-17 (44)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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	2020-07-28 (55)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051043	2020-06-11 (9)	Missing Endpoint Assessments	P07: SUBJECT DIARY NOT COMPLETED (IN ENTIRETY) FOR SAFETY DATA COLLECTION (POST VACCINATION)
US2061001	2020-07-10 (37)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-08-19 (77)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-08-25 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-22 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (167)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-26 (237)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061009	2020-08-25 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-21 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061011	2020-08-19 (78)	Visit Scheduling	P10: SITE FAILS TO FOLLOW UP VIA TELEPHONE (AT LEAST 2 ATTEMPTS MUST BE DOCUMENTED) WITH SUBJECT WHO WHO ARE NON COMPLIANT WITH SAFETY DIARY ENTRIES (FOR DIARY ENTRIES DAY 71 AND BEYOND)
	2020-08-25 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-21 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (237)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061013	2020-08-25 (82)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-23 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-19 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-26 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061019	2020-07-21 (49)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
	2020-08-19 (78)	Visit Scheduling	P10: SITE FAILS TO FOLLOW UP VIA TELEPHONE (AT LEAST 2 ATTEMPTS MUST BE DOCUMENTED) WITH SUBJECT WHO WHO ARE NON COMPLIANT WITH SAFETY DIARY ENTRIES (FOR DIARY ENTRIES DAY 71 AND BEYOND)
US2061026	2020-08-19 (76)	Visit Scheduling	P10: SITE FAILS TO FOLLOW UP VIA TELEPHONE (AT LEAST 2 ATTEMPTS MUST BE DOCUMENTED) WITH SUBJECT WHO WHO ARE NON COMPLIANT WITH SAFETY DIARY ENTRIES (FOR DIARY ENTRIES DAY 71 AND BEYOND)
	2020-08-26 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-23 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061026	2021-01-26 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2071004	2020-08-20 (78)	Informed Consent	P03.01: RECONSENT NOT COLLECTED FOR NEW ICF
US2071029	2020-06-12 (8)	Inv Record Keeping Source Docs	I10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE DOCUMENTATION.
	2020-07-10 (36)	Missing Endpoint Assessments	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE, (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)
		Study Treatment Admin/Dispense	P05.01: VACCINATION IS NOT ACCORDING TO THE PROTOCOL, UNKNOWN ROUTE OF ADMIN; UNKNOWN IF IP WAS ACCEPTABLE FOR USE
	2020-08-05 (62)	Missing Endpoint Assessments	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE, (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)
US2071030	2020-07-23 (51)	Inv Record Keeping Source Docs	I10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE DOCUMENTATION.
	2020-08-11 (70)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2071033	2020-07-07 (30)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2071033	2020-07-09 (32)	Study Treatment Admin/Dispense	P05.01: 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 COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2081036	2020-07-15 (42)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-11-20 (170)	Inv Safety Reporting (CRF)	I11: UNREPORTED AE IN CRF
	2020-12-15 (195)	Inv Safety Reporting (CRF)	I11: UNREPORTED AE IN CRF
US2081039	2020-06-26 (19)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-09-04 (89)	ICF Process/Timing	I02.01: 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
US2081052	2020-10-27 (145)	ICF Process/Timing	I02.01: 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

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011018	2020-09-30 (122)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-25 (270)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011019	2020-09-29 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011039	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011041	2020-06-10 (9)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-07-07 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-10-26 (147)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-12-29 (211)	Missing Endpoint Assessments	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE, (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)
	2021-03-04 (276)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011046	2020-10-01 (122)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-23 (236)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011050	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-22 (236)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-19 (264)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011059	2020-09-30 (121)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011065	2020-09-29 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011080	2020-12-18 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-29 (241)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-03-02 (273)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011085	2020-09-29 (119)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011085	2021-01-10 (222)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-03-05 (276)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011089	2020-09-03 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-02 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-30 (148)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-08 (218)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-22 (263)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011103	2020-07-07 (30)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-12-21 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011103	2021-02-26 (264)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2021059	2021-01-21 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021063	2020-09-21 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (167)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (238)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021067	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021067	2020-10-20 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021068	2021-01-21 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021074	2020-09-21 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-18 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-16 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021074	2021-02-18 (262)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021080	2020-09-09 (97)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-22 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (237)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021093	2020-09-11 (101)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021093	2020-09-21 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-18 (169)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-24 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-02-22 (265)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021101	2020-09-14 (99)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-18 (103)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-23 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021101	2020-11-20 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021121	2020-12-11 (192)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021145	2020-09-15 (104)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-21 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-16 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2021145	2021-01-25 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021151	2020-09-25 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-23 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-24 (170)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-29 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021154	2020-09-22 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-22 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021154	2020-11-17 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021164	2020-10-23 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-23 (169)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021180	2020-09-29 (114)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-27 (142)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-20 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021180	2021-01-27 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021182	2021-02-24 (262)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031020	2020-10-14 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-18 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041008	2020-08-11 (72)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2021-01-20 (234)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041010	2020-12-12 (198)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-19 (267)	Concomitant Medication	P09.01 ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION (ANY INVESTIGATIONAL DRUG OR VACCINE OTHER THAN THE STUDY IP) (PROHIBITED CONCOMITANT MEDICATION OR VACCINE RECEIVED BY SUBJECT)
US2041026	2020-12-17 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041046	2020-12-19 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041048	2020-11-17 (169)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-12-17 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041060	2020-09-02 (93)	ICF Process/Timing	I02.01: ICF NOT SIGNED OR INCORRECT ICF SIGNED OR ICF NOT SIGNED AND DATED BY SUBJECT, IAR AND INVESTIGATOR OR SIGNED AFTER COMMENCING STUDY PROCEDURES; RECONSENT NOT COLLECTED FOR NEW ICF; DEVIATION RESULTED IN AN INVALID CONSENT
		Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041060	2021-04-13 (316)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041061	2020-09-02 (93)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2051001	2020-05-26 (-9)	ICF Process/Timing	I02.01: 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
US2051002	2020-05-26 (-7)	ICF Process/Timing	I02.01: 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
US2051003	2020-05-26 (-3)	ICF Process/Timing	I02.01: 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

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2051003	2020-05-29 (1)	Study Treatment Admin/Dispense	VACCINATION IS NOT ACCORDING TO THE PROTOCOL - DAY 1 VISIT DOSING PROCEDURE WAS NOT PERFORMED ACCORDING TO THE PHARMACY MANUAL AND DOSING WORKSHEET INSTRUCTION.
	2020-06-11 (14)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2051017	2020-11-04 (153)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051024	2020-11-04 (156)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051025	2020-11-04 (153)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051028	2020-09-08 (97)	Study Treatment Admin/Dispense	P05.04: SUBJECT DID NOT COMPLY WITH STUDY VACCINATION SCHEDULE (2ND VACCINATION NOT GIVEN )
US2051029	2020-11-04 (154)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051030	2020-09-24 (114)	Missing Endpoint Assessments	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT PROCESSED AS OUTLINED IN LAB MANUAL)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061008	2020-08-25 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-21 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-26 (238)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061010	2020-08-19 (78)	Visit Scheduling	P10: SITE FAILS TO FOLLOW UP VIA TELEPHONE (AT LEAST 2 ATTEMPTS MUST BE DOCUMENTED) WITH SUBJECT WHO WHO ARE NON COMPLIANT WITH SAFETY DIARY ENTRIES (FOR DIARY ENTRIES DAY 71 AND BEYOND)
	2020-08-25 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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	2020-09-21 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (237)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061023	2020-08-26 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-24 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-19 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2061023	2021-01-26 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
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
	2020-08-19 (78)	Visit Scheduling	P10: SITE FAILS TO FOLLOW UP VIA TELEPHONE (AT LEAST 2 ATTEMPTS MUST BE DOCUMENTED) WITH SUBJECT WHO WHO ARE NON COMPLIANT WITH SAFETY DIARY ENTRIES (FOR DIARY ENTRIES DAY 71 AND BEYOND)
US2061027	2020-08-31 (88)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-23 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-19 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061027	2021-01-26 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2071002	2020-07-16 (46)	Study Procedures/Assessments	P08: PROCEDURE NOT PERFORMED (NASOPHARYNGEAL SWAB COLLECTIONS AT D1, D29, D57, UNS, MAAE), (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS)
	2020-07-27 (57)	Study Procedures/Assessments	P08: PROCEDURE NOT PERFORMED (NASOPHARYNGEAL SWAB COLLECTIONS AT D1, D29, D57, UNS, MAAE), (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS)
US2071026	2020-06-08 (1)	Inv Record Keeping Source Docs	I10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE DOCUMENTATION.
US2071038	2020-07-13 (40)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2071039	2020-07-13 (39)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2071071	2020-06-05 (1)	Exclusion Criteria	P03.01: SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18), (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
US2081023	2020-06-11 (9)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2081025	2021-01-25 (237)	Inv Safety Reporting (CRF)	I11: UNREPORTED AE IN CRF
US2081045	2020-06-01 (-3)	Exclusion Criteria	P03.01: SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18), (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-06-11 (8)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-07-14 (41)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2081051	2020-07-08 (34)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2081063	2020-10-12 (127)	Inv Safety Reporting (CRF)	I11: UNREPORTED AE IN CRF

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2011007	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011011	2020-08-27 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-11 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-03-04 (280)	Concomitant Medication	P09.01 ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION (ANY INVESTIGATIONAL DRUG OR VACCINE OTHER THAN THE STUDY IP)
US2011023	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011109	2020-09-30 (97)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-23 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2011109	2021-03-02 (250)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011114	2020-09-24 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-03-04 (252)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011116	2020-09-25 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-09 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011120	2020-09-29 (95)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2011120	2020-10-21 (117)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-09 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-03-02 (249)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011124	2020-07-31 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011126	2020-09-24 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-02-16 (236)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2011130	2020-09-26 (93)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-08 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011131	2020-09-24 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-21 (118)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-08 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-03-05 (253)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011142	2020-10-06 (100)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-11 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2011142	2021-03-05 (250)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011145	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011152	2020-09-29 (93)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-11 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011155	2020-09-29 (92)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-12 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011156	2020-09-29 (92)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-12 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2011156	2021-03-06 (250)	Concomitant Medication	P09.01 ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION (ANY INVESTIGATIONAL DRUG OR VACCINE OTHER THAN THE STUDY IP) (PROHIBITED CONCOMITANT MEDICATION OR VACCINE RECEIVED BY SUBJECT)
US2011157	2020-09-28 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-12 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2021015	2020-05-29 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
US2021021	2020-05-29 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
US2021022	2020-06-01 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
	2020-09-07 (99)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-21 (113)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-16 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2021022	2020-11-13 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021043	2020-10-16 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (163)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021130	2020-09-25 (92)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021185	2020-10-16 (113)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2021185	2020-11-12 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021189	2020-09-17 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-15 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021196	2020-09-21 (82)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-22 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2021196	2020-11-17 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021198	2020-09-21 (85)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-22 (86)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (142)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (169)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021206	2020-09-21 (82)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2021206	2020-10-19 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031100	2020-09-21 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-19 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031131	2020-10-19 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041102	2020-12-11 (169)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041114	2020-08-03 (39)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-12-10 (168)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2041115	2020-09-22 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041121	2020-10-21 (113)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-11-18 (141)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-15 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041132	2020-12-11 (169)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-10 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041142	2020-11-19 (141)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

Listing 16.2.2.2  
Major Protocol Deviations  
Randomized Set

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

Subject ID	Date Deviation (Day)	Deviation	Description
US2041146	2020-11-19 (141)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-16 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041151	2020-11-23 (141)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2051072	2020-09-09 (66)	Visit Scheduling	P10: VISIT NOT PERFORMED (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS)
US2061035	2020-07-20 (25)	Study Treatment Admin/Dispense	P05.02: SUBJECT DID NOT COMPLY WITH STUDY VACCINATION SCHEDULE (VACCINATION GIVEN OUT OF WINDOW EXCEPT IN THE CASES OF RESTRICTIONS DUE TO COVID-19 PANDEMIC, WHERE 2ND DOSE WILL BE ALLOWED UP TO +21 DAYS WINDOW. )
US2061051	2020-06-30 (1)	ICF Process/Timing	I02.01: 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
US2071041	2020-11-06 (158)	Missing Endpoint Assessments	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE, (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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 SourceI10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE Docs	DOCUMENTATION.
US2071088	2020-07-27 (32)	Visit Scheduling	P08: PROCEDURE NOT PERFORMED (NASOPHARYNGEAL SWAB COLLECTIONS AT D1, D29, D57, UNS, MAAE) (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS) , THAT IS THE ONE WE CAN USE
US2071092	2020-10-29 (126)	Inclusion Criteria	P02: SUBJECT DOES NOT MEET ENTRY CRITERIA (INC#) (INCLUSION CRITERIA NOT MET, BUT SUBJECT RANDOMIZED)
US2071094	2020-08-04 (30)	Study Procedures/Assessments	P08: PROCEDURE NOT PERFORMED (NASOPHARYNGEAL SWAB COLLECTIONS AT D1, D29, D57, UNS, MAAE), (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS)
		Study Procedures/Assessments	P08: PROCEDURE NOT PERFORMED (NASOPHARYNGEAL SWAB COLLECTIONS AT D1, D29, D57, UNS, MAAE), (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS)
US2071098	2020-08-05 (36)	Inv Record Keeping SourceI10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE Docs	DOCUMENTATION.
	2020-08-24 (55)	Exclusion Criteria	P03.01: EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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	I02.01: 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	2020-08-25 (61)	ICF Process/Timing	I02.01: 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	P03.01: SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18), (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
US2081119	2020-08-11 (37)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2021-01-29 (208)	Visit Scheduling	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE, (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011012	2020-09-29 (121)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-19 (264)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011014	2020-10-01 (123)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011032	2020-09-29 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-15 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-03-05 (277)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011040	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011040	2021-01-26 (240)	Concomitant Medication	P09.1 ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION (IMMUNOSUPPRESSANTS OR OTHER IMMUNE-MODIFYING DRUGS ADMINISTERED CHRONICALLY (IE, MORE THAN 14 DAYS IN TOTAL) DURING THE STUDY PERIOD. FOR CORTICOSTEROIDS, THIS WILL MEAN THAT PREDNISONE = 20 MG/DAY OR THE EQUIVALENT IS NOT PERMITTED. ) (PROHIBITED CONCOMITANT MEDICATION OR VACCINE RECEIVED BY SUBJECT)
US2011117	2020-09-22 (89)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-08 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011123	2020-09-30 (97)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-02-17 (237)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011125	2020-09-29 (90)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011127	2020-09-23 (90)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-02-16 (236)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011137	2020-09-24 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-03-05 (253)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011138	2020-09-29 (95)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-22 (118)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-14 (202)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011153	2021-01-25 (211)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021004	2020-05-29 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
US2021012	2020-06-01 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
US2021018	2020-05-29 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
	2020-07-13 (46)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-08-24 (88)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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	2020-10-15 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-13 (169)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021019	2020-05-29 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
	2020-09-15 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-13 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021020	2020-06-01 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
	2020-10-16 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021133	2020-09-14 (81)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-14 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-12 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-10 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021190	2020-09-07 (74)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-21 (88)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (117)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021190	2021-02-17 (237)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021192	2020-11-10 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021205	2020-09-21 (88)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-09-22 (89)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-17 (145)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (172)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2021205	2021-02-16 (236)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031086	2020-10-14 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2031106	2020-09-15 (82)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-14 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041094	2020-08-11 (47)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2041103	2020-12-10 (168)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041104	2020-12-18 (176)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-19 (208)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041109	2020-11-12 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-12 (170)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041113	2020-07-07 (8)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-07-28 (29)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
	2020-10-08 (101)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041118	2021-01-15 (201)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041119	2021-01-11 (190)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041127	2020-12-10 (168)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041139	2021-01-13 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041145	2020-11-19 (141)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-12-17 (169)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041150	2020-10-24 (116)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-20 (143)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-12-17 (170)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041155	2020-10-08 (95)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-02 (150)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-20 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2051059	2020-08-18 (54)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2051071	2020-08-25 (58)	Concomitant Medication	P09: ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION
US2061037	2020-09-19 (86)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-16 (113)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-11 (139)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2061064	2020-09-24 (87)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (113)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061068	2020-08-25 (57)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-12-14 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2071099	2020-07-07 (1)	Exclusion Criteria	P03.01: SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18), (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-08-11 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY NOT COMPLETED (IN ENTIRETY) FOR SAFETY DATA COLLECTION (POST VACCINATION)
US2071101	2020-08-24 (57)	Exclusion Criteria	P03.01: EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED
	2020-08-31 (64)	Study Treatment Admin/Dispense	P05.01: VACCINATION IS NOT ACCORDING TO THE PROTOCOL, UNKNOWN ROUTE OF ADMIN; UNKNOWN IF IP WAS ACCEPTABLE FOR USE
US2071104	2020-07-21 (16)	Inv Record Keeping SourceI10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE Docs	DOCUMENTATION.

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2071106	2020-08-10 (36)	Visit Scheduling	P10.01: SUBJECT DID NOT COMPLY WITH BLOOD DRAW SCHEDULE (VISIT PERFORMED OUF OF WINDOW - SAFETY LABS NOT COLLECTED AT D29, D57)
	2020-09-28 (85)	Study Treatment Admin/Dispense	P05.02: SUBJECT DID NOT COMPLY WITH STUDY VACCINATION SCHEDULE (VACCINATION GIVEN OUT OF WINDOW EXCEPT IN THE CASES OF RESTRICTIONS DUE TO COVID-19 PANDEMIC, WHERE 2ND DOSE WILL BE ALLOWED UP TO +21 DAYS WINDOW. )
	2021-03-17 (255)	Concomitant Medication	P09.01 ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION (ANY INVESTIGATIONAL DRUG OR VACCINE OTHER THAN THE STUDY IP) (PROHIBITED CONCOMITANT MEDICATION OR VACCINE RECEIVED BY SUBJECT)
US2081003	2020-06-11 (14)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2081085	2020-08-11 (40)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-08-26 (55)	ICF Process/Timing	I02.01: 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	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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	I02.01: 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
	2021-01-27 (209)	ICF Process/Timing	I02.01: 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	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-08-25 (57)	ICF Process/Timing	I02.01: 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

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011004	2020-09-30 (122)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-03-05 (278)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011009	2020-09-28 (120)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011028	2020-12-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-02-24 (269)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011113	2021-01-26 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2011118	2020-09-28 (95)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-08 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-03-04 (252)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011121	2020-09-29 (90)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-14 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2011122	2020-08-21 (57)	Visit Scheduling	P07.01: IMMUNOGENICITY RESULTS NOT AVAILABLE, (ANTIBODY-MEDIATED IMMUNOGENICITY SAMPLES NOT COLLECTED)
	2020-09-24 (91)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-20 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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	2021-03-05 (253)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011128	2020-09-29 (92)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-25 (210)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011139	2020-09-23 (90)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011149	2021-01-26 (212)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2011159	2020-09-29 (90)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-26 (209)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2011162	2021-01-18 (197)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2021003	2020-05-29 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
	2020-09-15 (110)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-13 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-01-18 (235)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2021-03-15 (291)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021007	2020-06-01 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
US2021011	2020-05-29 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	
US2021031	2020-06-01 (1)	Inv Record Keeping SourceI10: SOURCE DOCUMENTATION DOSE NOT MEET ALCOA Docs	

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021114	2020-09-15 (82)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-20 (117)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-09 (167)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021115	2020-09-21 (88)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-14 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-10 (138)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2021186	2020-09-17 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-15 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-12 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-08 (166)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2021230	2021-02-17 (227)	Concomitant Medication	P09.01 ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION (ANY INVESTIGATIONAL DRUG OR VACCINE OTHER THAN THE STUDY IP) (PROHIBITED CONCOMITANT MEDICATION OR VACCINE RECEIVED BY SUBJECT)
US2031101	2020-07-20 (22)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2031112	2020-09-02 (69)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041096	2020-11-15 (140)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041107	2020-12-10 (168)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041108	2020-10-14 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-12 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041112	2020-08-18 (54)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2020-12-11 (169)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041117	2020-12-11 (169)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041125	2020-10-20 (114)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2021-01-15 (201)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041126	2020-09-17 (84)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-15 (112)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-11-12 (140)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-12-12 (170)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041131	2020-08-10 (43)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
	2021-01-13 (199)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2041136	2020-11-21 (144)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
	2020-12-15 (168)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2041144	2020-12-11 (169)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2041149	2020-11-23 (141)	Visit Scheduling	P10: MISSED VISIT: SAFETY CALL NOT COMPLETED AS OUTLINED IN SOE BEGINNING DAY 85
US2051084	2020-08-11 (42)	Concomitant Medication	P09: ADMINISTRATION OF FORBIDDEN VACCINE OR MEDICATION
US2051111	2020-11-04 (122)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (EXCLUDING DOSING VISITS)
US2061036	2020-09-16 (83)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
	2020-10-14 (111)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)
US2061063	2020-08-11 (43)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2071006	2020-07-07 (36)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2071013	2020-07-09 (38)	Visit Scheduling	P10: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021



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
US2071087	2020-07-06 (11)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2071091	2020-10-05 (102)	Visit Scheduling	P08: PROCEDURE NOT PERFORMED (NASOPHARYNGEAL SWAB COLLECTIONS AT D1, D29, D57, UNS, MAAE) (EXCLUDING IMMUNOGENICITY BLOOD DRAWS AND VACCINATIONS) , THAT IS THE ONE WE CAN USE
US2071093	2020-06-29 (1)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2071096	2020-06-24 (-8)	Exclusion Criteria	P03.01: SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18), (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-08-05 (35)	Inv Record Keeping Source Docs	I10: ECRF ENTRY IS NOT SUPPORTED BY SOURCE DOCUMENTATION.
US2081016	2020-05-27 (-5)	Exclusion Criteria	P03.01: SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18), (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)
	2020-06-11 (11)	Missing Endpoint Assessments	P07: SUBJECT DIARY HAS 2 OR MORE CONSECUTIVE DAYS OF SOLICITED ENTRIES MISSING
US2081069	2020-07-24 (29)	Study Procedures/Assessments	P08: PROCEDURE PERFORMED OUT OF WINDOW (OTHER THAN VACCINATION OR BLOOD SAMPLE VISITS), (SAFETY FOLLOW UP CALLS)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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
US2081076	2021-01-27 (211)	ICF Process/Timing	I02.01: 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
US2081081	2020-08-27 (60)	ICF Process/Timing	I02.01: 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
	2021-01-27 (213)	ICF Process/Timing	I02.01: 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	I02.01: 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	P03.01: SUBJECT DOES NOT MEET ENTRY CRITERIA (EX#18), (EXCLUSION CRITERIA MET, BUT SUBJECT RANDOMIZED)

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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: VISIT COMPLETED OUT OF WINDOW (VISITS WHERE IMMUNOGENICITY SAMPLES ARE COLLECTED)
US2081120	2020-08-26 (57)	ICF Process/Timing	I02.01: 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	2021-01-28 (211)	ICF Process/Timing	I02.01: 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

---

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020202.sas 19JUL2021 20:30 Database Lock Date: 10JUN2021

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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020203.sas 19JUL2021 20:31 Database Lock Date: 10JUN2021

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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020203.sas 19JUL2021 20:31 Database Lock Date: 10JUN2021

ModernaTX, Inc.  
mRNA-1273-P201

Page 3 of 7

Part A end of Part A (Extraction Date: 11JUN2021)

Listing 16.2.2.3  
COVID-19 Impact  
Safety Set

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

Subject ID	Visit	Case Report Form	Date of Missed or Out of Window Visit or Assessment (Day)	Category	Relationship to COVID-19
------------	-------	------------------	---	----------	-----------------------------

There are no observations for this section.

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020203.sas 19JUL2021 20:31 Database Lock Date: 10JUN2021

ModernaTX, Inc.  
mRNA-1273-P201

Page 4 of 7

Part A end of Part A (Extraction Date: 11JUN2021)

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
------------	-------	------------------	---	----------	-----------------------------

There are no observations for this section.

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020203.sas 19JUL2021 20:31 Database Lock Date: 10JUN2021

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
US2061046	Day 209	SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment, SARS-CoV-2 or COVID-19 Symptoms Assessment	2021-01-15 (201)	MISSED ASSESSMENT	Exposure to COVID-19, Symptoms of COVID-19

Day is defined as study day from first injection date.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020203.sas 19JUL2021 20:31 Database Lock Date: 10JUN2021



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
US2071104	Day 57	SARS-CoV-2 or COVID-19 Symptoms Assessment	2020-09-16 (73)	ASSESSMENT 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\116020203.sas 19JUL2021 20:31 Database Lock Date: 10JUN2021

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\Part A end of Part A\TLF\116020203.sas 19JUL2021 20:31 Database Lock Date: 10JUN2021